

Opioid Resources Master List

1. **Feds to distribute \$53 million to states to fight opioids.** August 31, 2016. *Department of Health and Human Services.*
<http://www.modernhealthcare.com/article/20160831/NEWS/308319997>
2. **HHS awards \$ 53 million to help address opioid epidemic.** August 31, 2016. *Department of Health and Human Services.*
<https://www.hhs.gov/about/news/2016/08/31/hhs-awards-53-million-to-help-address-opioid-epidemic.html>
3. **How to prevent opioid abuse: training and education.** *American Medical Association.*
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4. **Hospital-county collaboration prevents opioid abuse.** *CHI Health.*
<http://www.hpoe.org/resources/chair-files/2867>
5. **Minnesota Accountable Health Model-State Innovation Model Grant.** Health reform Minnesota.
http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=SIM_Home
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<https://www.gpo.gov/fdsys/pkg/FR-2016-07-08/pdf/2016-16067.pdf>
7. **Legislation signed into law addressing opioid epidemic.** August 18, 2016. *American Hospital Association.*
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 - (i) **S. 524- Comprehensive Addiction and Recovery Act of 2016:**
<https://www.congress.gov/bill/114th-congress/senate-bill/524>
 - (ii) **AHA-endorsed measures:**
<http://www.aha.org/advocacy-issues/letter/2016/160301-let-s524cara.pdf>
 - (iii) **AHA legislation bulletin:**
<http://www.aha.org/bulletins>
8. **Study: Medicare Beneficiaries May Face 'Treatment Gap' For Painkiller Abuse, Misuse.** July 20, 2016. *Kaiser Health News.*
<http://khn.org/news/study-medicare-beneficiaries-may-face-treatment-gap-for-painkiller-abuse-misuse/>
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10. **OHSU: Our Community Responds to the Opiate Epidemic.** July 22, 2016. *American Hospital Association's Physician Leadership Forum.*
<http://www.ahaphysicianforum.org/webinar/2016/OHSU-Opiate-Epidemic/index.shtml>
11. **Providers' Clinical Support System for Opioid Therapies.** *National Council for Behavioral Health.*
<http://pcss-o.org/>
12. **Medicaid National Meeting on Prescription Drug Abuse and Overdose-February 1-2, 2016 (Free Webinar Series).** *National Council for Behavioral Health.*
<http://www.nationalcouncildocs.net/medicaid-national-meeting-on-prescription-drug-abuse-and-overdose>
13. **USDA Announces Telemedicine Funding to Address Opioid Epidemic in Appalachia.** June 30, 2016. *United States Department of Agriculture.*
<http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2016/06/0155.xml>
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<http://dhhs.ne.gov/publichealth/Licensure/Documents/GuidelinesForUseOfContSubst.pdf>
15. **Feds to Boost Opioid Treatment Options, But Seek Far More Funding.** July 6, 2016. *USA Today.*
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<http://www.wsj.com/articles/obama-administration-loosens-controls-on-medication-to-ease-opioid-cravings-146777660>

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<http://www.cnn.com/2016/08/25/health/us-surgeon-general-letter-doctors-opioid-use/index.html>
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19. **Charting the Road to Recovery: Nebraska's Response to Opioid Abuse.** August 2016. *Nebraska Beacon (BHECN Newsletter)*.
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25. **Implementing Medication-Assisted Treatment Statewide. White Paper.** August 2010. *Center for Substance Abuse Treatment*.
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https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/2013_model_policy_treatment_opioid_addiction.pdf
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<http://urbanobservatory.maps.arcgis.com/apps/Cascade/index.html?appid=f86499d99e4340b68229eaccfb02b29f>
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<http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/08/31/nurses-step-in-to-boost-treatment-for-opioid-addiction>
30. **Prescribing Opioids for Chronic Pain-Pocket Guide.** *Turn the Tide RX (Adapted from CDC guidelines)*.
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<https://www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis>
35. **What is Naloxone?** To find the latest information about naloxone, what it is and how it is administered, visit the Naloxone topic page from National Institute on Drug Abuse. Revised August 2016.
<https://www.drugabuse.gov/drugs-abuse/opioids/naloxone>

36. **National Institute on Drug Abuse.** To find out the most commonly abuse drugs. Prescription drugs and their possible health effects.
<https://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs-charts>
37. **Information about treatment options for drug addiction.**
<https://www.drugabuse.gov/related-topics/treatment>
38. **Pain Related Content.** *American Academy of Family Physicians.*
<http://www.aafp.org/afp/topicModules/viewTopicModule.htm?topicModuleId=61>
<http://www.aafp.org/patient-care/public-health/pain-opioids.html>
<http://www.aafp.org/patient-care/public-health/pain-opioids/resources.html>
39. **Resources from the Federation of State Medical Boards.**
<https://www.fsmb.org/policy-and-education/education-meetings/pain-policies>
40. **Opioids.** *Substance Abuse and Mental Health Services Administration.*
<http://www.samhsa.gov/atod/opioids>
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<http://www.cdc.gov/drugoverdose/data/overdose.html>
42. **Addicts for Sale.** March 19, 2016. *BuzzFeed News.*
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[https://www.nebmed.org/uploadedFiles/Nebmed/News/Pdfs/Brochure%20-%20InterdisciplinaryOpioidProgram%20\(Color\).pdf](https://www.nebmed.org/uploadedFiles/Nebmed/News/Pdfs/Brochure%20-%20InterdisciplinaryOpioidProgram%20(Color).pdf)
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<http://nmaevents.org/wp-content/uploads/2016/07/NMA-Annual-Session-Brochure-2016-Web.pdf>
50. **Applying Population Health Management to Opiate Prescription Medication Misuse.** April 13, 2016. Presentation by Joe Parks, MD, National Council Senior Medical Advisor. *National Council for Behavioral Health.*
<http://www.nationalcouncildocs.net/wp-content/uploads/2016/02/Joe-parks.pdf>
51. **Pain Management & Opioid Abuse.** *Nebraska Academy of Family Physicians.*
http://www.nebrafp.org/practice_support/pain_mgmt_opioid_abuse.html
52. **Prevention Status Reports: Prescription Drug Overdose.** *Centers for Disease Control and Prevention.*
<http://www.cdc.gov/psr/national-summary/pdo.html>
53. **Prescription Nation 2016: Addressing America's Drug Epidemic.** *National Safety Council.*
<http://www.nsc.org/RxDrugOverdoseDocuments/Prescription-Nation-2016-American-Drug-Epidemic.pdf>
54. **State and National Totals of Filled Prescriptions: All Opioid Analgesics.** *Xponent, IMS Health, Plymouth Meeting, PA.*
<http://www.mag.org/sites/default/files/downloads/prescriptions-filled-chart.pdf>
55. **Dose of Reality: Prevent prescription Painkiller Abuse in Wisconsin.** September 17, 2016. *Attorney General Brad D. Schimel.*
<http://legis.wisconsin.gov/eupdates/asm89/DOJ%20DOR%20release.pdf>

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Feds to distribute \$53 million to states to fight opioids

By Associated Press | August 31, 2016

The Obama administration says it will distribute \$53 million to 44 states in an effort to curb opioid abuse.

HHS Secretary Sylvia Burwell says the funding will focus on reducing over-prescribing of pain killers, increasing access to treatment and making sure the antidote naloxone is widely available.

The administration is also calling on Congress to provide \$1.1 billion in new money, saying legislation recently signed into law didn't do enough to expand treatment. That bill authorized \$181 million in new spending.

Steve Williams, the mayor of Huntington, West Virginia, said in a conference call announcing the funding that opioid abuse is so common he carries an overdose reversal kit with him. He says federal funding is urgently needed so people seeking treatment don't have to wait months.

Tags: [Government](#), [Opioid abuse](#), [Public Health](#)

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- [Naloxone price hike hinders Baltimore's drug overdose prevention efforts](#)
- [Surgeon general sends letter urging 2.3 million physicians to fight opioid epidemic](#)

FOR IMMEDIATE RELEASE

August 31, 2016

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HHS awards \$53 million to help address opioid epidemic

Additional funding needed to ensure access to evidence-based treatment

Today, the U.S. Department of Health and Human Services announced \$53 million in funding to 44 States, four tribes and the District of Columbia to improve access to treatment for opioid use disorders, reduce opioid related deaths, and strengthen drug misuse prevention efforts. In addition, funding will also support improved data collection and analysis around opioid misuse and overdose as well as better tracking of fatal and nonfatal opioid-involved overdoses.

“The epidemic of opioid use disorders involving the non-medical use of prescription opioid pain relievers and the use of heroin has had a devastating impact on individuals, families and communities across our nation,” said Substance Abuse and Mental Health Services Administration (SAMHSA) Principal Deputy Administrator Kana Enomoto. “These grants will help address the key elements of the opioid crisis by promoting effective prevention efforts, preventing overdose deaths and helping ensure that people with opioid use disorders are able to receive vital treatment and recovery support services.”

Administered by SAMHSA and the Centers for Disease Control and Prevention (CDC), the funding supports six programs.

The Medication-Assisted Treatment Prescription Drug Opioid Addiction Grants will provide up to \$11 million to 11 states to expand access to medication-assisted treatment (MAT) services for persons with opioid use disorder. This program targets states identified as having the highest rates of primary treatment admissions for heroin and prescription opioids per capita, and prioritizes those states with the most dramatic recent increases for heroin and opioids. Awardees are Alaska, Arizona, Colorado, Connecticut, Illinois, Louisiana, New Hampshire, North Carolina, Oklahoma, Oregon, and Rhode Island. (SAMHSA)

The Prescription Drug Opioid Overdose Prevention Grants will provide up to \$11 million to 12 states to reduce opioid overdose-related deaths. Funding will support training on prevention of opioid overdose-related deaths as well as the purchase and distribution of naloxone to first responders. Awardees are Alaska, Arkansas, Illinois, Missouri, New Jersey, New Mexico, Oklahoma, South Carolina, Washington, West Virginia, Wisconsin, and Wyoming. (SAMHSA)

The Strategic Prevention Framework Partnerships for Prescription Drugs Grants provide \$9.3 million to 21 states and four tribes to strengthen drug misuse prevention efforts. The grant program provides an opportunity for states, U.S. territories, Pacific jurisdictions, and tribal entities that have completed a Strategic Prevention Framework State Incentive Grant to target the priority issue of prescription drug misuse. The program is designed to raise awareness about the dangers of sharing medications and work to address the risks of overprescribing. The program also seeks to raise community awareness and bring prescription drug misuse prevention activities and education to schools, communities, parents, prescribers, and their patients. Awardees are Alabama, Connecticut, Delaware, Georgia, Iowa, Louisiana, Maine, Maryland, Minnesota, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas, Utah, Vermont, West Virginia, and Wisconsin as well as Little Traverse Bay Bands of Odawa Indians, Cherokee Nation, Southern Plains Tribal Health Board, and the Nooksack Indian Tribe. (SAMHSA)

“States are on the frontline of preventing prescription opioid overdoses—it is critical that state health departments have the support they need to combat the epidemic,” said CDC Director Tom Frieden, MD, MPH. “States can use these funds to develop, implement, and evaluate programs that save lives.”

The Prescription Drug Overdose: Prevention for States program provides up to \$11.5 million in supplemental funding to 14 states. This supplemental funding will support the ongoing work of awardees, allowing awardees to address issues such as high overdose death rates in tribal communities and improve toxicology and drug screening. States can use this funding to enhance prescription drug monitoring programs (PDMPs), further prevention efforts, and execute and evaluate strategies to improve safe prescribing practices. Awardees are California, Colorado, Indiana, Kentucky, New Mexico, New York, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Washington, and Wisconsin. (CDC)

The Prescription Drug Overdose: Data-Driven Prevention Initiative (DDPI) will award \$6 million to 13 states and DC to advance and evaluate state-level prevention activities to address opioid misuse and overdose.

That includes enhancing their ability to:

- Improve data collection and analysis around opioid misuse and overdose;
- Develop strategies that impact behaviors driving prescription opioid misuse and dependence; and
- Work with communities to develop more comprehensive opioid overdose prevention programs.
- Awardees are Alabama, Alaska, Arkansas, Georgia, Hawaii, Idaho, Kansas, Louisiana, Michigan, Minnesota, Montana, New Jersey, South Dakota, and Washington, D.C. (CDC)

The Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality program is awarding \$4.27 million in funds to 12 states to better track fatal and nonfatal opioid-involved overdoses.

States will use the funding to:

- Increase the timeliness of reporting nonfatal and fatal opioid overdose and associated risk factors;
- Disseminate surveillance findings to key stakeholders working to prevent opioid-involved overdoses; and
- Share data with CDC to support improved multi-state surveillance of and response to opioid-involved overdoses.
- Awardees are Kentucky, Maine, Massachusetts, Missouri, New Hampshire, New Mexico, Ohio, Oklahoma, Pennsylvania, Rhode Island, West Virginia, and Wisconsin. (CDC)

These awards contribute to a total of \$52.5 million awarded by CDC for Prescription Drug Overdose and opioids activities in FY 2016.

The funding announced today is part of the U.S. Department of Health and Human Services' [Opioid Initiative - PDF](#), which was launched in March 2015 and is focused on improving opioid prescribing practices; expanding access to medication-assisted treatment (MAT) for opioid use disorder; and increasing the use of naloxone to reverse opioid overdoses. The initiative concentrates on evidence-based strategies that can have the most significant impact on the crisis. But additional funding is necessary to ensure that every American who wants to get treatment for opioid use disorder will have access. Under the [President's FY 2017 Budget proposal](#), states would be eligible for up to \$920 million over two years to expand access to treatment. At this time, Congress has not funded the budget proposal. See [here](#) for a state by state breakdown of the President's budget and, if fully funded, the impact it would have on states' ability to further expand access to treatment.

More information about SAMHSA grants and the grantees is available at: <http://www.samhsa.gov/grants/>.

More information about CDC grants and the grantees is available at:

<http://www.cdc.gov/drugoverdose/states/index.html>.

“ HHS awards \$53 million to help address opioid epidemic. <http://go.usa.gov/xWXYh> ”

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How to Prevent Opioid Abuse: Training and Education

Physicians Taking More Education

An AMA survey⁷ found that 49,903 courses related to opioid prescribing, pain management or other related areas have been accessed and/or completed by physicians since October 2015.

7. AMA survey of 37 medical societies. New information will be added as it becomes available.

The [AMA Task Force to Reduce Opioid Abuse](#) encourages physicians across the nation to educate themselves on managing pain and promoting safe, responsible opioid prescribing. The resources on this page reflect many of the recommendations of the Task Force.

Explore our state-specific opioid prevention [educational tools and resources](#) recommended by the nation's medical societies and locate issue-specific resources related to [increasing naloxone](#), using PDMPs, and supporting comprehensive treatment for substance use disorders.

CME Courses & Webinars on Safe Opioid Prescribing

Physicians can earn CME credit for studying many of these Task Force-approved resources.

- [Webinar | Opioid Agonist Therapy: To Maintain or Not to Maintain](#)
American Psychiatric Association
- [CME | Stigma in Methadone and Buprenorphine Maintenance Treatment](#)
American Society of Addiction Medicine
- [CME | SCOPE of Pain: Safe and Competent Opioid Prescribing Education](#)
Boston University School of Medicine
- [CME | COPE-REMS: Learn to help patients safely manage pain](#)
University of Washington School of Medicine
- [CME | Smart and Safe: Information About Opioid Medication for Patients, Prescribers, and Policymakers](#)
Massachusetts Medical Society
- [CME | Improving Provider Skills in Reducing the Risk of Opioid Therapy](#)
Clinical Tools Inc.
- [CME | FP Essentials™: Chronic Pain Management](#)
American Academy of Family Physicians
- [CME | ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care](#)
Collaborative for REMS Education (CO*RE)
- [CME | Extended-Release and Long-Acting Opioids: Assessing Risks, Safe Prescribing](#)
supported by the Federation of State Medical Boards
- [CME | Enhancing Clinical Treatment Through Use of Prescription Drug Monitoring Programs](#)
American Psychiatric Association

Pain Management Training & Information

Resources From the Providers' Clinical Support System for Opioid Therapies
The AMA and members of the Task Force to Reduce Opioid Abuse are collaborating on the [Providers' Clinical Support System](#) initiative, funded by the Substance Abuse and Mental Health Services Administration and administered by the American Academy of Addiction Psychiatry. The PCSS-O project maintains an inventory of more than 100 online modules and webinars on topics at the intersection of pain, opioids and addiction, as well as a support network.

- [CME | Clinical Guidelines for Opioid Use in Chronic Noncancer Pain](#)
American Pain Society & American Academy of Pain Medicine
- [Online Module | Opioids for Pain Treatment in Persons With Addiction](#)
By Seddon R. Savage, MD
- [Webinar | Assessing for Risk, Benefit and Harm When Prescribing Opioids for Chronic Pain](#)
American Medical Association
- [Webinar | Difficult Conversations in Opioid Management: Limiting, Reducing, or Stopping Opioids](#)
American Medical Association
- [Webinar | Doc, What Else Can I Do? The Evidence Behind Alternative/Complementary Chronic Pain Management—Part 1](#)
American Psychiatric Association
- [Webinar | Best Practices: Eight Principles for Safer Opioid Prescribing for Pain Management](#)
American Academy of Pain Medicine

Scholarly Articles on Pain Management & Addiction

Learn more about safe opioid prescribing, prescription drug addiction, pain management and more from these selected scholarly articles.

- [Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain](#)
Nuckols TK, Anderson L, Popescu I, et al. Ann Int Med. 2014;160:38-47.
- [Association Between Mental Health Disorders, Problem Drug Use, and Regular Prescription Opioid Use](#)
Sullivan MD, Edlund MJ, Zhang L, Unützer J, Wells KB. Arch Int Med. 2006;166:2087-2093.
- [Neonatal Abstinence Syndrome](#)
Kocherlakota P. Pediatrics. 2014; 134:e547-e561.

Resources for Patients

Patients can refer to this information to learn how to store and dispose of unused medication, find parenting tips on preventing drug abuse and advice for caregivers.

- [Safe Use, Storage, and Disposal of Opioid Drugs | Printable Patient Tip Sheet](#)
Content provided by the California Academy of Family Physicians
- [Eight Opioid Safety Principles for Patients and Caregivers](#)
American Academy of Pain Medicine
- [Family Checkup: Positive Parenting Prevents Drug Abuse](#)
National Institute on Drug Abuse
- [Video | Storing Medications](#)
American Chronic Pain Association
- [Disposal of Unused Medicines: What You Should Know](#)
U.S. Food and Drug Administration
- [Got Drugs?: National Prescription Drug Take-Back Day](#)
U.S. Drug Enforcement Administration
- [Get Smart About Drugs](#)
U.S. Drug Enforcement Administration



Chair Files

Hospital-County Collaboration Prevents Opioid Abuse

A health system in rural Minnesota has helped develop an innovative model to prevent prescription drug and opioid abuse. Staff at CHI St. Gabriel’s Health in Little Falls, Minn., began researching the issue after noticing that a large number of patients in the emergency department were requesting drugs for pain. According to one report, nearly a third of patients covered by the county’s Medicaid-managed insurance plan had eight or more prescriptions for opioids. In January 2015, CHI St. Gabriel’s Health received a two-year [State Innovation Model grant](#). With this funding, the hospital hired a nurse, social worker and pharmacist to coordinate efforts to tackle the opioid abuse problem, including improving communication and patient monitoring among physicians and hospitals. It also helped establish a volunteer prescription drug task force, which meets monthly and has participation from the county sheriff’s office, local police department, county social service and public health agencies, local school district, local pharmacies and home health services, and skilled nursing facilities. As a result, prescription drug usage has decreased, lowering costs substantially. From January through April 2016, the difference in total Medicaid claims paid was \$2.3 million less than the same time in 2015. The Morrison County Prescription Drug Task Force, which includes representatives from the health system and its foundation, received the 2016 Minnesota Rural Health Team Award from the state’s Department of Health.

For more information, contact Kathleen Lange, foundation director, at KathleenLange@catholichealth.net, or Rhonda Buckallew, clinic administrator, at RhondaBuckallew@catholichealth.net



Additional Resources

<p>HPOE Live Webinars September 21st, 2016 Improving the Patient Experience through the Health Care Physical Environment September 21, 20.....</p>	<p>Infographics September 20th, 2016 Using the Triple Aim framework, hospitals and health systems can effectively address behavioral h.....</p>	<p>Chair Files September 19th, 2016 Since September 2015, the AHA/HRET HEN 2.0 hospitals have been working to reduce hospital-acquire.....</p>
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Minnesota Accountable Health Model - State Innovation Model Grant

In February 2013 the [Center for Medicare and Medicaid Innovation](#) (CMMI) awarded Minnesota a [State Innovation Model \(SIM\)](#) testing grant of over \$45 million to use across a three-year period ending October 2016. As a joint effort between the [Department of Health](#) (MDH) and the [Department of Human Services](#) (DHS) with support from Governor Mark Dayton's office, Minnesota will use the grant money to test new ways of delivering and paying for health care using the Minnesota Accountable Health Model framework. The goal of this model is to improve health in communities, provide better care, and lower health care costs.

The Minnesota Accountable Health Model expands patient-centered, team-based care through service delivery and payment models that support integration of medical care, behavioral health, long-term care and community prevention services. Accomplished by building on Minnesota's current [Integrated Health Partnership](#) (IHP) demonstration, the model uses IHPs to adopt Accountable Care Organization (ACO) style contracts with providers to better coordinate care. Minnesota Accountable Health Model activities also build on a strong foundation of service delivery and payment reform models in Minnesota that support secure exchange of clinical data across settings, a system of statewide quality reporting and measurement for healthcare providers, and strong systems for coordinated care through the multi-payer Health Care Home and evolving Behavioral Health Home initiatives.

Goals

- • Minnesota Accountable Health Model will include the establishment of up to 15 Accountable Communities for Health. These communities will develop and test strategies for creating healthy futures for patients and community members.
- • By expanding ACOs using a multi-payer approach, Minnesota will test how to provide and pay for value-based care.
- • Multi-payer alignment will occur through initiatives such as common measurement tools across payers, improved clinical data exchange at the provider level and aligned payment and risk adjustment methods for complex populations.
- • The project will also provide support to providers for health information technology and data analytics, as well as for transformation of their practices to more effectively deliver high-quality, coordinated care.

individual or entity used Federal facilities or consulted with Federal employees during a Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.

General Submission Requirements

In order for a Submission to be eligible to win this Challenge, it must meet the following requirements:

1. No HHS or ONC logo—The Solution must not use HHS' or ONC's logos or official seals and must not claim endorsement.
2. Functionality/Accuracy—A Solution may be disqualified if it fails to function as expressed in the description provided by the participant, or if it provides inaccurate or incomplete information.

Registration Process for Participants

To register for this Challenge, participants can access <http://www.challenge.gov> and search for "Blockchain and Its Emerging Role in Healthcare and Health-related Research."

Prize

Winners will be provided the following:

- Opportunity to present their paper at a Blockchain & Healthcare Workshop Hosted at NIST
- Paid travel to the Workshop;
- Paid room and board for the Workshop; and
- Paid Per Diem.

Payment of the Prize

Prize will be paid by contractor.

Basis Upon Which Winner Will Be Selected

The evaluation process will begin by removing those that are not responsive to this Challenge or not in compliance with all rules for eligibility. Judges will examine all responsive and compliant submissions, and rate the entries. Judges will determine the most meritorious submissions, based on these ratings and select up to eight (8) finalists. Honorable Mentions may be included and announced, along with the winners on Challenge.gov.

The judging panel will rate each submission based upon the effectiveness of the overall concept to help foster transformative change in the HealthIT culture, the viability of the proposed recommendations, the innovativeness of the approach, and its potential for achieving the objectives of ONC.

Up to eight (8) submissions will be selected as winners. Winners will be

awarded with the opportunity to present their White Paper at a two-day Blockchain & Healthcare Workshop. In lieu of a monetary prize, finalists will be provided with full expenses for travel to the Workshop, which will be held at the NIST Headquarters in Gaithersburg, MD.

At the end of the submission period, Submissions will be posted on the challenge Web site and will be reviewed, graded, and voted on by a steering committee.

Additional Information

General Conditions: ONC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at ONC's sole discretion.

Intellectual Property: Each participant retains title and full ownership in and to their Submission. Participants expressly reserve all intellectual property rights not expressly granted under the challenge agreement. By participating in the Challenge, each entrant hereby irrevocably grants to the Government a limited, non-exclusive, royalty-free, perpetual, worldwide license and right to reproduce, publically perform, publically display, and use the Submission to the extent necessary to administer the challenge, and to publically perform and publically display the Submission, including, without limitation, for advertising and promotional purposes relating to the Challenge. This may also include displaying the results of the Challenge on a public Web site or during a public presentation.

Representation, Warranties and Indemnification

By entering the Challenge, each applicant represents, warrants and covenants as follows:

- (a) Participant is the sole author, creator, and owner of the Submission;
- (b) The Submission is not the subject of any actual or threatened litigation or claim;
- (c) The Submission does not and will not violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party;

Participants must indemnify, defend, and hold harmless the Federal Government from and against all third party claims, actions, or proceedings of any kind and from any and all damages, liabilities, costs, and expenses relating to or arising from participant's Submission or any breach or alleged breach of any of the representations, warranties, and covenants of participant hereunder. The Federal Agency sponsors reserve the right to disqualify any Submission that, in their discretion,

deems to violate these Official Rules, Terms & Conditions.

Authority: 15 U.S.C. 3719.

Karen DeSalvo,

National Coordinator for Health Information Technology.

[FR Doc. 2016-16133 Filed 7-6-16; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information: Opioid Analgesic Prescriber Education and Training Opportunities To Prevent Opioid Overdose and Opioid Use Disorder

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), HHS.

ACTION: Request for information.

SUMMARY: Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury death in the United States. Prescription drugs, especially opioid analgesics—a class of prescription drugs such as hydrocodone, oxycodone, morphine, and methadone used to treat both acute and chronic pain—have been increasingly implicated in drug overdose deaths over the last decade. Alarming, deaths related to opioid analgesic overdose have quadrupled since 1999, and this increase in deaths has been linked to parallel increases in opioid prescribing. As part of its comprehensive response to the opioid epidemic, HHS is actively working to stem overprescribing of opioids in a number of ways, including by providing clinicians with the tools and education they need to make informed prescribing decisions. In particular, HHS has developed a number of activities that support opioid analgesic prescriber education. This Request for Information (RFI) seeks comment on the most promising approaches in prescriber education and training programs and effective ways to leverage HHS programs to implement/expand them.

DATES: Comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2016.

ADDRESSES: Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- *Federal eRulemaking Portal:* You may submit electronic comments at <http://www.regulations.gov>. Follow the

instructions for submitting electronic comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.

- *Regular, Express, or Overnight Mail:*

You may mail written comments (one original and two copies) to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: 1557 RFI (RIN 0945-AA02), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW., Washington, DC 20201. Mailed comments may be subject to delivery delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

- *Hand Delivery or Courier:* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to the following address only: Office for Civil Rights, Attention: 1557 RFI (RIN 0945-AA02), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

- *Inspection of Public Comments:* All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Office of the Assistant Secretary for Planning and Evaluation, 202-690-7858.

SUPPLEMENTARY INFORMATION:

I. Background

Education and training in pain management and appropriate opioid analgesic prescribing, including how to identify patients who may be at risk for opioid misuse and ensuring patients treated with opioids receive the appropriate dose and quantity of medication for their condition, are key elements of the response to the opioid epidemic. Surveys of healthcare providers indicate that they receive inadequate training on pain management, and many feel uncomfortable managing patients with pain. In addition, research has identified significant gaps and fragmentation in pain education in

health professional schools, and the National Pain Strategy indicates that health professional education is a central component of advancing a system of care in which all people receive high quality and evidence-based pain care.

To improve education and training on pain management and appropriate opioid prescribing, HHS has developed programs that engage prescribers throughout their training and professional career. For example, in an effort to educate health professional students, the National Institutes on Drug Abuse (NIDA) coordinates the National Institutes of Health Pain Consortium's Centers of Excellence in Pain Education that develop and distribute pain management curriculum resources for medical, dental, nursing, and pharmacy schools.

Many HHS training initiatives target practicing clinicians throughout their learning and practice lifecycles. Some programs, such as NIDA's NIDAMED program, offer opioid and pain management training as continuing education credit opportunities. Additionally, the Food and Drug Administration (FDA) has put in place a risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioid medications. The ER/LA Opioid Analgesic REMS requires manufacturers to make prescriber training available through accredited continuing education (CE) programs funded by the ER/LA sponsors. To assure that the training is balanced and to protect from industry influence, the training is based upon the FDA blueprint for Prescriber Education for ER/LA opioids and is made available through third-party CE providers.

Other programs utilize a peer-to-peer mentoring model. The Substance Abuse and Mental Health Services Administration's Providers' Clinical Support System for Opioid Therapies (PCSS-O) is one such model that offers colleague support and mentoring as well as evidence-based educational resources on how to effectively utilize opioid analgesics for patients with pain and patients with opioid use disorders. And, other resources are intended to support decision making during an active patient encounter. The Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain facilitates providers' decision-making regarding appropriate pain treatment for patients 18 years and older in the primary care setting.

II. Solicitation of Comments

This RFI is seeking comment on the range of approaches to educating and

training providers on pain management and appropriate opioid analgesic prescribing, including identifying patients at risk for abuse and prescribing the appropriate dose and quantity of medication for their condition. As noted above HHS has undertaken several programs to engage providers on these topics, and this RFI is meant to solicit input not only on those but also on other approaches. For example, HHS seeks comment on the impact of non-federal prescriber training policies or programs on opioid analgesic prescriber competency:

- How states have developed, promoted, and made pain management and opioid analgesic prescriber education available,
- whether state requirements for mandatory pain management and opioid prescribing training have led to any changes in prescriber behavior and/or other outcomes as a result of these programs,
- the challenges opioid education providers have faced in implementing opioid prescriber education initiatives,
- which measures education providers use to evaluate the success of their interventions, or
- how health information technology has been implemented to assist the prescriber in appropriate opioid prescribing and pain management.

HHS also is soliciting suggestions for additional activities the Department could implement to ensure universal prescriber education on appropriate pain management and opioid prescribing. For example, additional HHS activities could include:

- Adding new opioid prescriber education to Medicare Conditions of Participation and/or to Medicare enrollment requirements,
- adding quality measures around safe opioid use to the specialty core measures that clinicians may choose to report under the Merit-based Incentive Payment System (MIPS), or
- revising the ER/LA Opioid Analgesic REMS to require that prescribers of opioids receive appropriate training on pain management and safe opioid use before being able to prescribe specific opioids.

Finally, HHS seeks feedback through this RFI on the ability of existing HHS education and training programs to educate all opioid analgesic prescribers on appropriate pain management and opioid prescribing including comments on the development and delivery of the content and on efforts to assess the impact of the training initiatives.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble.

Dated: June 29, 2016.

Kathryn E. Martin,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2016-16067 Filed 7-6-16; 8:45 am]

BILLING CODE 4150-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Public Workshop—Iron Screening and Supplementation of Iron-Replete Pregnant Women and Young Children

SUMMARY: The Office of Dietary Supplements at the National Institutes of Health (NIH) is sponsoring an open public workshop titled, “Iron Screening and Supplementation of Iron-replete Pregnant Women and Young Children,” September 28–29, 2016, on the NIH main campus in Bethesda, Maryland. It will also be available to be viewed live or later on-demand as a videocast. The workshop discussions will focus on the U.S. and developed countries and will serve to specify data gaps and research needs by (1) exploring current understanding of iron homeostasis in pregnant women and in young children (6-24 months); (2) identifying the challenges associated with measuring iron status and with screening practices; and (3) considering emerging issues associated with routine supplementation of iron-replete individuals. All persons are invited to attend, especially clinical educators, those who develop clinical recommendations, health care providers and researchers. Persons wishing to attend are required to register in advance of the conference.

DATES: September 28–29, 2016; 8:30 to 5:15 p.m. (Eastern Time) on the first day and 8:00 to 12:30 p.m. on the second day.

ADDRESSES: National Institutes of Health, William H. Natcher Building; Natcher Conference Center, Building 45, Bethesda, Maryland, 20892.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Rooney, Office of Dietary Supplements, National Institutes of Health, 6100 Executive Boulevard,

Room 3B01, Bethesda, MD 20892-7523, Email: rooneyc@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The conference is sponsored by the NIH Office of Dietary Supplements along with co-sponsors from other federal agencies. Information about the conference agenda, registration procedures, and videocast arrangements can be found at: https://events-suport.com/events/NIH_Iron_Workshop.

Through its Iron Initiative, the National Institutes of Health (NIH) Office of Dietary Supplements leads efforts to advance scientific understanding of iron and health: <https://ods.od.nih.gov/Research/Iron.aspx>.

Dated: July 1, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016-16254 Filed 7-7-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request National Institutes of Health (NIH) Loan Repayment Programs; Office of the Director (OD)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Division of Loan Repayment (DLR), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 19, 2016, and page numbers 8514–8516, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Steve Boehlert, Director of Operations, Division of Loan Repayment, National Institutes of Health, 6011 Executive Blvd., Room 206 (MSC 7650), Bethesda, Maryland 20892-7650. Mr. Boehlert may be contacted via email at BoehlerS@od.nih.gov or by calling 301-451-4465. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: National Institutes of Health (NIH) Loan Repayment Programs (LRP). *Type of Information Collection Request:* Revision of a currently approved collection (OMB No. 0925-0361, expiration date 06/30/17). Form Numbers: NIH 2674-1, NIH 2674-2, NIH 2674-3, NIH 2674-4, NIH 2674-5, NIH 2674-6, NIH 2674-7, NIH 2674-8, NIH 2674-9, NIH 2674-10, NIH 2674-11, NIH 2674-12, NIH 2674-13, NIH 2674-14, NIH 2674-15, NIH 2674-16, NIH 2674-17, NIH 2674-18, NIH 2674-19, and NIH 2674-20 (new).

Need and Use of Information Collection: The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm.D., Psy.D., D.O., D.D.S., D.M.D., D.P.M., D.C., N.D., O.D., D.V.M., or equivalent degree holders who perform biomedical or behavioral research in NIH intramural laboratories or as extramural grantees or scientists funded by domestic non-profit organizations for a minimum of two years (three years for the General Research LRP) in research areas supporting the mission and priorities of the NIH.

The AIDS Research Loan Repayment Program (AIDS-LRP) is authorized by section 487A of the Public Health Service Act (42 U.S.C. 288-1); the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) is authorized by section 487E (42 U.S.C. 288-5); the General Research Loan Repayment Program (GR-LRP) is authorized by section 487C of the Public Health Service Act (42 U.S.C. 288-3); the Clinical Research Loan Repayment Program (LRP-CR) is authorized by section 487F (42 U.S.C. 288-5a); the Pediatric Research Loan Repayment Program (PR-LRP) is authorized by

S.524 - Comprehensive Addiction and Recovery Act of 2016

114th Congress (2015-2016) | [Get alerts](#)LAW [Hide Overview](#)

Sponsor: [Sen. Whitehouse, Sheldon \[D-R\]](#) (Introduced 02/12/2015)

Committees: Senate - Judiciary

Committee Reports: [H. Rept. 114-669 \(Conference Report\)](#)

Latest Action: 07/22/2016 Became Public Law No: 114-198. ([TXT](#) | [PDF](#)) ([All Actions](#))

Roll Call Votes: There have been [16 roll call votes](#)

Tracker:

Introduced Passed Senate Passed House Resolving Differences To President **Became Law**

More on This Bill

[CBO Cost Estimates \[3\]](#)

Subject — Policy Area:

Crime and Law Enforcement

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There are 3 summaries for S.524.

Passed House amended (05/13/2016) ▼

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[Bill summaries](#) are authored by [CRS](#).

Shown Here:

Passed House amended (05/13/2016)

TITLE I--PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE

(Sec. 101) This bill requires the Department of Health and Human Services (HHS) to convene a Pain Management Best Practices Inter-Agency Task Force to: (1) review, modify, and update best practices for pain management and prescribing pain medication; and (2) examine and identify the need for, development of, and availability of medical alternatives to opioids (drugs with effects similar to opium, such as heroin and certain pain medications).

TITLE II--COMPREHENSIVE OPIOID ABUSE REDUCTION ACT

Comprehensive Opioid Abuse Reduction Act of 2016

(Sec. 202) This bill amends the Omnibus Crime Control and Safe Streets Act of 1968 to authorize the Department of Justice (DOJ) to award grants to state, local, and tribal governments to provide opioid abuse services, including:

- enhancing collaboration between criminal justice and substance abuse agencies;
- developing, implementing, or expanding programs to prevent, treat, or respond to opioid abuse;
- training first responders to administer opioid overdose reversal drugs; and
- investigating unlawful opioid distribution activities.

(Sec. 203) DOJ's Office of the Inspector General must audit a number of DOJ grant recipients each year. Grants may not be awarded to nonprofit organizations that hold money in offshore accounts to avoid tax liability.

(Sec. 204) DOJ must award grants to state, local, and tribal governments to establish or expand programs for veterans, including veterans treatment courts, peer-to-peer services, and treatment, rehabilitation, legal, or transitional services for incarcerated veterans.

(Sec. 205) As an offset, this title amends the Justice Assistance Act of 1984 to eliminate existing authority for DOJ to award grants under the Emergency Federal Law Enforcement Assistance Program through FY2021.

(Sec. 206) The Family-Based Substance Abuse Treatment Program is expanded to include prison-based family treatment programs for pregnant women.

(Sec. 207) The Government Accountability Office (GAO) must report on how DOJ grant programs address substance use and substance use disorders among adolescents and young adults.

TITLE III--JASON SIMCAKOSKI PROMISE ACT

Promoting Responsible Opioid Management and Incorporating Scientific Expertise Act or the Jason Simcakoski PROMISE Act

(Sec. 302) This bill directs the Department of Veterans Affairs (VA) to expand its Opioid Safety Initiative to include all VA medical facilities.

The VA must direct VA health care providers, before initiating opioid therapy, to use the VA's Opioid Therapy Risk Report tool, which must include: (1) information from state prescription drug monitoring programs, (2) a patient's most recent information, (3) information on controlled substances prescribed to a patient outside the VA, (4) the most recent time the tool was accessed by a VA health care provider regarding a patient, (5) the results of a patient's most recent drug test, and (6) the ability to determine whether a health care provider prescribed an opioid to a patient without checking information in the tool.

The VA must establish enhanced standards for urine drug tests before and during opioid therapy to help prevent substance abuse, dependence, and diversion.

The VA must use the Interdisciplinary Chronic Pain Management Training Team Program to provide education and training on pain management and safe opioid prescribing practices.

Each VA medical facility must designate a pain management team of health care professionals to coordinate pain management therapy for patients experiencing pain that is not related to cancer. The VA must establish standard protocols for the designation of pain management teams. The protocols must ensure that a health care provider without expertise or training in prescribing pain medications does not prescribe opioids unless the health care provider: (1) consults with a provider who has pain management expertise or who is on the pain management team; and (2) refers the patient to the pain management team for subsequent prescriptions and therapy.

VA health care providers must provide information on prescriptions of controlled substances received by veterans to state prescription drug monitoring programs.

The VA must report on improving the Opioid Therapy Risk Report tool to allow for improved real-time tracking and access to data on certain clinical indicators, concurrent prescribing of opioids by VA health care providers, and mail-order opioid prescriptions.

The VA must: (1) maximize the availability to veterans of opioid overdose reversal drugs, such as naloxone; (2) equip each VA pharmacy with such medications for outpatient use; and (3) expand the Overdose Education and Naloxone Distribution program to ensure that veterans receiving VA health care who are at risk of opioid overdose may access such drugs and training on the proper administration of such drugs.

The VA must modify its patient record system to ensure that health care providers who access a veteran's record will be immediately notified about whether the veteran is receiving opioid therapy, has a history of substance use disorder or overdose, or is at risk of opioid abuse.

(Sec. 303) The VA and the Department of Defense (DOD) must ensure that the VADOD Pain Management Working Group: (1) includes a focus on specified practices, (2) coordinates with other working groups, (3) consults with other federal agencies, and (4) and consults with the VA and DOD regarding proposed updates to the VADOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.

The VA and DOD must update the VADOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.

(Sec. 304) The GAO must report on the VA's Opioid Safety Initiative and the opioid prescribing practices of VA health care providers.

The VA must report on the prescription of opioids to certain patients at each VA facility and notify Congress and investigate if a provider's or facility's prescription rate is inconsistent with safe care standards.

(Sec. 305) VA disclosure of certain information to a state prescription drug monitoring program in order to prevent misuse of prescription medicines by a veteran or dependent is made mandatory.

(Sec. 306) This bill amends the Veterans Access, Choice, and Accountability Act of 2014 to reduce the aggregate amount of awards and bonuses that may be paid by the VA in each of FY2017-FY2021.

TITLE IV--KINGPIN DESIGNATION IMPROVEMENT ACT

Kingpin Designation Improvement Act of 2016

(Sec. 402) This bill amends the Foreign Narcotics Kingpin Designation Act to allow classified information to be submitted to a reviewing court ex parte (without all parties present) or in camera (in private) in a judicial review of a determination by the President that a foreign person is subject to sanctions as a significant foreign narcotics trafficker.

TITLE V--GOOD SAMARITAN ASSESSMENT ACT

Good Samaritan Assessment Act of 2016

(Sec. 503) The GAO must report on the Office of National Drug Control Policy's review of state and local Good Samaritan laws that exempt from criminal or civil liability any individual who administers an opioid overdose reversal drug or device (e.g., naloxone) or who contacts emergency services providers in response to an overdose.

TITLE VI--OPEN ACT

Opioid Program Evaluation Act or the OPEN Act

(Sec. 602) DOJ and HHS must each enter into an arrangement with the National Academy of Sciences to identify outcomes and develop metrics to evaluate: (1) the incidence of opioid abuse and illegal opioid distribution, and (2) the effectiveness of department grant programs regarding opioid abuse. DOJ and HHS must each publish outcomes and metrics and require grant recipients to collect and report data. The National Academy of Sciences must publish the evaluations.

(Sec. 606) As an offset, this title reduces the authorization of appropriations for financial assistance under the Emergency Federal Law Enforcement Assistance program for FY2022.

TITLE VII--INFANT PLAN OF SAFE CARE IMPROVEMENT ACT

Infant Plan of Safe Care Improvement Act

(Sec. 702) This bill amends the Child Abuse Prevention and Treatment Act to require the national clearinghouse for information relating to child abuse to maintain and disseminate information about requirements and best practices relating to the development of plans of safe care for infants born affected by illegal substance abuse symptoms, withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder.

(Sec. 703) The plan of safe care for such infants that is required for a state to receive a grant to improve its child protective services system must: (1) address the health and substance use disorder treatment needs of the infant and affected family or caregiver, and (2) specify a system for monitoring whether and in what manner local entities are providing services in accordance with state requirements.

(Sec. 704) Annual state data reports must include the number of such infants, the number for whom a plan of safe care was developed, and the number for whom referrals are made for services, including services for the affected family or caregiver.

(Sec. 705) HHS must monitor state compliance with child protective services system grant requirements.

TITLE VIII--NAS HEALTHY BABIES ACT

Nurturing and Supporting Healthy Babies Act or the NAS Healthy Babies Act

(Sec. 802) The GAO must report on:

- the prevalence of neonatal abstinence syndrome (NAS), which is the symptoms of withdrawal in a newborn;
- NAS treatment services for which coverage is available under state Medicaid programs;
- the care settings and reimbursement for NAS treatment;
- the prevalence of use of various care settings for NAS treatment under state Medicaid programs;
- any federal barriers to treating infants with NAS under state Medicaid programs; and
- its recommendations for improvements that will ensure access to NAS treatment under state Medicaid programs.

(Sec. 803) This bill amends title XIX (Medicaid) of the Social Security Act to exclude abuse-deterrent prescription drugs from the requirement that manufacturers of single-source or innovator drugs pay additional rebates to state Medicaid programs.

(Sec. 804) Under current law, the Centers for Medicare & Medicaid Services must use analytic technologies to identify improper Medicaid claims. The bill prohibits a state agency from using or disclosing such technologies except for purposes of administering a state Medicaid program or Children's Health Insurance Program (CHIP). State agencies must have adequate data security and control policies to ensure that access to such information is restricted to authorized persons for authorized uses.

(Sec. 805) The bill places \$5 million in the Medicaid Improvement Fund to be available beginning in FY2021.

TITLE IX--CO-PRESCRIBING TO REDUCE OVERDOSES ACT

Co-Prescribing to Reduce Overdoses Act of 2016

(Sec. 902) HHS may establish a grant program to support prescribing opioid overdose reversal drugs (e.g., naloxone) for patients at an elevated risk of overdose, including patients prescribed an opioid.

Grant recipients may use the funds to purchase opioid overdose reversal drugs, establish a program for prescribing such drugs, train health care providers and pharmacists, track patients and outcomes, offset patient cost sharing, conduct community outreach, and connect patients to treatment.

(Sec. 903) HHS may provide information to prescribers in federally qualified health centers and Indian Health Service facilities on best practices for prescribing opioid overdose reversal drugs for patients at an elevated risk of overdose.

(Sec. 904) This title amends the Public Health Service Act to reduce, as an offset, the authorization of appropriations for Centers for Disease Control and Prevention facilities for FY2018.

TITLE X--IMPROVING TREATMENT FOR PREGNANT AND POSTPARTUM WOMEN ACT

Improving Treatment for Pregnant and Postpartum Women Act of 2016

(Sec. 1002) Support for residential substance abuse treatment programs for pregnant and postpartum women is extended through FY2021.

(Sec. 1003) The Center for Substance Abuse Treatment must carry out a pilot program to make grants to state substance abuse agencies to support services for pregnant and postpartum women who have a primary diagnosis of a substance use disorder, including opioid use disorders. The Center for Behavioral Health Statistics and Quality must fund an evaluation of the pilot program.

(Sec. 1004) As an offset, this title reduces the authorization of appropriations for Centers for Disease Control and Prevention facilities for FY2017.

TITLE XI--VETERAN EMERGENCY MEDICAL TECHNICIAN SUPPORT ACT

Veteran Emergency Medical Technician Support Act of 2016

(Sec. 1102) HHS must establish a demonstration program for states with a shortage of emergency medical technicians (EMTs) to streamline state requirements and procedures to assist veterans who completed military EMT training to meet state EMT certification, licensure, and other requirements.

TITLE XII--JOHN THOMAS DECKER ACT

John Thomas Decker Act of 2016

(Sec. 1202) HHS must report on the availability of information regarding prescription of opioids after youth sports injury, including information on opioid use and misuse, injury treatments that do not involve opioids, and treatment for opioid addiction. The report must determine the extent this information is available to teenagers and adolescents who play youth sports, their families, youth sports groups, and health care providers.

Taking into consideration the findings of the report, HHS must develop and disseminate such information.

TITLE XIII--LALI'S LAW

Lali's Law

(Sec. 1302) HHS may make grants to states that allow standing orders (documents that allow a person to acquire, dispense, or administer a prescription medication without a person-specific prescription) for opioid overdose reversal drugs (e.g., naloxone). Grants may be used for:

- developing standing orders for opioid overdose reversal drugs for pharmacies,

- encouraging pharmacies to dispense drugs pursuant to such a standing order,
- implementing best practices for prescribing opioids and prescribing and discussing with patients opioid overdose reversal drugs,
- developing training for prescribers to use in educating the public on administration of opioid overdose reversal drugs, and
- educating the public on the availability and public health benefits of opioid overdose reversal drugs.

States must report on pharmacies that dispense opioid overdose reversal drugs under a standing order and the number of pharmacists trained in educating the public on administration of opioid overdose reversal drugs.

(Sec. 1303) As an offset, this title reduces the authorization of appropriations for Centers for Disease Control and Prevention facilities for FY2017.

TITLE XIV--REDUCING UNUSED MEDICATIONS ACT

Reducing Unused Medications Act of 2016

(Sec. 1402) This bill amends the Controlled Substances Act to allow a pharmacist to partially fill a prescription for a schedule II controlled substance (such as an opioid) if: (1) such partial fills are not prohibited by state law, (2) a partial fill is requested by the patient or prescribing practitioner, and (3) the total quantity dispensed in partial fillings does not exceed the quantity prescribed. Such prescriptions may also be partially filled in accordance with existing Drug Enforcement Administration (DEA) regulations that permit partial fills when a pharmacist cannot supply a full quantity, a patient resides in a long-term care facility, or a patient is terminally ill.

The bill specifies time limits for filling the remaining portion of a partially filled prescription.

TITLE XV--OPIOID REVIEW MODERNIZATION ACT

Opioid Review Modernization Act of 2016

(Sec. 1502) This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to refer new drug applications for opioids to an advisory committee before approval, unless the FDA finds that such a referral is scientifically unnecessary and not in the interest of protecting and promoting public health and the FDA notifies Congress of its rationale.

The FDA must convene an advisory committee on labeling opioids for pediatric use before approving any such labeling.

(Sec. 1503) As part of its evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, the FDA must develop recommendations regarding education programs for prescribers of opioids.

(Sec. 1504) The FDA must finalize the draft guidance entitled "General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products."

TITLE XVI--EXAMINING OPIOID TREATMENT INFRASTRUCTURE ACT

Examining Opioid Treatment Infrastructure Act of 2016

(Sec. 1602) The GAO must report on inpatient and outpatient treatment capacity, availability, and needs, including detoxification programs, clinical stabilization programs, transitional residential support services, rehabilitation programs, treatment programs for pregnant women or adolescents, and treatment through Indian health programs. The report must include the barriers to real-time reporting of drug overdoses at the federal, state, and local level and ways to overcome those barriers.

TITLE XVII--OPIOID USE DISORDER TREATMENT EXPANSION AND MODERNIZATION ACT

Opioid Use Disorder Treatment Expansion and Modernization Act

(Sec. 1703) This bill revises the qualifications required for a practitioner to administer, dispense, or prescribe narcotic drugs for maintenance or detoxification treatment in an office-based opioid treatment program.

The bill expands qualifying practitioners to include licensed nurse practitioners and physician assistants who have expertise and prescribe medications for opioid use disorder in collaboration with or under the supervision of a qualifying physician if state law requires physician oversight of prescribing authority. Qualifying practitioners must comply with reporting requirements and have the capacity to provide all FDA-approved drugs for opioid use disorder.

HHS may change the maximum patient limit for qualifying practitioners. If HHS increases the limit, then a qualifying practitioner must obtain written consent from each patient regarding assessment and treatment.

HHS must update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings.

HHS may recommend revoking or suspending the registration of a practitioner who fails to comply with the requirements of the Controlled Substances Act.

(Sec. 1705) This section repeats section 1402.

TITLE XVIII--NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING REAUTHORIZATION ACT

National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015

(Sec. 1802) This bill amends the National All Schedules Prescription Electronic Reporting Act of 2005 to include as a purpose of state prescription drug monitoring systems ensuring access to prescription history information for the investigative purposes of law enforcement, regulatory, and state professional licensing authorities.

(Sec. 1803) The grant program for state prescription drug monitoring programs is extended through FY2020 and revised, including to:

- allow grants to be used to maintain and operate existing state prescription drug monitoring programs,
- require HHS to redistribute any returned funds among the remaining grantees,
- require a state to provide HHS with aggregate data and other information to enable HHS to evaluate the success of the state's program, and
- expand the program to include any commonwealth or territory of the United States.

The DEA, HHS, a state Medicaid program, a state health department, or a state substance abuse agency receiving nonidentifiable information from a prescription drug monitoring database for research purposes may make that information available to other entities for research purposes.

A state receiving a grant must: (1) facilitate prescriber and dispenser use of the state's prescription drug monitoring system, and (2) educate prescribers and dispensers on the benefits of the system both to them and society.



**American Hospital
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March 1, 2016

The Honorable Sheldon Whitehouse
United States Senate
530 Hart Senate Office Building
Washington, DC 20510

The Honorable Rob Portman
United States Senate
448 Russell Senate Office Building
Washington, DC 20510

The Honorable Amy Klobuchar
United States Senate
302 Hart Senate Office Building
Washington, DC 20510

The Honorable Kelly Ayotte
United States Senate
144 Russell Senate Office Building
Washington, DC 20510

Dear Senators Whitehouse, Portman, Klobuchar, and Ayotte:

On behalf of our nearly 5,000 member hospitals, health systems, and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) thanks you for your leadership in crafting legislation to help stem the epidemic of opioid abuse. We are pleased to support S. 524, the Comprehensive Addiction and Recovery Act, as an important first step toward addressing this burgeoning crisis.

Hospitals see firsthand the effects of opioid abuse, addiction and overdoses in the communities we serve across the nation. Our members' experiences in treating those affected by opioid use disorders have demonstrated that only a multifaceted approach that invests in education, prevention, treatment and rehabilitation can end the public health crisis that threatens the health and lives of millions of Americans. While numerous state legislatures have enacted legislation to address the misuse of opioids, we believe that a coordinated nationwide strategy, including grant programs to support the efforts of state and local governments and community-based organizations, and expanded use of prescription drug monitoring programs (PDMPs), is required. The AHA also supports the provisions of your bill that would increase training for first responders to administer life-saving medications such as Naloxone to those experiencing opioid overdoses. Additionally, we support increased access to medication assisted treatment (MAT), which has been proven effective in treatment and recovery.

Finally, we note that hospitals and health systems play a distinct role in helping to end the opioid epidemic -- a role that others cannot fulfill.



Senators Whitehouse, Portman, Klobuchar, and Ayotte
March 1, 2016
Page 2 of 2

Hospitals treat patients for pain; physicians and other practitioners employed and affiliated with hospitals prescribe opioids; and individuals present at emergency departments every day seeking opioids. While other stakeholders in the community have a role to play in stopping the epidemic, they do not treat patients on an ongoing basis, prescribe opioids or have emergency departments. The AHA applauds your efforts in moving this important legislation and we look forward to working with you to ensure its passage.

Sincerely,

/s/

*Our vision is of a society of healthy communities where
all individuals reach their highest potential for health*



Bulletin

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Bulletin Items 1 - 5 of 31

CMS Issues Proposed Notice of Benefit and Payment Parameters for 2018🔒

August 30, 2016

The CMS Aug. 29 issued a proposed rule that would implement the standards governing health insurance issuers and the Health Insurance Marketplaces for 2018. [Learn More](#)

CMS Issues Proposed Rule on Medicaid DSH Payments🔒

August 16, 2016

CMS published in the Aug. 15 Federal Register a proposed rule on Medicaid disproportionate share hospital payments regarding the treatment of third-party payers in calculating uncompensated care. [Learn More](#)

HRSA Issues Proposed Rule on Dispute Resolution for 340B Program🔒

August 15, 2016

HRSA published in the Aug. 12 Federal Register a proposed rule implementing the Affordable Care Act provision requiring a binding administrative dispute resolution process for 340B Drug Pricing Program hospitals and clinics that claim they have been overcharged for drugs purchased through the program. [Learn More](#)

CMS Issues FY 2017 Final Rules for Three Post-Acute Care Settings: LTCHs, IRFs & SNFs🔒

August 03, 2016

CMS recently issued final rules for fiscal year 2017 for three post-acute care prospective payment systems. [Learn More](#)

CMS Releases FY 2017 Hospital Inpatient PPS Final Rule🔒

August 03, 2016

CMS on Aug. 2 issued its hospital inpatient prospective payment system and long-term care hospital PPS final rule for fiscal year (FY) 2017. [Learn More](#)

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Forum News & Updates



Archives

August 18, 2016



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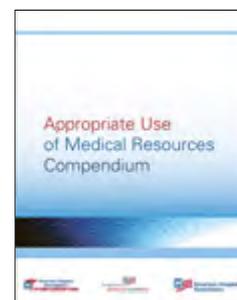
- [AHA issues compendium of appropriate use toolkits](#)
- [AHA comments on proposed changes to hospital, CAH conditions of participation](#)
- [Legislation signed into law addressing opioid epidemic](#)
- [FDA revises warnings for oral and injectable fluoroquinolone antibiotics](#)
- [Half of physicians still unaware of MACRA, survey finds](#)
- [CDC provides health departments \\$67 million to fight antibiotic resistance](#)
- [ASCO releases guidelines for treating chronic pain in cancer survivors](#)

AHA issues compendium of appropriate use toolkits

The AHA's Physician Leadership Forum and Hospitals in Pursuit of Excellence initiative have released a compendium to help hospitals, in partnership with their clinical staff and patients, to closely examine the appropriate use of medical resources for five hospital-based procedures or interventions. The compendium offers a toolkit on each of the five areas: blood management, antimicrobial stewardship, ambulatory care sensitive conditions, elective percutaneous coronary intervention, and aligning treatment with patient priorities for use of the ICU. The toolkits are an outgrowth of the AHA white paper, "[Appropriate Use of Medical Resources](#)," which recommends a way forward that will place hospitals at the forefront of innovative change for reducing the use of specific non-beneficial services while improving health care overall. AHA collaborated with a

FEATURED RESOURCE

Appropriate Use of Medical Resources Compendium



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broad group of national organizations and content experts to produce each toolkit. The new compendium is available at www.aha.org/appropriateuse.

AHA comments on proposed changes to hospital, CAH conditions of participation

The American Hospital Association (AHA) recently submitted [comments](#) on a Centers for Medicare & Medicaid Services (CMS) proposed rule revising several Medicare Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs). Among other provisions, CMS proposes to adopt specific non-discrimination language for the CoPs, and require hospitals and CAHs to have antibiotic stewardship programs. The AHA said it supports many of CMS's proposals but urged the agency to make several revisions "to improve clarity and ensure the final standards are practical and effective in meeting desired outcomes," wrote AHA Executive Vice President Tom Nickels. For example, AHA urged the agency to provide technical assistance to help CAHs implement the new programs, and at least a year for CAHs to come into compliance with the requirements. It also urged CMS to carefully review the rule's potential overlap with other laws, regulations and pending rules "to ensure alignment across the numerous requirements imposed on hospitals and their clinicians."

Legislation signed into law addressing opioid epidemic

The Senate recently voted 92-2 to approve the conference report to the Comprehensive Addiction and Recovery Act ([S. 524](#)), legislation designed to help stem the epidemic of opioid abuse through education, prevention, treatment and rehabilitation. The bill incorporates several key [AHA-endorsed measures](#), including the creation of a multi-agency task force with a hospital representative that will develop best practices for prescribing and pain management; more stringent pre-market review of new opioids by the Food and Drug Administration; increased access to opioid overdose reversal drugs and medication-assisted treatment; and expanded research and treatment for vulnerable populations. The House passed the conference reports and President Obama has signed the legislation into law. AHA members received a [Special Bulletin](#) with more on the legislation, as well as recent actions by the administration and AHA to combat the opioid abuse epidemic.

FDA revises warnings for oral and injectable fluoroquinolone antibiotics

The U.S. Food and Drug Administration (FDA) has made changes to the labels for fluoroquinolone antibacterial drugs administered by mouth or injection to address potential serious safety issues. The revised "boxed warning," the agency's strongest warning, notes that the drugs are "associated with disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system" that can occur together. "Health care professionals should not prescribe systemic fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI) because the risks

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CMS proposes bundled payment models for cardiac and hip fracture care

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FORWARD TO A FRIEND

outweigh the benefits in these patients," the agency states. For more, see the [FDA Safety Announcement](#).



Half of physicians still unaware of MACRA, survey finds

Roughly half of physicians have never heard of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), according to a recent [survey](#) of 600 physicians by the Deloitte Center for Health Solutions. In addition to their awareness of the law, they also asked physicians about their readiness and attitudes toward payment change. Almost 80 percent of respondents prefer fee-for-service or salary for their compensation, the survey found. In addition, 58 percent of respondents said the financial risk of the new payment system makes them more likely to join a larger organization where they would have access to more resources.

CDC provides health departments \$67 million to fight antibiotic resistance

The Centers for Disease Control and Prevention [said](#) it will provide \$67 million in funding to public health departments across the country to help combat antibiotic resistance. The funds will support CDC's [Antibiotic Resistance Solutions Initiative](#) and implementation of the [National Action Plan for the Combating Antibiotic-Resistant Bacteria](#). They also will be used to tackle health care-associated infections. In addition to all 50 states and Puerto Rico, local health departments in Chicago, the District of Columbia, Houston, Los Angeles County, New York City and Philadelphia will receive funds.

ASCO releases guidelines for treating chronic pain in cancer survivors

The American Society of Clinical Oncology (ASCO) has released [updated guidelines](#) for the management of chronic pain in adult cancer survivors that urge clinicians to screen for pain at each encounter and carefully weigh the use of opioids for certain patients who do not respond to more conservative management, among other recommendations. "Many guidelines and recommendations have been advanced to support the management of cancer pain, yet the focus of these documents has been primarily on relieving acute pain or pain associated with advanced disease," the authors wrote. "Few evidence-based cancer pain guidelines address the more nuanced care required when pain persists for months or years. This situation is in part caused by the relative absence of studies exploring the experiences of chronic pain in cancer survivors, or the long-term safety and effectiveness of analgesic interventions." The guidelines were endorsed by an ASCO-convened panel after a systematic literature review of more than 60 studies investigating chronic pain management in adult cancer survivors.

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Study: Medicare Beneficiaries May Face 'Treatment Gap' For Painkiller Abuse, Misuse

By Carmen Heredia Rodriguez | July 20, 2016



When most people think of the victims of the nation's opioid abuse epidemic, they seldom picture members of the Medicare set.

But a research letter published Wednesday in *JAMA Psychiatry* found Medicare beneficiaries had the highest and most rapidly growing rate of "opioid use disorder." Six of every 1,000 recipients struggle with the condition, compared with one out of every 1,000 patients covered through commercial insurance plans.

The letter also concluded that Medicare beneficiaries may face a treatment gap. In 2013, doctors prescribed a high number of opioid prescription painkillers for this population — which put patients at risk for addiction — but far fewer prescriptions for buprenorphine-naloxone, the only effective drug therapy for opioid use disorder covered by Medicare Part D.

"The take home message is we have very effective treatments," said Anna Lembke, one of the research letter's authors and assistant professor at the Stanford University School of Medicine. "But they're not widely accessible."

Researchers analyzed 2013 Medicare Part D claims to count the number of prescriptions for Schedule II opioids and buprenorphine-naloxone. The latter drug curbs addiction by partially stimulating the same brain receptors as a stronger opioid, but with a lower risk of overdose.

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The data showed the number of doctors who prescribed buprenorphine-naloxone equaled less than 2 percent of the 381,575 prescribers responsible for 56,516,854 Schedule II opioid claims. For instance, the researchers found that for every 40 family physicians prescribing pain killers, only one family physician prescribed the addiction management drug.

The letter also found states in the northeast, including Maine, Massachusetts and Vermont, had the highest ratio of buprenorphine-naloxone claims in the country, more than 300 times the national average.

In the last decade, the incidence of opioid addiction in the United States has reached crisis levels. According to the latest data from the Centers for Disease Control and Prevention, more than 19,000 Americans died from prescription opioid overdoses in 2014.

More than 300,000 Medicare recipients battle with opioid use disorder, according to the study. Among beneficiaries, hospitalizations due to complications caused by opioid abuse or misuse increased 10 percent every year from 1993 to 2012.

Lembke said part of the reason doctors do not prescribe more addiction management medications is because they view the problem as one of medicine's lost causes.

"Doctors feel helpless and hopeless when it comes to addiction," she said. "They feel that nothing can be done for them."

And Medicare patients face additional obstacles when it comes to addiction treatment. First, Part D, Medicare's prescription drug program, only covers buprenorphine-naloxone. Other effective treatments such as methadone are not covered, posing a barrier to access, said Lembke.

Buprenorphine-naloxone also usually requires prior authorization before a patient can receive the treatment. In addition, in order to prescribe it, physicians must take an 8-hour class, apply for a waiver and receive a special Drug Enforcement Administration number in addition to his or her regular DEA registration number. It becomes a hassle many medical professionals do not feel is worth the time, said Dr. Jonathan Chen, co-author of the study and instructor at Stanford.

"Why is it hard to [prescribe buprenorphine-naloxone], yet so easy for me to hand out things that get people dependent in the first place?" he said.

A different JAMA [study](#) found only 2 percent of doctors nationwide had obtained the authorization needed to prescribe the medication in 2014. And over half of the nation's counties did not have a health provider with the ability to prescribe the medication.

But the letter's authors note that physicians who prescribe opioid painkillers have in place a relationship with their patients that makes them well-positioned — with some additional training — to take steps to intervene when opioids are being misused.

"The bottom line is it's a heck of a lot more work to get patients off of opioids than to get them on opioids," said Lembke.

KHN's coverage of aging and long term care issues is supported in part by a grant from The SCAN Foundation.

CATEGORIES: Aging, Medicare, Public Health, Syndicate

TAGS: Prescription Drugs, Study, Substance Abuse

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Letters

RESEARCH LETTER

Use of Opioid Agonist Therapy for Medicare Patients in 2013

Despite public policy efforts to prevent opioid overdose and addiction, opioid overdose rates reached record high numbers in 2014.¹ The population that uses Medicare, the federal insurance program for Americans who have certain disabilities or are 65 years or older, has among the highest and most rapidly growing prevalence of opioid use disorder, with more than 6 of every 1000 patients (more than 300 000 of 55 million) diagnosed² and with hospitalizations increasing 10% per year.³ Data on patients with commercial insurance plans (the other likely source for national population data) show just more than 1 of every 1000 patients diagnosed.² Prevention initiatives are essential for reducing the number of new patients with opioid use disorder, but treatment will be required for those already addicted to opioids. Opioid agonist therapy (OAT), including buprenorphine-naloxone (Suboxone) and methadone, is the most effective pharmacotherapy for opioid addiction.⁴

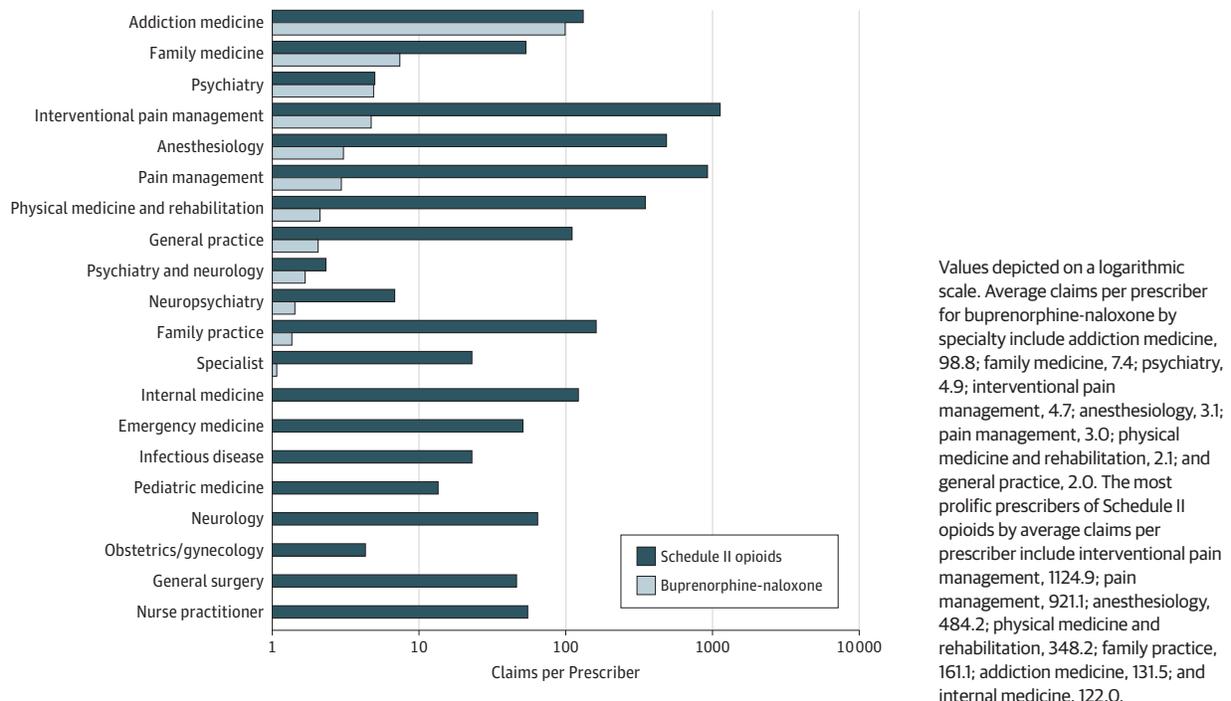
An analysis of Medicare data on buprenorphine-naloxone prescribing allows us to make inferences on prescribers' use of this treatment. Medicare Part D (prescription drug coverage) does not pay for methadone maintenance treatment for opioid addiction. Hence, buprenorphine-naloxone (or buprenorphine alone, in the case of pregnancy) is the only covered OAT

option for patients with opioid use disorder. We hypothesized that the rates of buprenorphine-naloxone prescribing would be below the projected need.

Methods | We examined data from individual prescribers from the 2013 Medicare Part D claims data set created by the Centers for Medicare and Medicaid Services. Part D covers approximately 68% of the roughly 55 million people on Medicare. For each of the included 808 020 prescriber National Provider Identifier numbers, the data identify each drug prescribed, number of beneficiaries, total number of claims, and total costs. Each National Provider Identifier includes location and specialty of practice. The data represent 1 188 393 892 claims that cost \$80 941 763 731. We focused on buprenorphine-naloxone and how the prescription of buprenorphine-naloxone compares with the prescription of Schedule II opioid painkillers. Institutional review board approval and patient consent were waived because the data were deidentified and publicly available.

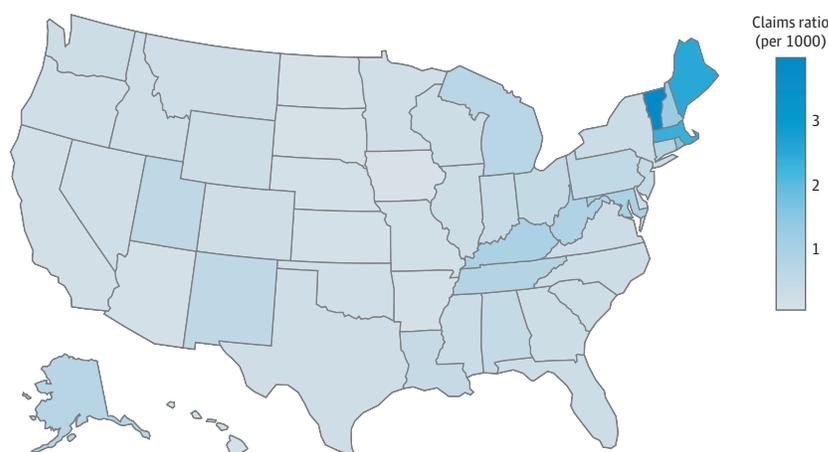
Results | We found 6707 prescribers with 486 099 claims for buprenorphine-naloxone, written for approximately 81 000 patients. Buprenorphine-naloxone prescribers equaled less than 2% of the 381 575 prescribers with 56 516 854 Schedule II opioid claims. For every 40 family practice physicians who prescribed an opioid painkiller, only 1 family practice physician prescribed buprenorphine-naloxone (71 718 vs 1793). Pain physicians

Figure 1. Average Prescription Claims per Prescriber by Specialty



Values depicted on a logarithmic scale. Average claims per prescriber for buprenorphine-naloxone by specialty include addiction medicine, 98.8; family medicine, 7.4; psychiatry, 4.9; interventional pain management, 4.7; anesthesiology, 3.1; pain management, 3.0; physical medicine and rehabilitation, 2.1; and general practice, 2.0. The most prolific prescribers of Schedule II opioids by average claims per prescriber include interventional pain management, 1124.9; pain management, 921.1; anesthesiology, 484.2; physical medicine and rehabilitation, 348.2; family practice, 161.1; addiction medicine, 131.5; and internal medicine, 122.0.

Figure 2. Ratio of Buprenorphine-Naloxone Claims vs All Drug Claims by State



averaged on the order of thousands of opioid painkiller prescriptions per prescriber compared with a negligible number of buprenorphine-naloxone prescriptions (mostly <5). Prescribers with a primary specialty in addiction medicine prescribed the most buprenorphine-naloxone per prescriber (98.8 claims per year), but there were only 100 such Medicare prescribers in the nation (Figure 1). The top 6 states by buprenorphine-naloxone claims ratio (the number of claims for the given drug subset divided by the total number of claims for all drugs) were Vermont, Maine, Massachusetts, Rhode Island, District of Columbia, and New Hampshire, all with a claims ratio more than 300 times the national average (Figure 2).

Discussion | These data do not necessarily reflect clinicians' complete practices or patient factors (eg, comorbidities or whether buprenorphine-naloxone was prescribed for its approved indication of opioid use disorder). With those cautions, important findings remain evident.

Approximately 81 000 Medicare enrollees are receiving buprenorphine-naloxone therapy (the only OAT available through Medicare Part D) despite more than 300 000 Medicare patients estimated to be struggling with an opioid use disorder and 211 200 per year requiring hospitalization for opioid overuse.³ We believe this reflects a significant treatment gap, although we are limited in providing precise estimates; not all patients with an opioid use disorder warrant OAT, but on the other hand, opioid disorders are systematically underdiagnosed and increasing in prevalence.⁵ Furthermore, more than one-third of Part D enrollees fill at least 1 prescription for an opioid in any given year,³ putting many more patients at risk for iatrogenic addiction.⁶

Conclusions | Buprenorphine-naloxone is underused by Medicare prescribers. Geographic differences in buprenorphine-naloxone prescribing should be explored to assess state-level variations in advocacy for and barriers to its use. To combat the current prescription opioid epidemic, integration and promotion of OAT should be encouraged, and not just among addiction medicine specialists, who are far too few to meet the current and projected need. Physicians who prescribe high volumes of opioids and thus

already have an established therapeutic alliance and prior experience with opioid prescribing are especially well-situated, with some additional training, to intervene when cases of prescription opioid misuse, overuse, and use disorders arise.

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Author Contributions: Dr Chen had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Lembke.

Acquisition, analysis, or interpretation of data: Both authors.

Drafting of the manuscript: Lembke.

Critical revision of the manuscript for important intellectual content: Both authors.

Statistical analysis: Chen.

Obtained funding: Lembke.

Administrative, technical, or material support: Lembke.

Study supervision: Lembke.

Conflict of Interest Disclosures: None reported.

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Disclaimer: This content is solely the responsibility of the authors and does not necessarily represent the official views of the US Department of Veterans Affairs, National Institutes of Health, or Stanford Health Care.

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Trends in Stimulant Medication Use in Commercially Insured Youths and Adults, 2010-2014

Stimulants are the most commonly prescribed treatment of attention-deficit/hyperactivity disorder (ADHD) in youths, and according to a nationally representative US household survey, there has been a sizeable increase in stimulant use among youth, from 4.0% between 1996 and 1998 to 6.6% between 2010 and 2012.¹ Also, during the last decade, the US Food and Drug Administration approved an indication for stimulant use in adults to treat ADHD.

Studies of office-based physician visits by adults showed that the proportion of visits with a prescribed stimulant grew 7-fold, from 0.1% between 1994 and 1997 to 0.7% between 2006 and 2009,² and the percentage of visits with ADHD diagnosis doubled from 0.3% between 1999 and 2002 to 0.7% between 2007 and 2010.³ Also, compared with youth ADHD visits, adult ADHD visits comprised a distinctly larger proportion of female and commercially insured visits.³ However, little is known about the trends in stimulant use within the past few years, specifically within commercially insured US populations. This study uses data from a large, commercially insured population to characterize recent trends and patterns of stimulant use according to age and sex.

Methods | A repeated cross-sectional design was applied to 5 years (2010-2014) of administrative claims data on youths (0-19 years) and adults (20-64 years) who were continuously enrolled (>90% of total enrollees) in a Blue Cross Blue Shield health insurance plan annually in Illinois, New Mexico, Oklahoma, or Texas (>3.5 million persons/year). We assessed stimulant use (persons with ≥1 methylphenidate and amphetamine-related product dispensings) expressed as percentage of continuous enrollees in each year according to sex and age group. With multivariable logistic regression models, we assessed the odds of stimulant use in 2014 vs 2010, adjusting for sociodemographic factors. We also examined clinician-reported ADHD diagnosis (*International Classification of Diseases, Ninth Revision, Clinical Modification* code 314.xx) in stimulant-treated youth and adults. The study used deidentified data and the University of Maryland Institutional Review Board did not require approval.

Results | From 2010 to 2014, the prevalence of stimulant use increased across all age groups, although it was markedly greater among adults ($P < .001$) (Table). Stimulant use increased from 2.7% to 3.1% in 0- to 9-year-olds (adjusted odds ratio [AOR], 1.16; 95% CI, 1.13-1.18); from 6.2% to 7.2% in 10- to 19-year-olds (AOR, 1.27; 95% CI, 1.25-1.29); from 2.2% to 3.6% in 20- to 39-year-olds (AOR, 1.84; 95% CI, 1.81-1.87); and from 1.0% to 1.5% in 40- to 64-year-olds (AOR, 1.66; 95% CI, 1.63-1.69) (Table). Slight but statistically significant differences were observed in growth of stimulant use by sex among 10- to 19-year-olds and 20- to 39-year-olds (Table).

In 2014, stimulant prevalence was substantially greater in boys than girls from ages 0 to 19 years (7.1% vs 3.5%; $P < .001$), but it did not differ by sex from ages 20 to 34 years (4.0% vs 4.0%; $P = .95$) (Figure). In contrast, stimulant use was greater in women than men from ages 35 to 64 years (1.9% vs 1.3%; $P < .001$) (Figure).

Table. Trends in Annual Prevalence of Stimulant Use Among Blue Cross Blue Shield Enrollees According to Age Group and Sex, 2010-2014^a

Variable	Annual Prevalence, %					AOR (95% CI) ^b	P Value for Interaction
	2010	2011	2012	2013	2014		
Youths (0-19 y)	4.6	4.8	5.2	5.3	5.3	1.24 (1.22-1.25)	<.001
Adults (20-64 y)	1.5	1.8	2.0	2.2	2.4	1.77 (1.74-1.79)	
0-9 y	2.7	2.9	3.1	3.2	3.1	1.16 (1.13-1.18)	.54
Boys	3.9	4.1	4.4	4.5	4.4	1.15 (1.12-1.19)	
Girls	1.5	1.6	1.7	1.8	1.7	1.16 (1.11-1.21)	
10-19 y	6.2	6.5	6.9	7.1	7.2	1.27 (1.25-1.29)	.01
Boys	8.1	8.5	8.9	9.2	9.3	1.25 (1.23-1.27)	
Girls	4.2	4.5	4.8	5.0	5.1	1.31 (1.28-1.34)	
20-39 y	2.2	2.7	3.1	3.3	3.6	1.84 (1.81-1.87)	.02
Men	2.1	2.6	3.0	3.3	3.5	1.89 (1.85-1.94)	
Women	2.3	2.8	3.2	3.4	3.6	1.81 (1.77-1.85)	
40-64 y	1.0	1.2	1.3	1.4	1.5	1.66 (1.63-1.69)	.06
Men	0.8	0.9	1.0	1.1	1.2	1.65 (1.60-1.70)	
Women	1.2	1.4	1.5	1.6	1.8	1.68 (1.63-1.72)	

Abbreviation: AOR, adjusted odds ratio.

^a Continuously enrolled populations in each calendar year were in 2010, 2 621 920 adults and 1 056 477 youths; in 2011, 2 641 054 adults and 1 049 752 youths; in 2012, 2 727 751 adults and 1 072 293 youths; in 2013, 2 940 599 adults and 1 142 102 youths; and in 2014, 3 123 138 adults and 1 213 012 youths. Across study years, in both youth and adults, both sexes (boys/men and

girls/women) were equally represented, with a majority of white individuals (>70%) and nonrural area residents (>80%).

^b For stimulant use in 2014 compared with stimulant use in 2010, adjusted for race/ethnicity, plan state, urbanicity of area of residence, and annual household income.


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OHSU: Our Community Responds to the Opiate Epidemic

Friday, July 22, 2016

[Download Presentation Slides](#) (pdf)

This webinar highlights one community's response to the opioid epidemic. Oregon Health & Science University (OHSU) Chief Integration Officer, Tom Yackel, MD and Assistant Professor of Medicine and Associate Program Director, Addiction Medicine Fellowship, Melissa Weimer, DO, MCR discuss how the three-county collaborative involving 14 hospitals from four health systems, two community care organizations and four health departments developed a community standard to reduce the use of and addiction to opiates.

About the Physician Leadership Forum:

As part of the American Hospital Associations (AHA) ongoing mission to improve the health of patients and communities, AHA introduced the Physician Leadership Forum to engage and partner with physicians to collaboratively advance excellence in patient care. AHA's Physician Leadership Forum also seeks to gather input from physicians to inform AHA policy and advocacy efforts while advancing physician leadership within the health care delivery system. For more information, go to www.ahaphysicianforum.org.

About the Section for Psychiatric and Substance Abuse Services:

The AHA Section for Psychiatric and Substance Abuse Services (SPSAS) provides perspective on behavioral health issues. SPSAS represents over 1,660 providers, including psychiatric services provided in general acute care hospitals, as well as freestanding adult, child and adolescent psychiatric hospitals and alcohol and drug hospitals. The purpose of the Section is to promote and enhance the understanding and importance of behavioral health care through AHA policy, advocacy and service efforts specific to psychiatric and substance abuse service providers. For more information, visit the AHA website at www.aha.org/psych.

Presenters:



Thomas R. Yackel, MD, MPH, FACP
Clinical Integration Officer, OHSU
Partners
Associate Dean for Clinical Affairs,
Oregon Health & Science University



Melissa Weimer, DO, MCR
Assistant Professor of Medicine,
Division of Internal Medicine &
Geriatrics
Addiction Medicine Physician,
Improving Addiction Care Team
(IMPACT)
Associate Program Director,
Addiction Medicine Fellowship,
Oregon Health & Science University

Hosted By:

AHA's Section for Psychiatric and
Substance Abuse Services

AHA's Physician Leadership Forum

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Providers' Clinical Support System

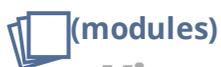
For Opioid Therapies

ABOUT THE PROGRAM
(GOALS-OBJECTIVES)

What We Do

LEARN MORE (GOALS-OBJECTIVES)

PCSS-O is a national training and mentoring project developed in response to the prescription opioid overdose epidemic. The consortium of major stakeholders and constituency groups with interests in safe and effective use of opioid medications offers extensive experience in the treatment of substance use disorders and specifically, opioid use disorder treatment, as well as the interface of pain and opioid use disorder. PCSS-O makes available at no cost CME programs on the safe and effective use of opioids for treatment of chronic pain and safe and effective treatment of opioid use disorder.



(modules)

View Modules (modules)

The foundation for provider education on topics related to pain management and the treatment of opioid use disorder.

Start Training ▶
(modules)



(<http://pcss-o.org/colleague-support/request-a-mentor/>)

Find a Mentor (<http://pcss-o.org/colleague-support/request-a-mentor/>)

The mentor program provides individualized

(http://pcss-o.org/calendar-of-events/list/?tribe_event_display=past&tribe_eventcategory=87)

[/calendar-of-events/list/?](http://pcss-o.org/calendar-of-events/list/?tribe_event_display=past&tribe_eventcategory=87)

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Watch Webinars ([http://pcss-o.org/calendar-of-events/list/?](http://pcss-o.org/calendar-of-events/list/?tribe_event_display=past&tribe_eventcategory=87)

Medicaid National Meeting on Prescription Drug Abuse and Overdose – February 1-2, 2016

Medicaid National Technical Assistance

Webinar: Illusion of Opioids: Knowing the Truth about these Medicines and Policy Implications

Presenter: Dr. Don Teater, National Safety Council

[PowerPoint Slides](#)

[Webinar Recording](#)

[Evidence-based Practice Center Technical Brief Protocol: Medication-Assisted Treatment Models of Care for Opioid Use Disorder](#)

Webinar: Applying Population Health Management to Opiate Prescription Medication Misuse

Presenter: Dr. Joe Parks, National Council Senior Medical Advisor

[PowerPoint Slides](#)

[Webinar Recording](#)

Webinar: Prescriber Considerations when Treating Chronic Pain

Presenter: Dr. Roger Chou, Professor of Medicine, Oregon Health & Science University

[PowerPoint Slides](#)

[Webinar Recording](#)

Webinar: Clinical Tools for Chronic Pain Management Among Individuals with Substance Use Disorders (SUDs)

Presenter: Dr. Joji Suzuki

[PowerPoint Slides](#)

[Webinar Recording](#)

Webinar: Adjunct Approaches to Chronic Pain Management for Individuals with SUD

Presenter: Dr. Stephen Wyatt

[PowerPoint Slides](#)

[Webinar Recording](#)

Presentations from the Medicaid National Meeting on Prescription Drug Abuse and Overdose

[I. Medicaid and Prescription Drug Abuse](#) – Lindsey Browning, Senior Policy Associate, National Association of Medicaid Directors

[II. State Approaches to Improving Opioid Prescribing](#) – Moderator: Dr. Grant Baldwin, CDC; Dr. Charissa Fotinos, Washington Medicaid Program; Dr. Christopher Pezzullo, MaineCare; Dr. Vaughn Frigon, Bureau of TennCare, Tennessee Health Care Finance and Administration

[III. Update on Medicaid Prescription Drug Program](#) – John M. Coster, Ph.D., R.Ph., Director, Division of Pharmacy, Centers for Medicare & Medicaid Services

[IV. The Truth about Opioids](#) – Dr. Don Teater, Medical Advisor, National Safety Council

[V. Prescription Drug Abuse in Medicaid](#) – Cynthia Reilly, Director, Prescription Drug Abuse, The Pew Charitable Trusts

[VI. Methadone and Pain Prescribing](#) – Moderator: Cynthia Reilly, The Pew Charitable Trusts; Dr. Kim Wentz, Oregon Health Authority; Nancy Nesser, Oklahoma Health Care Authority

[VII. Continuum of Care in a Medicaid Setting](#) – David R. Gastfriend, MD, Scientific Advisor, Treatment Research Institute, Chief Architect, CONTINUUM – The ASAM Criteria Decision Engine™

[VIII. MAT among Medicaid Programs](#) – Moderator: Dr. Don Teater, National Safety Council; Joe Moser, Indiana Medicaid; Dr. Joe Parks, MO HealthNet

[Day 2 Facilitation Slides](#)

Additional Resources

[Strategies to Reduce Prescription Drug Abuse: Lessons Learned from the ACAP SUD Collaborative](#)

[Fact Sheet: President Obama Proposes \\$1.1 Billion in New Funding to Address the Prescription Opioid Abuse and Heroin Use Epidemic](#)

[State Medicaid Interventions for Preventing Prescription Drug Abuse and Overdose: A Report For The National Association Of Medicaid Directors](#)

[CMCS Informational Bulletin: Best Practices for Addressing Opioid Overdoses, Misuse and Addiction](#)

[The SnuggleME Project: Embracing Drug Affected Babies and their Families in the First Year of Life to Improve Medical Care and Outcomes Maine](#)

[Providers' Clinical Support System for Opioid Therapies](#)

[Providers' Clinical Support System for Medication Assisted Treatment](#)

[Reducing Opioid Overdose, Misuse and Dependency: A Guide for CCOs](#)

[NCHS Data Visualization Pilot](#)

[PDMP Best Practices](#)

[SoonerCare Pain Management Program](#)

[Best Practices for Addressing Prescription Opioid Overdoses, Misuse](#)

[Opioid Prescribing Guideline in the Acute Care Setting](#)



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News Release

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USDA Announces Telemedicine Funding to Address Opioid Epidemic in Appalachia

ABINGDON, Virginia, June 30, 2016 – Agriculture Secretary Tom Vilsack today announced five Distance Learning and Telemedicine (DLT) grant awards to help provide treatment for the growing opioid epidemic in rural central Appalachia. Vilsack made the announcement as he hosted a town hall in Abingdon to address the opioid crisis in rural America, the first in a series. In January, President Obama tasked Secretary Vilsack, who is chair of the White House Rural Council, with leading a federal interagency effort focused on rural opioid use.

"Because addiction treatment is often out of reach for many in rural America, expanding access to telemedicine is an important step towards making sure rural communities have the tools they need to fight the opioid epidemic," Vilsack said. "USDA is committed to provide the critical resources rural areas need to reduce the staggering increase in opioid overdose deaths that is driving up health care costs and devastating communities."

Today's announcement is the first part of a new round of DLT projects that are to be announced this summer and includes nearly \$1.4 million for five projects in Kentucky, Tennessee and Virginia to help rural areas address the opioid epidemic.

In Kentucky, USDA approved two applications of over \$720,000 to establish telemedicine networks that will provide treatment for medical conditions, including mental health and drug addiction treatment.

USDA awarded The Baptist Health Foundation Corbin, Inc. a \$377,121 grant that will help connect clinical specialists to ten school-based health centers and two primary care sites. This project will provide mental, behavioral and psychiatric care services in high poverty [StrikeForce](#) areas and Kentucky's southeastern [Promise Zone](#). The StrikeForce and Promise Zone initiatives are part of the Obama Administration and USDA's efforts to target investments to areas of persistent economic hardship.

In Whitesburg, Kentucky USDA awarded the Mountain Comprehensive Health Corporation a grant of \$343,600 to provide a telemedicine network that allows greater access to primary and behavioral health care for those facing transportation and economic challenges, some of which are Promise Zone counties.

In Tennessee, USDA awarded a grant of \$67,572 to the Carey Counseling Center to expand and improve six rural counseling centers with mental, behavioral and psychiatric care services and substance treatment services. This project will serve two StrikeForce Counties.

USDA awarded over \$587,000 to Virginia telemedicine projects that will provide health care services in rural areas, including mental health and drug addiction treatment. A grant of \$434,182 will help the Carilion Medical Center deliver health care in 12 rural counties in southwest Virginia, including 18 sites—15 of which are in StrikeForce counties. A \$153,082 grant will help the Rectors and Visitors of the University of Virginia invest in an advanced system to provide 11 rural community care centers with access to care that will serve 9 StrikeForce

Counties. Two mobile health units will canvass 6 of these counties to provide on-site care and telemedicine video conferencing with doctors and specialists.

In addition to DLT investments, USDA Rural Development has funded rural hospitals and health care clinics from its Community Facilities, and Business and Industry Guaranteed Loan Programs. These projects provide communities with much-needed services to help address health care, including overdose and opioid addiction.

Throughout his administration, President Obama has made clear that addressing the opioid overdose epidemic is a priority and has highlighted tools that are effective in reducing drug use and overdose, like evidence-based prevention programs, prescription drug monitoring, prescription drug take-back events, medication-assisted treatment and the overdose reversal drug naloxone. The President submitted a budget proposal and continues to call on Congress to provide \$1.1 billion in new funding to help every American with an opioid use disorder who wants treatment get the help they need. Under the President's current proposal, Kentucky could receive \$18 million, Tennessee could receive \$24 million, and Virginia could receive \$17 million over 2 years to expand access to treatment.

Since 2009, USDA Rural Development has provided more than \$213 million in grants for 634 DLT projects in rural areas nationwide, many providing mental health treatment. Since 2009, USDA Rural Development has provided \$336 million through [Business & Industry program](#) loan guarantees for 80 healthcare-related projects in rural America. Since fiscal year 2014, USDA Rural Development has invested \$235 million in [Community Facilities program](#) funds for mental health facilities in rural America. To find out more about USDA Rural Development's work to improve the health of rural Americans, visit www.rd.usda.gov/files/RD-Opiod-Factsheet.pdf.

Since 2009, USDA Rural Development has invested \$31.3 billion in 963 electric projects that have financed more than 185,000 miles of transmission and distribution lines serving 4.6 million rural residents. USDA also has invested \$11 billion to start or expand 103,000 rural businesses; helped 1.1 million rural residents buy homes; funded nearly 7,000 community facilities such as schools, public safety and health care facilities; and helped bring high-speed Internet access to nearly 6 million rural residents and businesses. For more information, visit www.usda.gov/results.

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GUIDELINES FOR THE USE OF
CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN
Reaffirmed by the Nebraska Board of Medicine and Surgery on June 17, 2016

Section I: Preamble

“Drug overdose deaths were second only to motor vehicle crash deaths among leading causes of unintentional injury death in 2007 in the United States.”

Centers for Disease Control and Prevention (CDC) “Unintentional Drug Poisoning in the United States”, July, 2010.
<http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

The Nebraska Board of Medicine and Surgery recognizes that principles of quality medical practice dictate that the people of the State of Nebraska have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can improve the quality of life for those patients who suffer from pain, as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes non-treatment, under-treatment, over-treatment, or the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic. Pain management is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board’s position on pain control, particularly as related to the use of controlled substances, as well as to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment can result from a lack of knowledge about pain management. Fears of investigation or sanction by federal, state, or local agencies can also result in inappropriate treatment of pain. Appropriate pain management is the treating physician’s responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances, including opioid analgesics, are essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Nebraska Board of Medicine and Surgery is obligated under the laws of the State of Nebraska to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, can lead to drug diversion and abuse by individuals who seek them for other than legitimate medical uses. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a medical diagnosis and the documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in the patient's functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program could be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, with persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining the patient's responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy can be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment can be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder usually requires extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic, and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage, and quantity prescribed),
9. instructions and agreements,
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense, or administer controlled substances, the physician must be licensed in the State of Nebraska and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and to any relevant documents issued by the Nebraska Board of Medicine and Surgery and the Nebraska Department of Health and Human Services for specific rules governing controlled substances as well as applicable state statutes and regulations. The Federation of State Medical Boards (FSMB) has published and makes available a book entitled “Responsible Opioid Prescribing – A Clinician’s Guide” by Scott M. Fishman, M.D.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that can or cannot be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of a pharmacologic antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are the drug-seeking behaviors commonly seen with addiction. The relief-seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance can or cannot be evident during opioid treatment and does not equate with addiction.

Feds to boost opioid treatment options, but seek far more funding



Jayne O'Donnell, USA TODAY 7:40 a.m. EDT July 6, 2016



(Photo: Gabriella Demczuk, Getty Images)

Federal regulators will nearly triple the number of patients doctors can treat with the most common drug to treat opioid addiction and plan to push Congress Wednesday to approve about \$1 billion in funding to increase treatment options across the United States for the drug epidemic.

The Department of Health and Human Services (HHS) also proposes to eliminate potential financial incentives for doctors to prescribe opioids out of fear that patients will give them low marks in patient experience surveys if they experience a lot of untreated pain after procedures.

Under the rule that takes effect August 5, physicians who are authorized to prescribe buprenorphine can go from having a maximum of 100 patients on the drug to 275. HHS estimates between 10,000 and 90,000 new patients will be able to get buprenorphine in the first year as a result. Another 2,000 to 15,000 new patients should be able to get the treatment in subsequent years.

If Congress would approve the budget request of \$1.1 billion more, there would be more doctors trained in buprenorphine, particularly in rural areas where there is a shortage of physicians who can prescribe the drug, said White House drug policy director Michael Botticelli.

HHS Secretary Sylvia Burwell said the money is needed if "we truly want to turn the tide on this epidemic."

House and Senate conferees are expected to meet Wednesday on the conference report for the Comprehensive Addiction and Recovery Act, which would improve treatment for addiction and overdoses and reform prescribe practices.

Baltimore health commissioner Leana Wen, a physician, applauded HHS' announcements, but said there should be no limit on the number of patients doctors can treat with buprenorphine, which is often sold under the brand name Suboxone. She says the limit is based on the misconception that the treatment drug is potentially addictive.

"It's based on stigma and not science," says Wen. "There are no limits on opioid (patients) so why is there a limit on that?"



Baltimore Health Commissioner, Dr. Leana Wen is pictured during a June 2016 visit to USA TODAY headquarters in McLean, Va. (Photo: Jarrad Henderson, USA TODAY)

Kana Enomoto, principal deputy administrator of HHS' Substance Abuse and Mental Health Services Administration, said Tuesday that current drug law doesn't allow the agency to remove the limit on prescribing. Many of those who commented on the proposed rule warned about the risk of buprenorphine being diverted for illegal uses, she added.



Many experts have cited this limit as a barrier to treatment for what is known as opioid use disorder. Opioids are controlled substances that are typically used to treat pain. The rule aims to increase access to medication-assisted treatment and therapy for tens of thousands of people with opioid use disorders, while preventing diversion, HHS says.

Botticelli also defended the cap, calling it only "one of the vehicles we're utilizing to increase access" to treatment.

Kana Enomoto is the principal deputy administrator at the Substance Abuse and Mental Health Services Administration. She has been delegated the duties of the Administrator to oversee an agency with four centers, four offices, over 600 employees, and a budget of \$3.7 billion. (Photo: Substance Abuse and Mental Health Services Administration)



[USATODAY](#)

[Doctors told to avoid prescribing opiates for chronic pain](#)

[\(http://www.usatoday.com/story/news/2016/03/15/cdc-issues-new-guidelines-opiate-prescribing-reduce-abuse-overdoses/81809704/\)](http://www.usatoday.com/story/news/2016/03/15/cdc-issues-new-guidelines-opiate-prescribing-reduce-abuse-overdoses/81809704/)

Department of Veteran's Affairs and Indian Health Service prescribers and pharmacists will also be required to check state Prescription Drug Monitoring Program databases before prescribing or dispensing opioids for pain. HHS is also launching more than a dozen new scientific studies on opioid misuse and pain treatment and soliciting feedback to improve and expand prescriber education and training programs.

"Expanding the use of the prescription drug monitoring program will help identify those who are addicted and trying to fill multiple prescriptions, and stop criminals from reselling opioids," said Becky Vaughn, of addictions at the National Council for Behavioral Health. "We applaud the commitment to more research, as well as increased opioid prescriber education and training so that providers can help people manage pain without the increased risk of addiction."

Patrick Kennedy, co-founder of the drugmaker-funded Advocates for Opioid Recovery, says HHS isn't going far enough. But he'll take what he can get.

"If this were pancreatic cancer or diabetes, this whole thing would be laughable," says Kennedy, who has battled addiction and mental illness. But the federal actions are "better than nothing even if it doesn't amount to much."

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<http://www.wsj.com/articles/obama-administration-loosens-controls-on-medication-to-ease-opioid-cravings-1467777660>

U.S.

Obama Administration Loosens Controls on Medication to Ease Opioid Cravings

Limits have left many patients unable to find doctor to prescribe buprenorphine



A drug user takes a needle before injecting himself with heroin in New London, Conn. A record 47,000 Americans died of drug overdoses in 2014. Opioid painkillers and heroin were the biggest drivers of those deaths. PHOTO: GETTY IMAGES

By **JEANNE WHALEN**

July 6, 2016 12:01 a.m. ET

In an effort to expand treatment for opioid addiction, the Obama administration is loosening strict controls of a medication doctors prescribe to ease cravings for heroin and other opioid drugs.

The Department of Health and Human Services says it will now allow doctors to prescribe the medication, called buprenorphine, to 275 patients at a time, up from 100 previously.

The limits were put in place to try to keep tight control of the medication, which addicts sometimes buy and sell on the black market because it prevents painful withdrawal symptoms from heroin and other drugs. Federal officials believed that keeping a tight lid on prescribing would thwart this black-market trade.

But the limits have left many patients unable to find a doctor who can prescribe them buprenorphine, a medication public-health officials call an important tool in combating the growing epidemic of opioid abuse and overdose deaths. More than 47,000 Americans died of drug overdoses in 2014—a record that exceeded the number killed in car accidents, according to the Centers for Disease Control and Prevention. The biggest drivers of those deaths were opioid painkillers and heroin.

RELATED

- [FDA Approves New Arm Implant to Treat Opioid Dependence](#)
- [House Passes Bills to Combat Opioid Abuse in U.S.](#)
- [Hooked: One Family's Ordeal With Fentanyl](#)

Not every doctor will take advantage of the raised prescribing caps, but those who do could help up to 90,000 additional people receive buprenorphine treatment in the first year of the new regulation, which takes effect next month, officials from HHS and the White House Office of National Drug Control Policy told reporters on a conference call.

About 650,000 Americans received buprenorphine to treat opioid addiction in 2014, so the expanded caps could potentially boost that pool by about 14%.

Officials announced the new caps alongside several other executive actions to combat opioid addiction. HHS officials said the agency will propose that Medicare no longer use patient views on the quality of a hospital's pain treatment to help judge hospital performance or determine Medicare payment levels to that hospital. Under the new rule, hospitals would continue surveying patients on how well their pain was controlled during their stay, but the answers wouldn't affect Medicare payment levels. Some doctors have argued that linking these surveys to Medicare payments has encouraged overuse of addictive opioid pain medications.

On the conference call, Sylvia Burwell, Secretary of Health and Human Services, also urged Congress to fund the Obama administration's budget request for \$1.1 billion to fight opioid abuse, much of which would go toward expanding addiction treatment. "We need our partners in Congress to do their part and fund the president's budget

request,” she said. “In the absence of congressional action we’re taking every step forward we can.”

Write to Jeanne Whalen at jeanne.whalen@wsj.com

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A historic 1st: the Surgeon General reaches out to all drs for help with a vicious epidemic



Story highlights

- Letter marks the first time that America's top doctor has reached out to all physicians
- From 1999 to 2014, more than 165,000 Americans died from opioid-related overdoses

(CNN)In the next few days, every doctor in the United States will be receiving [this letter](#) (PDF) from the [US surgeon general](#).

It's the first time that America's top doctor has reached out to all physicians.

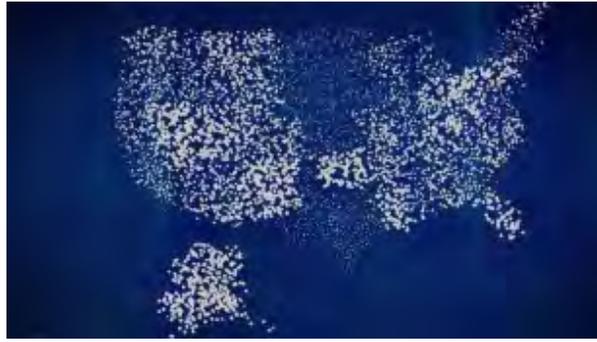
But Dr. Vivek Murthy has an urgent reason: Americans are dying each year by the tens of thousands from overdoses of prescription painkillers such as Oxycontin and Vicodin.

"I am asking for your help to solve an urgent health crisis facing America: the opioid epidemic," Murthy wrote.

In his letter, which also appears on turnthetidex.org, Murthy told physicians he understood their desire to keep their patients out of pain.

"It is important to recognize that we arrived at this place on a path paved with good intentions," he wrote.

But those good intentions have gone horribly wrong.



From 1999 to 2014, more than 165,000 people in the United States died from overdoses related to opioid pain medications, [according to the Centers for Disease Control and Prevention](#).

While some of those bought their drugs on the streets, many did not. In 2012, health care providers wrote 259 million prescriptions for opioid pain medication -- enough for every adult in the United States to have a bottle of pills, [according to the CDC](#).

"The results have been devastating," Murthy wrote to the doctors as well as nurse practitioners and dentists, who also prescribe drugs.

Even the surgeon general's friend

Murthy said he was inspired to write the letter after touring the country and learning that despite widespread media attention to the opioid overdose epidemic, many doctors still didn't realize how dangerous the drugs could be.

He said even a friend of his didn't know.



"I was having dinner with him and I said, 'Can you believe that we were taught that these opioid medications weren't addictive in our training?' " Murthy told a group at the [Aspen Ideas Festival](#) in Colorado in June.

"And he put down his fork and he looked up at me and he said, 'Wait, you mean they are addictive?' " Murthy added.

Like many doctors, his friend, a cardiologist in Florida, learned in medical school and in residency that opioids weren't addictive as long as a patient was truly in pain, Murthy said.

"He's trained at some of the best institutions in the country. He's one of the most compassionate doctors that you'll ever meet," he said.

Murthy told CNN that unfortunately his friend is not alone.



"Many clinicians have told me they weren't aware of just how bad the problem had gotten," he said. "Many were not aware of the connection between the epidemic and prescribing habits."

Essentially to retrain physicians, Murthy included in his [mailing a card](#) with tips for prescribing opioids.

The card instructs physicians that they should try other pain relief approaches, such as physical therapy or nonaddictive medications, with most patients before prescribing opioids.

If they do choose to prescribe opioids, he instructs them to "start low and go slow" -- meaning to prescribe the lowest dose for the shortest duration of time.

'Where are the learned people?'

Dr. Gary Franklin, an addiction specialist at the University of Washington, said while he welcomes the surgeon general's letter, much more needs to be done to change physicians' prescribing habits.

He said more states should follow the example of [Massachusetts](#), which in March passed sweeping new regulations for prescription painkillers, including a seven-day limit on first-time adult opioid prescriptions and a seven-day limit on every opiate prescription for minors, with certain exceptions.

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Franklin also said greater impact could be made if the doctors who helped market opioids back in the 1990s publicly admitted that, contrary to what they told physicians, the painkillers are addictive.

Many of the doctors who vouched for opioids were highly respected and backed by powerful pharmaceutical companies, he said.

"Where are the learned people who originally caused this problem?" Franklin asked. "Why aren't they coming out saying, 'Hey -- we were wrong'?"

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UNITED STATES SURGEON GENERAL

Vivek H. Murthy, M.D., M.B.A.

August 2016

Dear Colleague,

I am asking for your help to solve an urgent health crisis facing America: the opioid epidemic. Everywhere I travel, I see communities devastated by opioid overdoses. I meet families too ashamed to seek treatment for addiction. And I will never forget my own patient whose opioid use disorder began with a course of morphine after a routine procedure.

It is important to recognize that we arrived at this place on a path paved with good intentions. Nearly two decades ago, we were encouraged to be more aggressive about treating pain, often without enough training and support to do so safely. This coincided with heavy marketing of opioids to doctors. Many of us were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.

The results have been devastating. Since 1999, opioid overdose deaths have quadrupled and opioid prescriptions have increased markedly – almost enough for every adult in America to have a bottle of pills. Yet the amount of pain reported by Americans has not changed. Now, nearly two million people in America have a prescription opioid use disorder, contributing to increased heroin use and the spread of HIV and hepatitis C.

I know solving this problem will not be easy. We often struggle to balance reducing our patients' pain with increasing their risk of opioid addiction. But, as clinicians, we have the unique power to help end this epidemic. As cynical as times may seem, the public still looks to our profession for hope during difficult moments. This is one of those times.

That is why I am asking you to pledge your commitment to turn the tide on the opioid crisis. **Please take the pledge at www.TurnTheTideRx.org.** Together, we will build a national movement of clinicians to do three things.

First, we will educate ourselves to treat pain safely and effectively. A good place to start is the enclosed pocket card with the CDC Opioid Prescribing Guideline. Second, we will screen our patients for opioid use disorder and provide or connect them with evidence-based treatment. Third, we can shape how the rest of the country sees addiction by talking about and treating it as a chronic illness, not a moral failing.

Years from now, I want us to look back and know that, in the face of a crisis that threatened our nation, it was our profession that stepped up and led the way. I know we can succeed because health care is more than an occupation to us. It is a calling rooted in empathy, science, and service to humanity. These values unite us. They remain our greatest strength.

Thank you for your leadership.

Nebraska Beacon

A publication of the Behavioral Health Education Center of Nebraska (BHECN)

August 2016



Campaign Offers Mental Health Resources to Nebraska College Students



College students throughout Nebraska are being welcomed to school this semester with wooden pennies promoting the message “Penny for Your Thoughts Campaign – 1 in 5 Nebraskans have a mental illness. 5 in 5 can do something about it.” The wooden token also provides [a link to the campaign website](#), which contains crisis information and hotlines along with content about common mental health conditions and other resources, such as on-campus counseling services.

Student mental health organizations, including Active Minds and student chapters of NAMI (National Alliance on Mental Illness), distributed the pennies at welcome events to help make their peers feel more comfortable discussing mental health issues and utilizing counseling services.

“Any outreach to educate others about mental health issues is a step toward awareness and acceptance,” said Abby Stewart, secretary of the Wayne State College Active Minds chapter. “Also, these tokens are clever little ways to get a foot in the door of people’s lives...even if one person internalizes the quotation on the back, it may be just enough to get the gears turning and start a revolution in his or her thinking.”

Student organizations at the University of Nebraska Medical Center, University of Nebraska at Omaha, University of Nebraska at Lincoln, and Wayne State College have distributed the wooden pennies. Other student organizations interested in the campaign and handing out the tokens may contact laura.holly@unmc.edu for more information.

The Penny for Your Thoughts campaign originated from a group of undergraduate students attending BHECN’s College Ambassador Conference in 2015. Students were tasked with creating

Campaign creators (pictured above, left to right): Kaitlin Clancy, Pete Lass, Chelsea Musfeldt, Ciera Afrank, Allison Vlach, and Alan Epley

BHECN Presents State Workforce Solutions Webinar, Sept. 7

BHECN is hosting the first installment of a free webinar series highlighting current innovative behavioral health workforce development practices throughout the nation. SAMHSA is sponsoring the series along with NASADAD, NASMHPD, BHECN and The Annapolis Coalition on the Behavioral Health Workforce.

September 7, 2016
1:00 p.m. Central Time

[Learn more and register here.](#)



Dr. Watanabe-Galloway Joins BHECN as Research Director

Shinobu Watanabe-Galloway, Ph.D., has joined the Behavioral Health Education Center of Nebraska (BHECN) as research director.

Dr. Watanabe-Galloway, associate professor and vice chair of the department of epidemiology, College of Public Health, will focus on strengthening BHECN's workforce evaluation and reporting efforts to produce evidence-based practices.

[Read more.](#)



1st Annual Psychiatric Nursing Workforce Summit, Sept. 28

Join us as BHECN hosts the 1st Annual Psychiatric Nursing Workforce Summit on Sept. 28 in Omaha. The focus of discussion is on the current psychiatric nursing landscape and ways to strengthen the workforce through practice, education and policy.

Keynote Presenter:

Gail Stuart, Ph.D., RN, FAAN
Dean and tenured Distinguished University Professor in the College of Nursing and Professor in the College of Medicine in the Department of Psychiatry and Behavioral Sciences at the Medical University of South Carolina

September 28, 2016
8:00 a.m. - 4:30 p.m.
Scott Conference Center in Omaha
Cost: \$45

[Click here](#) to learn more about the conference and to register by Sept. 21.

Upcoming Seminars:

Creating a Prudent Supervision Practice
Dorinda Noble, Ph.D., LCSW
Sponsored by



Sept. 17, 2016
 9 a.m. - 1 p.m.
 Thompson Alumni Center
 Registration: \$30
[Click here for more details.](#)

Charting the Road to Recovery: Nebraska's Response to Opioid Abuse



Oct. 14, 2016
 7:30 a.m. - 4:30 p.m.
 University of Nebraska Medical Center
 Registration: No fee, but pre-registration is required by Oct. 7.
[Click here for more details.](#)

The Nebraska Behavioral Health Workforce Dashboard

BHECN and UNMC's College of Public Health have developed the [Nebraska Behavioral Health Workforce Dashboard](#), a tool designed to help policy makers, employers, and behavioral health care stakeholders understand the state of the behavioral health workforce and make decisions that impact its future.

The interactive webpage allows the user to search behavioral health provider data by region, county and type of provider, including psychiatrists, nurse practitioners, physician assistants, psychologists, LIMHPs, LMHP and addiction counselors.



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Consistent Adherence To Guidelines Improves Opioid Dependent Patients' First Year Outcomes

Jodie A. Trafton, PhD
Keith Humphreys, PhD
Alex H. S. Harris, PhD
Elizabeth Oliva, M.A.

Abstract

Clinical practice guidelines for opioid substitution treatment (OST) for opioid dependence recommend that patients receive at least 60 mg daily methadone and have access to a broad array of psychosocial services. However, there is still wide variation in clinical practice in OST clinics. In real-world settings, patients could receive lower methadone doses and less psychosocial care because they require less intensive care for recovery; alternatively, barriers to delivery of guideline concordant care could limit treatment received and impair recovery. The Multisite Opioid Substitution Treatment (MOST) study examines the impact of more consistent adherence to guideline recommendations in eight Veterans Affairs OST clinics. While patients at all clinics demonstrated improvements in substance use over the first year in treatment, patients at clinics that more consistently adhered to guidelines had greater reductions in heroin and cocaine use

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and greater improvement in mental health. These results suggest that efforts to increase guideline adherence in OST will improve patient outcomes.

Introduction

Opioid substitution therapy (OST) is acceptable to and effective for a large proportion of opioid-dependent patients, consistently reducing heroin use and criminal activity and usually reducing other substance use and mental health problems.¹⁻⁵ This treatment has been well studied in numerous randomized clinical trials, and these trials have identified a number of factors related to improved treatment outcomes in OST. Specifically, in randomized trials, greater reductions in substance use are produced by higher daily methadone doses (>60–80 mg) as compared to lower ones (<60 mg),⁶⁻⁹ and more intensive psychosocial service availability versus less to no psychosocial service availability.¹⁰ For example, in a randomized trial, adding standard weekly substance use disorder counseling visits improved treatment outcomes as compared to methadone dosing alone, and adding on-site medical/psychiatric, employment, and family therapy improved outcomes additionally.¹¹ Results from these trials have been incorporated into clinical practice guidelines that recommend dosing patients above 60 mg methadone and providing substantial counseling services.¹²⁻¹⁵

Use of methadone maintenance is based on the theory that binding of methadone to mu opioid receptors prevents opioid withdrawal symptoms and blocks the “high” produced by heroin and other rapidly absorbed opiate drugs, reducing craving for heroin and other illicit opiates and normalizing physiological functions disrupted by use of short-acting opioids.¹⁶ Psychosocial counseling services are thought to reduce thoughts and behaviors that lead to drug use, increase contact with non-drug rewards, and reduce ambivalence about quitting drug use to encourage a drug-free lifestyle.¹⁷

Despite this long history of research and the availability of evidence-based guidelines, guideline recommendations are applied inconsistently across OST clinics and clinical practice varies widely.¹⁸⁻²⁰ For example, D’Aunno and Pollack¹⁸ found that 35% of OST patients in the USA received less than the recommended 60 mg/day in 2000. The reasons for this inconsistency, however, are not clear. It is possible, and in fact suggested by these same randomized trial results, that a subset of patients have positive outcomes with a level of treatment below that recommended by guidelines. Perhaps, some clinics identify this subset of patients and provide them only the level of care that they need to achieve their goal of abstinence from illicit drugs. In this case, clinics that less strictly follow guidelines would have similar treatment outcomes to those that more strictly follow guidelines and might provide more efficient care. Alternatively, lack of adherence to clinical practice guidelines might stem from identified barriers such as lack of faith in the results of randomized clinical trials, negative community attitudes regarding OST, philosophical opposition to treating “drug addiction with drugs”, administrative and pharmacy/formulary barriers at the facilities where the clinics are operating, lack of staff, qualified prescribing clinicians, or funding, low demand or priority, lack of confidence in effectiveness,²¹⁻²³ or patient preferences concerning methadone treatment.^{24,25} If barriers limit guideline adherence, and guideline adherence is important for optimizing treatment outcomes, then treatment outcomes at clinics that more strictly adhere to clinical practice guidelines should be superior.

The MOST study investigates the effects of higher versus lower adherence to clinical practice guidelines for OST in a quasi-experimental observational study of clinical practices and outcomes in eight Veterans Health Administration OST clinics in US cities. New opioid-dependent patients entering treatment at one of four highly guideline-adherent clinics or one of four less guideline-adherent clinics were followed over the subsequent year to determine treatment outcomes.

This study design allows for the examination of the real-world consequences of clinical guideline adherence. Clinicians were allowed to follow their clinical judgment and modify treatment over time rather than following strict protocol in treating patients. Additionally, unlike in most randomized clinical trials where exclusion criteria are common, in this study, all entering patients were included to insure that results could be generalized to the full population of OST patients. Thus, this study allowed for the examination of the effectiveness of OST as it is provided in real-world clinical practice.

We hypothesize that patients attending clinics that are more compliant with clinical practice guidelines for methadone dosing and psychosocial treatment provision will have greater improvements in treatment outcomes than patients attending clinics that are not as compliant. If this hypothesis is supported, efforts to increase adherence to clinical practice guidelines for OST may improve health outcomes for opioid-dependent patients.

Methods

Selection of clinics and creation of study conditions

This study was conducted in the US Veterans Affairs (VA) health system, a federal, publicly funded network of clinics and hospitals. All 34 VA OST clinics completed a one-page screener assessing their concordance with practice guidelines regarding dosing patients above 60 mg/methadone per day and providing extensive psychosocial services. From these data, four clinics that were relatively concordant and four clinics that were relatively non-concordant with both of these two aspects of practice guidelines were identified (i.e., a group of clinics providing relatively high doses and amount of psychosocial services and a group of clinics providing relatively low doses and amount of psychosocial services). This resulted in two study conditions (concordant and non-concordant OST care), each with four urban OST clinics throughout the country. At the end of the study, the eight clinics were resurveyed with the one-page screener to assess for changes in clinic practice that may have occurred during the study period.

Recruitment of subjects

Patients were recruited from opioid substitution treatment programs located in eight cities throughout the USA. Approval was obtained from Stanford University's Institutional Review Board plus the Institutional Review Board affiliated with each of the eight medical centers. A certificate of confidentiality was obtained from the National Institute of Mental Health to further protect patient confidentiality. Clinic staff explained the study to patients entering OST clinics. All patients completed written informed consent before participation. Patients then completed a structured interview with trained researchers by telephone at treatment entry, 6 and 12 months. The treatment entry interview assessed life conditions and behaviors in the 30 days before treatment was initiated. This interview (described in "Measures") assessed patients' life conditions and treatment outcomes. Additionally, patients' medical records were accessed for the duration of the study period to determine clinical diagnoses, prescriptions, urinalysis drug screening results, and methadone dose levels.

Sample

The subjects consisted of 255 veterans seeking opioid substitution treatment between November 2000 and October 2001. Although 267 patients agreed to participate in the multisite

opioid substitution treatment (MOST) study, 12 could not be located to complete baseline interviews and were excluded from the current analyses. At 6 months, follow-up rate was 90.6%. At 12 months, three patients were known to have died, and four were known to be imprisoned. Of the remaining 248, the 12-month follow-up rate was 82%. The average age was 49 ± 7.2 (SD) and 97% of the patients were male. The population was racially diverse: 53.1% black, 32.4% non-Hispanic white, 12.2% Hispanic, and 2.3% Native American. Ten percent of the population was homeless, and 5% had recently been in a controlled environment (i.e., jail or an inpatient drug treatment program). Thirty days before entering treatment, 86.7% used heroin, 49.4% used cocaine, 45.9% used alcohol, 21.6% used cannabis, 16.1% used illicitly obtained opioid medications, and 10.2% used illicitly obtained sedatives. Few patients used amphetamines (3.1%), barbiturates (1.2%), or hallucinogens (0.4%).

Measures

The interviews comprised the Addiction Severity Index,²⁶ the SF-36V quality of life index,²⁷ and a high risk injection practices questionnaire.²⁸ The Addiction Severity Index (ASI) measures medical, employment, drug, alcohol, social, legal, and psychological problems in the last month and over the patient's lifetime. The SF-36V is a version of the SF-36 quality of life index that has been validated for use in veteran populations.²⁷ It assesses quality of life, including problems with health, mood, pain, physical, social and emotional functioning. The ASI and the SF-36 have been shown to be valid and reliable when conducted over the telephone.^{29,30} Interviewers were trained using DeltaMetrics Training Division's ASI-TV: training on tape video. The high risk injection practices questionnaire was developed for use by the NIDA clinical trials network to assess injection practices, including sharing and cleaning of needles and works. Patients were contacted by telephone for interviews at numbers they provided during consent procedures. The duration of baseline interviews was 1–2 h. Six- and 12-month follow-up interviews were completed in 20–90 min. Results of clinic-scheduled urinalysis tests were obtained from patients' medical records as a secondary measure of drug use.

Results

Clinic characteristics

Clinic characteristics at the start of the study are presented in Table 1. At study start, the concordant sites more consistently dosed patients over 60 mg methadone equivalents per day (Table 1) and generally had more favorable staff to patient ratios. These trends were generally maintained throughout the study. Site visits to the clinics confirmed the information collected in the surveys. Notably, non-concordant sites tended towards increased guideline adherence by the end of the study. Treatment received by new patients enrolled in the study was consistent with expectations based upon pre-study clinic characteristics. Study participants received higher methadone doses and more individual or group SUD counseling visits at concordant versus non-concordant sites (Table 2).³¹

Participant characteristics at baseline

Because of the quasi-experimental nature of this study, the patient populations at high and low concordance sites were not matched, and some baseline differences were observed (Table 3). Patients at less adherent sites were older, more likely to be Hispanic, had more physical problems, and used fewer street drugs (i.e., they used substances that could be more easily attained from home, e.g., pills and alcohol), but were more likely to inject drugs in the last 6 months than

Table 1
Clinic practices

Variable	Concordant sites	Non-concordant sites	F, p value
At the start of the study			
Patients dosed with over 60 mg methadone (%)	79.2% ± 12.3	46.5% ± 23.3	6.146, 0.048
Patient/staff ratio	17.8 ± 9.3	29.9 ± 22.8	0.956, 0.366
At the end of the study			
Patients dosed with over 60 mg methadone (%)	83.0% ± 9.4	68.2% ± 11.4	4.004, 0.092
Patient/staff ratio	17.4 ± 6.6	22.7 ± 7.4	1.122, 0.330

Means ± standard deviation are presented. F and p value for a one-way analysis of variance (ANOVA) comparing the concordant (n=4) and non-concordant (n=4) sites are presented.

patients at more adherent sites. A greater proportion of patients from less concordant clinics used opioids other than heroin or transferred from another clinic, resulting in higher heroin abstinence rates at treatment entry in these clinics (Table 4).

Patient outcomes at concordant versus non-concordant clinics

Self-reported abstinence

Self-reported abstinence in the last 30 days for heroin, cocaine, sedatives, and alcohol was assessed at intake, 6 and 12 months. Abstinence rates for each of these substances in guideline concordant and non-concordant sites at the three time-points are presented in Table 4. All patients who entered OST were included in these intent-to-treat analyses.

Heroin abstinence rates in both guideline concordant and non-concordant sites improved substantially by 6 months, and these improvements were mostly retained at 12 months. Although the patients at the concordant sites were less abstinent in the month before intake (10.4 vs 18.7%), by 6 months, 14.2% more patients were abstinent at the concordant sites compared to the non-concordant sites (69.1 vs 54.9%). By 12 months, the abstinence rate in the concordant sites increased 3.7% compared to 6 months, but dropped by 0.5% during this interval at the non-compliant sites. Using generalized estimating equations to compare the 1-year heroin abstinence of the patients at guideline concordant vs non-concordant sites, controlling for age and baseline abstinence and accounting for non-independence of observations within sites, confirmed that patients at concordant sites had significant better 1-year heroin abstinence than those at non-

Table 2
Study participant care received in the year after treatment start

Variable	Concordant sites	Non-concordant sites	F, p value
Mean methadone dose (mg)	76.9 ± 27.4	57.9 ± 19.5	34.021, <0.001
Highest methadone dose (mg)	91.7 ± 36.3	67.6 ± 23.7	32.446, <0.001
# SUD counseling visits	54.4 ± 80.9	29.9 ± 33.8	7.541, 0.006

Means ± standard deviation are presented. F and p value for a one-way ANOVA comparing the concordant (n=164) and non-concordant (n=91) sites are presented.

Table 3
Participant characteristics at baseline

Variable	Concordant	Non-concordant	<i>p</i> value
Gender, % male	97	100	NS
Race, % white/black/Hispanic	34/56/6	29/47/23	<0.001
Age	48.2 ± 7.5	50.8 ± 6.2	0.005
Religion, % Protestant, Catholic, Other	57/22/21	56/29/15	NS
% inject drugs in last 6 months	56	78	<0.001
Addiction severity index composite scores			
Medical	0.442 ± 0.378	0.595 ± 0.393	0.003
Employment	0.650 ± 0.297	0.619 ± 0.292	NS
Alcohol	0.090 ± 0.173	0.101 ± 0.179	NS
Drug	0.295 ± 0.109	0.301 ± 0.132	NS
Legal	0.102 ± 0.179	0.123 ± 0.180	NS
Family/Social	0.171 ± 0.204	0.193 ± 0.223	NS
Psychological	0.273 ± 0.264	0.294 ± 0.262	NS
SF-36V scores			
Mental Composite Score	40.1 ± 13.0	43.0 ± 12.3	NS
Physical Composite Score	45.8 ± 11.3	40.1 ± 12.6	<0.001

Means ± standard deviation are presented. The *p* value for a comparison between concordant (*n* = 164) and non-concordant (*n* = 91) sites is presented. One-way ANOVA was used for continuous variables, and Pearson's chi-squared was used for categorical variables. NS indicates *p* > 0.05.

Table 4

Self-reported abstinence for heroin, cocaine, sedatives, and alcohol in guideline concordant and non-concordant sites

Substance	Intake	6 months	12 months
Heroin			
Abstinent concordant sites (%)	10.4	69.1	72.8
Abstinent non-concordant sites (%)	18.7	54.9	54.4
Cocaine			
Abstinent concordant sites (%)	45.7	69.5	80.1
Abstinent non-concordant sites (%)	59.3	67.4	75.0
Sedatives			
Abstinent concordant sites (%)	92.1	96.6	93.9
Abstinent non-concordant sites (%)	85.7	89.0	94.1
Alcohol			
Abstinent concordant sites (%)	85.4	81.4	91.2
Abstinent non-concordant sites (%)	79.1	83.7	89.7
No injected drugs in last 6 months			
Concordant sites (%)	44.5	74.5	79.2
Non-concordant sites (%)	22.0	46.3	48.6
Sample size concordant sites (%)	164	149	136
Sample size non-concordant sites	91	82	68
Sample size total	255	231	204

concordant sites, OR (95%CI)=3.01 (1.39, 6.51). Assuming all patients lost to follow-up were using, abstinence rates from heroin ranged from 33 to 69% across our participating clinics at 1 year.

Cocaine abstinence rates in both guideline concordant and non-concordant sites improved significantly during the 12 months. Although the patients at the concordant sites had lower rates of cocaine abstinence in the month before intake (45.7 vs 59.3%), by 6 months, 2.1% more patients were abstinent at the concordant sites compared to the non-concordant sites (69.5 vs 67.4%). By 12 months, the cocaine abstinence rates improved to 80.1% in concordant programs and 75.0% in non-concordant programs. Using generalized estimating equations to compare the 1-year cocaine abstinence of the patients at guideline compliant vs non-compliant sites, controlling for age and baseline abstinence and accounting for non-independence of observations within sites, confirmed that patients at concordant sites had significantly better cocaine abstinence than those at non-concordant sites, OR (95%CI)=1.85 (1.41, 2.42).

Self-reported abstinence from sedatives was high at baseline at both concordant and non-concordant sites (92.1 vs 85.7%), and the groups had very similar abstinence rates at 1 year (93.9 and 94.1%). Self-reported abstinence from alcohol was also relatively high at baseline at both concordant and non-concordant sites (85.4 vs 79.1%) with modest improvements in abstinence rates at 1 year (91.2 and 89.7%). Generalized estimating equations comparing the patients at guideline compliant vs non-compliant sites, controlling for age and baseline abstinence and accounting for non-independence of observations within sites, confirmed that the differences in 1-year sedative and alcohol abstinence were not significant. Also examined at each assessment was whether or not patients had injected drugs in the previous 6 months, the rates of which are reported in Table 4. Both guideline concordant and non-concordant sites roughly doubled their rates of not injecting drugs from intake to 1 year.

Psychosocial outcomes

Indexes of mental health, physical health, and social functioning were assessed at intake, 6, and 12 months. Means and standard deviations of each of these indexes in guideline concordant and non-concordant sites at the three time-points are presented in Table 5. For each continuous outcome, a trajectory for each participant was modeled yielding estimates of each individual's

Table 5
Psychosocial indexes in guideline concordant and non-concordant sites

	Intake	6 months	12 months
Mental health composite			
Concordant sites	40.1 (13.0)	44.4 (13.2)	45.6 (13.8)
Non-concordant sites	43.0 (12.3)	41.7 (12.4)	44.5 (12.3)
Physical health composite			
Concordant sites	45.8 (11.3)	45.2 (11.8)	44.2 (12.2)
Non-concordant sites	40.1 (12.1)	39.8 (11.5)	39.9 (10.8)
Social functioning			
Concordant sites	59.7 (30.9)	67.2 (32.5)	69.9 (55.9)
Non-concordant Sites	60.9 (32.4)	65.4 (32.8)	63.9 (32.9)
Sample sizes concordant sites	157	145	134
Sample sizes non-concordant sites	90	79	70
Sample sizes total	247	224	204

score at the beginning of the study (intercept), the individual's slope, and error (how well the linear model fit that person's data). Then for each outcome, four between-person parameters were estimated: (a) the average baseline score for the non-concordant sites, (b) the effect of being at a concordant site on the baseline average, (c) the average slope over time in the non-concordant sites, and (d) the effect of being at a concordant site on the average slope. The full maximum likelihood estimation method and an unstructured covariance specification were used. This last parameter (d) is a measure of change per unit time associated with being at a concordant site after accounting for baseline averages and the non-independence of observations within sites.

Examining the trajectories of the mental health composite scores, being at a guideline concordant site, was associated with more improvement over time ($\beta = 2.11, se(\beta) = 0.92, p = .02$) compared to being at non-concordant sites, suggesting roughly four points more improvement over the 12-month study compared to the non-concordant clinics. Examining the trajectories of the physical health composite scores, being at a guideline concordant site, was associated with significantly higher baseline values ($\beta = 5.65, se(\beta) = 1.47, p < .001$), but change over time did not differ between the clinic types. No significant differences either over time or between the groups were found on social functioning.

Urine drug screens

The percentage of urine screens that tested positive for opiates, cocaine, and benzodiazepines were calculated for each patient with at least one urine test ($n = 247$) for each of the 12 months of the study. This proportion was then corrected for the number of tests administered as described by Goldstein and Brown.³² Data on the average percentage of tests that screened positive for opiates, cocaine, and benzodiazepines at months 0, 6, and 12 for guideline concordant and non-concordant clinics are presented in Table 6.

The trajectories of the opiate urine screen results are displayed in Figure 1. These trajectories are obviously non-linear. We therefore fitted a quadratic change trajectory for each patient then estimated the following between person parameters within three-level mixed-effects regression model: (a) the average baseline percent of positive screens for both concordant and non-concordant sites, (b) the instantaneous rate of change in the non-concordant sites, (c) the effect of being at a concordant site on the instantaneous rate of change, (d) a curvature parameter for the non-concordant sites, and (e) the effect of being at a concordant site on the curvature parameter. This model accounted for the non-independence of observations within patients and sites. Because patients in non-concordant sites were significantly older than those at concordant sites and

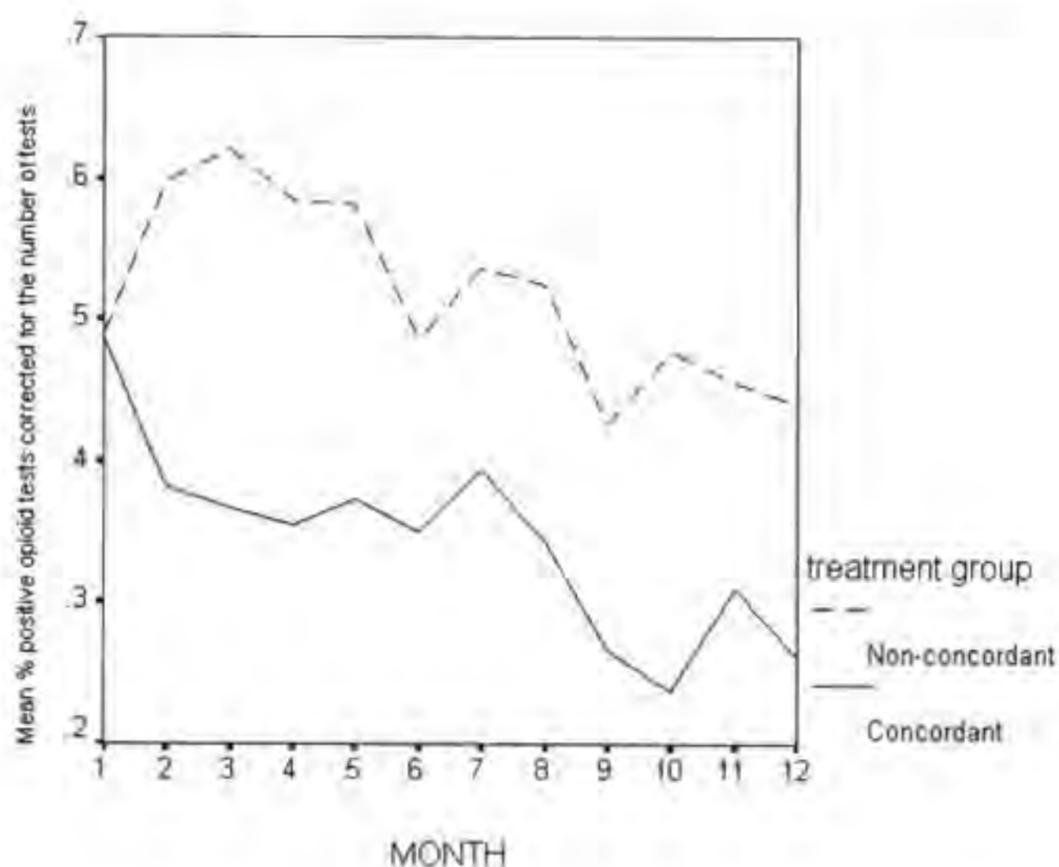
Table 6

Average percentage of positive (dirty) urine screens per patient in guideline concordant and non-concordant sites

	Intake	6 months	12 months
Mean (SD) % positive opiate screen			
Concordant sites	48.6 (33.7)	35.0 (44.9)	26.2 (41.2)
Non-concordant sites	48.9 (36.0)	48.7 (42.8)	44.1 (42.6)
Mean (SD) % positive cocaine screen			
Concordant sites	32.3 (37.0)	30.4 (43.7)	30.8 (44.3)
Non-concordant sites	27.5 (35.7)	39.2 (43.3)	34.5 (42.9)
Mean (SD) % positive benzodiazepine screen			
Concordant sites	6.9 (20.8)	15.2 (33.1)	7.1 (24.3)
Non-concordant sites	10.8 (25.4)	12.8 (28.7)	14.9 (30.5)

Figure 1

Opiate urine screen results over the first year of tests. Graph depicting the mean percentage of positive urine drug screens in patients attending concordant (*solid line*) versus non-concordant (*dashed line*) clinics over the first year of treatment. Patient level values were corrected for the number of drug screens conducted



because older age generally predicts better substance use outcomes,³³ age was also included in the model as a covariate. This approach allows for testing group differences in characteristics of the trajectories represented in Figure 1.

Because the quadratic model only approximated the shape of the trajectories, several other models were also fit, including linear and cubic models. All of the models confirm what is suggested by the results of the quadratic model and Figure 1: On average, the initial rate of improvement in average urine screen results for opiates was significantly better at guideline concordant sites ($\beta_{rate} = -0.04, se(\beta) = 0.01, p < .002$), an advantage that stays significant over time, although it decreases in size ($\beta_{curve} = 0.003, se(\beta) = 0.001, p < .02$). Being treated at a guideline concordant site did not however influence the overall trajectories of percentage of positive screens for either cocaine or benzodiazepines.

Discussion

General effectiveness of OST

These results support the real-world clinical effectiveness of OST even at the top and bottom extremes of the variation in current clinical practice. In all clinics, entry into an OST program was associated with substantial reductions in substance use 6 and 12 months following. Entry into OST treatment at any of our participating clinics was associated with at least a 33% increase in heroin abstinence 1 year later. Thus, even when all presenting patients are included and clinicians are allowed to make treatment decisions based their own judgment rather than research protocol, OST is an effective treatment for opioid dependence. This result strongly supports the conclusions of numerous randomized controlled trials of OST for everyday clinical practice with diverse patients.^{1-4,6-11,34}

Reasons for baseline differences

Patients at non-concordant sites were older and had more health problems than patients at concordant sites. Based upon discussions during site visits, we believe this may reflect a common sentiment among staff at less adherent sites that OST should be a treatment of last resort for patients (i.e., younger healthier patients with more life ahead of them should not be started on OST). Additionally, the baseline differences in rates of drug injection reflect a high rate of heroin snorting among patients at one clinic site. This use pattern likely reflects the availability of high purity snortable heroin in the metropolitan area served by this clinic.³⁵ Rates of heroin snorting were much lower at other sites where this form of heroin was less available.

Improved effectiveness of OST when guidelines are generally followed

Although all clinics generally reduced heroin and cocaine use in their patients, clinics that more strictly adhered to clinical practice guidelines produced greater improvements in heroin and cocaine use and mental health outcomes than clinics that less consistently followed guidelines. Notably, the differences in outcomes at the concordant and non-concordant clinics were substantial in magnitude, but restricted to the primary outcomes studied in randomized controlled trials. Closer adherence to clinical practice guidelines for OST may improve heroin and cocaine abstinence rates and mental health problems, but does not provide additional benefits for improving social functioning or improving physical health. As randomized controlled trials of OST have focused on reducing heroin and cocaine use and related distress, it is not surprising that variation in adherence to guidelines based upon these trial results is associated with variation in these substance use outcomes. However, the present data indicate that improvements in substance use and mental health do not necessarily translate into improvements in other important areas; additional intervention will likely be necessary to improve social functioning and physical health in this population.

The finding of improved OST effectiveness with higher guideline adherence was not altogether expected. For example, differences in dosing might have reflected differing treatment needs of patients. In an evaluation of eight VA clinics, patients maintained abstinence on lower methadone doses in clinics that stably retained patients for long-periods, suggesting an interaction between clinics' maintenance orientation and patients' methadone needs.³⁶ In the current sample, 38% of patients maintained heroin abstinence on methadone doses under 60 mg/day.³¹ Nevertheless, this study found that at less guideline-adherent clinics, fewer patients were dosed above guideline-recommended levels and fewer patients achieved abstinence. This suggests that dosing differences do not simply reflect regional variation in patient treatment needs.

The improved SUD and mental health outcomes in patients attending concordant clinics could be a direct result of receiving more guideline concordant care, as a greater dose of counseling,¹⁰ or reduced opioid withdrawal symptoms, and greater competitive antagonism of heroin's effect (i.e., blocking) from higher methadone doses would be expected to more effectively reduce substance use and mental health problems.³⁷ It is also possible that other factors related to guideline adherence, such as community support and hospital support for OST patients or clinician beliefs about drug dependence and treatment, also contribute to differences in outcomes at the clinics.²¹⁻²⁵ It is likely that some of the same factors that make it difficult for clinicians to provide guideline concordant care also make it difficult for patients to achieve abstinence and improve mental health.

Reasons for variation in guideline adherence

The reasons for variation in guideline adherence are likely multifactorial. Reasons may include clinic-related factors, such as differences in research knowledge among treatment clinicians, local hospital support, providers' treatment orientation, or economic constraints, but may also include

factors beyond the medical system.²¹⁻²⁵ For example, regional differences in beliefs about OST may alter patients' treatment preferences and acceptance of OST by local social service providers, potentially discouraging patients from making full use of possible services or accepting high methadone doses.^{22,23} To illustrate, multiple patients at two of our less adherent clinics reported that parole officers or halfway house directors pressured them to discontinue methadone treatment to comply with their rules. Thus, improving methadone maintenance treatment outcomes may require intervention both within the medical system and in broader society.

Future research should focus on identifying effective methods for encouraging adherence to clinical practice guidelines for OST. For example, Willenbring et al.³⁶ have developed and pilot tested a kit that provides tools to help clinics monitor their current dosing and counseling practices and relate these to urine drug screen outcomes, compare their practices to similar clinics, and develop quality improvement plans to remedy observed deviance from guideline-concordant care. Interventions such as this may address within-clinic barriers to adherence, such as lack of belief in the effectiveness of guideline recommended practices, and patient and clinician preferences regarding treatment. Additional interventions at the policy and community level (e.g., public education campaigns, clinician training requirements) will need to be developed to address barriers outside the clinic, such as difficulty obtaining funding, qualified staff, and pharmacy support, and lack of community support.

Limitations

Patients enrolled in this study were all veterans, almost universally male, generally middle-aged, and had long histories of poly-substance use. Whether these results generalize to clinics treating populations of younger adults, females, civilians, or patients with shorter histories of drug use is currently unknown. This was not a randomized controlled trial; the results reported in this study are associated with program guideline adherence, but causation cannot be assumed. It is possible that an unmeasured patient characteristic differed between concordant and non-concordant sites and was responsible for the differences in patient outcomes.

Implications for behavioral health

In all clinics, patients' entry into an OST program was associated with substantial reductions in heroin, cocaine, and injection drug use during the following year. However, at less guideline adherent clinics, fewer patients achieved abstinence. The present data suggest that closer adherence to clinical practice guidelines for OST improves heroin and cocaine abstinence rates and mental health problems. Thus, clinics that more closely follow clinical practice guidelines produce superior outcomes. Efforts to increase practice guideline adherence should improve the real-world effectiveness of OST. This result strongly supports the conclusions of numerous randomized controlled trials of OST for everyday clinical practice with diverse patients.^{1-4,6-11,34}

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**The New England Comparative Effectiveness Public Advisory Council
Public Meeting – June 20, 2014**

**Management of Patients with Opioid Dependence:
A Review of Clinical, Delivery System, and
Policy Options**

Final Report – July 2014

Authored by:



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Executive Summary

Abstract

On June 20, 2014 the New England CEPAC held a public meeting in Burlington, VT at which the Council discussed a systematic review of published evidence on options for the management of patients with opioid dependence. CEPAC held votes on the comparative clinical effectiveness and value of different management strategies, and then explored how best to apply the evidence to practice and policy with a distinguished Policy Expert Roundtable of patient advocates, clinical experts, and policy leaders from across New England.

In evaluating the evidence on different treatment options, CEPAC determined that long-term “maintenance” treatment approaches using methadone or Suboxone® to reduce the craving for opioids have been found to be more effective than short-term managed withdrawal methods that seek to discontinue all opioid use and “detoxify” patients. Short-term withdrawal management typically starts with maintenance treatment but attempts to wean patients off all opioids within 30 days, while maintenance treatment assumes that patients will remain on maintenance medication for longer periods. Studies comparing methadone and Suboxone found no major differences between them in reducing illicit drug use and preventing overdose or death. Although clinicians generally do not want to keep patients on medication indefinitely, there is little evidence or consensus on whether or how best to taper patients off maintenance therapy. Limited evidence suggests that patients who have not been addicted for long, do not inject heroin or other drugs, and who have a strong social support system may do well in “opioid withdrawal” programs that use injectable naltrexone, a drug that blocks the effects of opioids entirely.

CEPAC reviewed the results of economic modeling of different treatment options and voted that expanding access to maintenance therapy with either methadone or Suboxone represents “high value” because the added health care costs of treatment are offset by reductions in other health care costs that occur when individuals with opioid dependence begin treatment. Moreover, when broader societal costs such as criminal activity and work productivity are included, maintenance treatment is estimated to produce substantial overall savings. For every additional dollar spent on treatment, \$1.80 in savings would be realized. These savings imply that moving just 10% of untreated individuals in New England into treatment would generate over \$550 million in societal savings for the region.

Based on the evidence and expert input, CEPAC concluded that coordinated efforts are needed to improve access to opioid dependence treatment for the large number of individuals in New England who lack adequate access to high quality care options. An important component of achieving this goal will be to improve access for individuals in the criminal justice system by creating jail diversion programs in which non-violent offenders are assessed for addiction and referred to appropriate treatment in lieu of incarceration and by providing maintenance therapy to individuals who will be in prison for long periods. At the level of the healthcare delivery system, efforts to train and support more clinicians with capacity to treat addiction are needed. In addition, states should explore options to develop coordinated care networks to maximize existing capacity by allowing patients to receive short-term intensive outpatient care at specialized treatment units, following which they can be referred outward to other outpatient practices for lower levels of ongoing care in primary care settings or community-based practices.

Background

Opioid dependence has reached a critical level in the United States, driven by overprescribing and diversion of opioid painkillers, as well as the low cost and increased potency of heroin. The societal impact of this growing tide of opioid dependence is substantial in terms of costs related to treatment, lost work productivity, criminal activity, and social welfare expenditure (Hall, 2006).

Medication-assisted treatment options for opioid dependence

The goals of treatment for opioid dependence include a decrease in illicit opioid use, decreased mortality, and reductions in criminal activity (Thomas, 2014). Treatment options include methadone, buprenorphine (Subutex[®]), buprenorphine/naloxone (Suboxone[®]), and naltrexone (Revia[®], Vivitrol[®]). Federal law restricts the dispensing of methadone, an opioid agonist medication that, when taken daily in sufficient doses, prevents withdrawal and blocks the effects of other opioids, to federal- and state-approved opioid treatment programs (OTPs). OTPs are licensed and accredited opioid agonist treatment programs that dispense methadone according to highly structured protocols as determined by the federal and state government, including the Department of Health and Human Services (HHS), the Drug Enforcement Agency (DEA), and various state agencies. A summary of federal and state requirements pertaining to patient admission, methadone dosing and abuse concerns, patient evaluation, and the provision of social supportive services is included in the full report.

Office-based prescriptions of opioid replacement therapy with buprenorphine alone or Suboxone is also restricted by federal and state regulations. Buprenorphine is a partial opioid agonist similar to methadone but with a “ceiling effect” that limits its efficacy at high doses but also is felt to limit its adverse effects. Buprenorphine is available as a combination product with naloxone (Suboxone), which is included as an abuse deterrent feature and may precipitate withdrawal in some opioid users if they use buprenorphine via injection. The passing of the federal Drug Addiction Treatment Act (DATA) of 2000 allows qualified physicians to obtain a waiver (also known as an “X” license) to prescribe and/or dispense opioid replacement therapy after receiving special training. Due to abuse and diversion concerns, physicians with a waiver may not treat more than 30 patients concurrently, but can apply for a second waiver after one year to treat up to 100 patients at one time.

Access to Treatment in New England

Current provider capacity in New England is not sufficient to meet patient need for opioid dependence treatment. For example, data from SAMHSA’s National Survey on Drug Use and Health (NSDUH) from 2009-2012 indicates that 133,000 New Englanders are abusing or dependent on opioids, of whom 70% meet criteria for treatment but are not currently receiving it (SAMHSA, 2013c). The NSDUH survey indicates that approximately 2,000 individuals in New England were wait-listed for treatment in 2012; interviews with regional experts and policymakers suggest that this is a conservative estimate.

Geographic barriers to access are an important consideration across New England. Maps showing the wide gaps between the locations of available OTPs and office-based Suboxone programs for each New England state are shown in Appendix C of the report.

To help understand the status of treatment for opioid dependence in New England, ICER surveyed 32 federally certified OTPs, independent office-based Suboxone and buprenorphine prescribers, residential treatment providers, outpatient counseling programs, and centers specializing in the provision of opioid withdrawal management services. When asked to rank the extent to which different factors served as a barrier to providing treatment, respondents listed insurance coverage, efficiency of referral pathways (e.g., emergency room, court system), and regulatory structure and restrictions for practice (e.g., physician education and patient management caps for buprenorphine, regulation of methadone clinics) as the most significant obstacles. Many respondents also noted that patients lack the ability -- for geographic, financial, or other reasons -- to gain rapid access to treatment with either methadone or buprenorphine/Suboxone. The treatment choice selected, therefore, is usually the option that the patient can best afford and access. Complete survey results are described in the full report.

Evidence Review

We conducted a review of published evidence on the comparative effectiveness and value of medication-assisted maintenance therapy for the management of opioid dependence, which was framed according to multiple questions of policy interest in New England. Where available, considerations regarding adolescents were highlighted, as this was felt to be a subpopulation of high interest to clinicians and policymakers. The evidence is summarized briefly below; details on review methods as well as specific systematic reviews and key studies identified can be found in the full report.

Maintenance versus Short-Term (<30 Days) Opioid Withdrawal Protocols

A 2009 Cochrane systematic review of clinical trials found consistently superior outcomes for maintenance treatment approaches compared to short-term (i.e., <30 days) opioid withdrawal protocols. Maintenance was associated with better treatment retention and lower rates of illicit drug use compared to patients undergoing opioid withdrawal management. Other studies not included in the Cochrane review have produced similar findings. However, while maintenance treatment appears to be effective for most opioid-dependent patients, there may be a meaningful subset of individuals who are good candidates for a trial of opioid withdrawal management. The characteristics of these patients are described in detail in the full report. Retention in therapy at approximately one year varies widely across studies, but on average approximately two-thirds of patients on maintenance therapy remain in treatment, although approximately 50% of patients have evidence of illicit drug use during that time.

Comparative Effectiveness of Methadone, Buprenorphine, and Naltrexone

Both a recent Cochrane review as well as additional studies of maintenance treatment options consistently found that there are no major differences in mortality or illicit drug use achieved with methadone versus Suboxone or buprenorphine in any form. However, methadone appears to be associated with greater retention in treatment compared to buprenorphine in either flexible or low, fixed doses. Importantly, we note that the RCTs comparing these two drugs controlled for treatment setting (i.e., patients in both arms received the same ancillary services) so that the effects seen appear to be drug- and not setting-related. However, this does not reflect reality in the U.S., where methadone is used in a tightly-controlled environment and Suboxone is typically received in an office-based setting with less structured oversight.

Naltrexone appears to be no better than placebo at retaining patients in treatment, although limited data suggest that long-acting forms (injectable or implantable) may have advantages over oral naltrexone in this regard. The performance of these three medications across key measures of effectiveness over 3-12 months of follow-up is summarized in Table ES1 below.

Table ES1. Summary measures of effectiveness of medications for opioid dependence treatment over 3-12 months of follow-up.

Outcome	Methadone	Buprenorphine/Suboxone	Naltrexone/Vivitrol
Mortality (%)	< 1% (range: 0-6%)	<1% (range: 0-2%)	No deaths reported
Use of Illicit opioids (mean # positive urine tests)	12 (range: 3-25)	12 (range: 3-25)	Not reported (% of patients not achieving abstinence: 40-60%)
Retention in treatment (%)	63% (range: 54-71%)	52% (range: 40-65%)	28% (range: 16-30%)

Dosing and Duration Protocols

Studies examining dosing and duration of maintenance treatment have found both methadone (~100 mg/day) and Suboxone (16-32 mg/day) have clear dose thresholds above which clinical outcomes no longer improve. In terms of dosing frequency, daily methadone appears to produce better outcomes than less frequent dosing, while the dosing frequency of buprenorphine appears to make little difference in outcomes. Data suggest that dose tapering regimens with either methadone or Suboxone have limited success, but that longer tapers are superior to shorter-duration tapers.

Important Components of Treatment

Available evidence suggests that several types of positive incentives (e.g., contingency vouchers and rewards), as well as negative incentives (e.g., mandatory medication tapers for missed appointments), appear to improve patient retention in treatment. Evidence on the effectiveness of active, goal-oriented therapy such as cognitive-behavioral and interpersonal therapy is mixed; however, interventions to improve counseling adherence and the use of visual aids for goal-setting and tracking may improve treatment compliance. Supervised medication consumption and more frequent dispensing do not appear to improve adherence to treatment, in part because these interventions tend to be reserved for individuals with existing non-adherence patterns.

Delivery Models

Alternative delivery mechanisms for counseling in opioid dependence management (e.g., telephonic coaching, group therapy by videoconference) appear to produce similar rates of treatment retention and illicit drug use relative to in-person counseling. Wait-list maintenance interventions and pilot, office-based methadone programs appear to produce outcomes comparable to clinic-based care. Provision of opioid dependence management in alternative settings (e.g., primary care, office-based clinics) with adjunct services appears to retain patients at comparable or better rates relative to standard treatment approaches.

Economic Outcomes of Different Opioid Dependence Treatment Strategies

We estimated the outcomes of different opioid dependence management options using two simulation models: a cohort model and a population-based budget impact model for New England.

Cohort Model

The cohort model assessed the comparative value of different approaches to treating opioid dependence among 1,000 hypothetical patients entering treatment. Model outcomes and costs were calculated over a two-year time horizon. Six strategies of interest were evaluated: maintenance treatment with either methadone or Suboxone; stabilization on Suboxone followed by a 4-week taper to either oral naltrexone or Vivitrol; and opioid withdrawal management using either oral naltrexone or Vivitrol alone.

The model took into consideration different types of costs. For each different opioid dependence treatment strategy we used the simulation model to estimate the following: 1) the costs to Medicaid of substance abuse drug therapy and related services using Medicaid payment benchmarks; 2) other health care expenditures; and 3) the “social costs” of dependency in law enforcement, victimization, and productivity loss, with estimates for each component of social cost taken from the peer-reviewed literature.

Model results for two-year costs among 1,000 hypothetical individuals entering different treatment strategies are shown in Table ES2 on the following page. Two-year costs of methadone drug therapy

(~\$700) were much lower than the drug costs for all other strategies except oral naltrexone alone. But the costs of other substance abuse services for methadone maintenance (~\$14,000) were 2-7 times higher than costs of maintenance with other strategies, reflecting the regulated intensity of methadone-based care. The sum of all two-year health care costs did not substantially differ across maintenance treatment strategies because even though methadone maintenance treatment costs are higher, this maintenance strategy keeps more patients in treatment, and treatment retention has been found to be associated with a 50% reduction in the costs of other health care services among patients with opioid dependence. Of note, the two-year health care costs for relapsed patients are estimated to be nearly \$40,000, suggesting that the additional health care costs for substance abuse treatment, with *any* form of treatment, will be entirely offset within the first two years by reductions in other health care costs.

When the impact of maintenance therapy on broader social costs was added to the calculations, maintenance therapy options produced significant overall cost savings. The two-year social costs associated with opioid dependence are estimated to be over \$200,000. All versions of opioid dependence treatment therefore reduced social costs substantially compared to no treatment. Methadone maintenance therapy is projected to produce the lowest average total costs over a two-year period, a sum approximately \$100,000 less, per patient, than would be expected without treatment.

Table ES2. Two-year costs among 1,000 hypothetical patients treated for opioid dependence.

Outcome/Cost	MMT	BMT	SUB/VIV Taper	SUB/Oral NTX Taper	Vivitrol Alone	Oral NTX Alone
Treatment outcome (per 1,000):						
<i>In treatment</i>	630	523	550	500	416	277
<i>Relapsed</i>	185	292	265	315	400	538
<i>Drug -free</i>	177	176	177	176	173	169
<i>Died</i>	8	9	8	9	12	16
Cost (\$, per patient):						
<i>Drug therapy</i>	699	3,655	8,553	1,249	6,585	665
<i>Other SA services</i>	14,017	7,043	4,146	4,297	2,985	2,446
<i>Other health care</i>	23,926	25,993	25,454	26,441	28,109	30,844
SUBTOTAL	38,642	36,691	38,153	31,988	37,679	33,954
<i>Social costs</i>	92,068	102,337	98,033	105,917	119,239	141,076
TOTAL	130,710	139,028	136,187	137,905	156,918	175,030

MMT: methadone maintenance treatment; BMT: buprenorphine maintenance treatment; NTX: naltrexone; SUB: Suboxone; VIV: Vivitrol

New England Clinical and Budget Impact Analysis

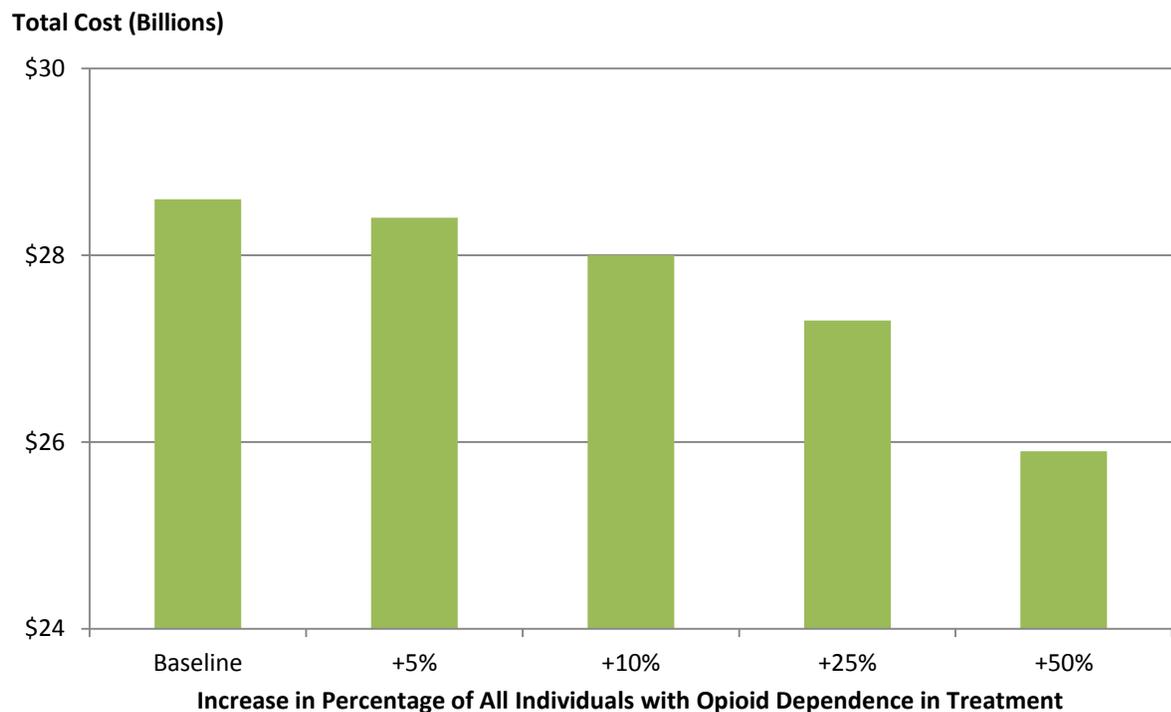
A budget impact analysis was also conducted over a two-year period. The analysis focused attention on the potential clinical outcomes (i.e., substance abuse-related deaths averted) and budgetary impact of moving different proportions of currently untreated individuals into maintenance treatment with Suboxone. Suboxone was assumed to be the modality of interest for expanded access to maintenance therapy given the regulatory hurdles required to expand access to methadone.

Currently, it is estimated that, of the 133,000 New Englanders with opioid dependence, 40,000 receive maintenance treatment. At baseline, approximately 2,800 opioid-related deaths would be expected to occur across New England in a two-year period, 450 of which would be among adolescents. Expanding treatment access by 10% would reduce the number of deaths by nearly 150 (30 of whom would be adolescents). A 50% expansion of patients brought into treatment would be expected to save nearly 700 lives in two years, including over 100 adolescents.

As noted earlier, even when considering health care costs alone, the additional costs associated with expanding access to maintenance treatment have been found to be fully offset by savings in the cost of other health care services. Moving 5% of untreated individuals in New England into treatment would increase treatment expenditures by \$73 million, but result in reductions in the cost of other health care services by about \$80 million. Greater levels of expansion would result in greater net cost savings. For example, a 10% expansion would increase treatment costs by \$183 million, but reductions in the cost of other health care services of nearly \$200 million would result in net cost savings of \$15 million.

The effects of expanded access to maintenance treatment on total (health care plus social) costs are more dramatic, as presented in Figure ES1 on the following page. At baseline, total costs of opioid dependence in the region are estimated to be approximately \$29 billion over two years, 81% of which is generated by dependent individuals not currently in treatment. At each level of treatment expansion, net savings are substantial, given that costs of health care services are already offset by treatment and reductions in social costs are pronounced. For example, expanding treatment by as little as 5% would decrease total costs by approximately \$220 million. A 25% expansion would decrease overall costs by approximately \$1.3 billion, and a 50% expansion would decrease overall costs by \$2.6 billion. Put another way, each additional health care dollar spent on expanding maintenance treatment would return approximately \$1.80 in savings. Importantly, all of these savings are realized even under the assumption that only slightly more than 50% of individuals newly-accessing Suboxone treatment would remain in treatment after two years.

Figure ES1. Total costs (health care plus social costs of opioid dependence) of persons with opioid dependence in New England, assuming different levels of increase in percentage of individuals brought into treatment. Total costs go down with each incremental increase in the percentage of patients in medication-assisted treatment programs.



CEPAC Votes on Comparative Clinical Effectiveness and Value

During CEPAC public meetings, the Council deliberates and votes on key questions related to the review of the evidence produced by the Institute for Clinical and Economic Review (ICER). At the June 20, 2014 meeting, CEPAC discussed and placed votes assessing the comparative clinical effectiveness and value of various treatment approaches addressed in this evidence review. When voting on comparative value, CEPAC was asked to assume the perspective of a state Medicaid program that must make resource decisions within a relatively fixed budget for care. For each question on value, CEPAC placed two separate votes: one considering only the direct medical costs associated with each intervention, and one considering both the societal and medical costs associated with each intervention. The voting results are presented on the next page.

1. Is the evidence adequate to demonstrate that long-term maintenance therapy with any medication is superior to short-term detoxification for most patients with opioid dependence?

12 yes (92%) 1 no (8%)

2. From the perspective of a state Medicaid program, would you judge the value of long-term maintenance therapy with any medication compared to detoxification to be high, reasonable, or low?

Considering only direct medical costs:

10 high (77%) 1 reasonable (8%) 1 low (8%) 1 abstain (8%)

Considering medical costs and societal costs together:

11 high (85%) 1 reasonable (8%) 1 low (8%)

3. From the perspective of a state Medicaid program, would you judge the value of expanded access to maintenance therapy with any medication versus the status quo to be high, reasonable, or low?

Considering only direct medical costs:

9 high (69%) 3 reasonable (23%) 1 low (8%)

Considering medical and societal costs together:

12 high (85%) 1 low (8%)

4. Is the evidence adequate to demonstrate that maintenance therapy with methadone is at least functionally equivalent to maintenance with Suboxone in treating patients with opioid dependence?

12 yes (92%) 1 no (8%)

5. From the perspective of a state Medicaid program, would you judge the value of methadone treatment compared to Suboxone treatment to be high, reasonable, or low?

Considering only direct medical costs:

2 high (15%) 8 reasonable (62%) 2 low (15%) 1 abstain (8%)

Considering medical and societal costs together:

3 high (23%) 8 reasonable (62%) 1 low (8%) 1 abstain (8%)

6. Among patients who can be successfully tapered from maintenance therapy with any medication (e.g., Suboxone, methadone) to opioid antagonist treatment, is the evidence adequate to demonstrate that Vivitrol is as good as or superior to oral naltrexone for patients with opioid dependence?

1 yes (8%) 12 no (92%)

Recommendations to Guide Practice and Policy in New England

Before the CEPAC public meeting, ICER staff conducted unstructured interviews with 15 policy experts to explore real world perspectives on recent practice and delivery system innovations, potential policy changes, and other opportunities to improve how patients utilize and access treatment for opioid addiction in New England. There were interviewees from each New England state, with positions in OTPs, patient advocacy organizations, state agencies, clinical societies, academic institutions, and office-based addiction treatment centers.

The results from these interviews were used to frame a set of policy and practice recommendations that are presented in the body of the report and which informed a moderated Policy Roundtable discussion during the CEPAC meeting between Council members and a panel of regional policy experts. Roundtable panelists are shown below:

Rebecca Boss, MA	Rhode Island	Deputy Director, Department of Behavioral Healthcare, Developmental Disabilities and Hospitals (BHDDH), State of Rhode Island
John Brooklyn, MD	Vermont	Physician, Community Health Centers of Burlington
Barbara Cimaglio	Vermont	Deputy Commissioner, Alcohol and Drug Abuse Programs, State of Vermont
TJ Donovan, JD	Vermont	State Attorney for Chittenden County, State of Vermont
Kevin Flanigan, MD	Maine	Medical Director, MaineCare Services, State of Maine
John Hammel, MD	New Hampshire & Vermont	Director, Substance Abuse Services, White River Junction VA
Lisa Muré, MEd, CPS	New Hampshire	Director for Prevention, New Hampshire Center for Excellence Senior Consultant, Community Health Institute
Stacey Sigmon, PhD	Vermont	Associate Professor of Psychiatry, University of Vermont Director, The Chittenden Clinic
Jeff Simmons, MD	Massachusetts	Medical Director for Behavioral Health, Blue Cross Blue Shield of Massachusetts
Tom Simpatico, MD	Vermont	Chief Medical Officer, Vermont Department of Health Access
Jacquelyn Starer, MD, FACOG, FASAM	Massachusetts	Associate Attending Physician, Faulkner Hospital Associate Director, Physician Health Services, Inc. President, Massachusetts Chapter of ASAM
Joycelyn Woods, MA, CMA	National	Executive Director, National Alliance for Medication Assisted Recovery

Combining the insights gained from the earlier policy expert interviews with the votes on the evidence by CEPAC and the ensuing Policy Expert Roundtable discussion, the following set of recommendations are presented to guide the application of evidence to improve opioid dependence management practice and policy in New England. The rationale for these recommendations is presented in the body of the report beginning on page 81, where we also present further nuance on different practice and policy options along with benchmarking information on recognized best practice organizations and approaches. The Policy Expert Roundtable discussion reflected multiple perspectives and opinions and therefore none of the recommendations below should be taken as a consensus view held by all participants.

1. Coordinated efforts are needed across New England to improve access to opioid dependence treatment for the large number of individuals who lack adequate access to high quality care options. Mechanisms that should be considered to help accomplish this goal include:

- Change regulations that isolate methadone treatment from the rest of clinical care and consider allowing the extension of methadone treatment to office-based settings.
- Provide more resources to develop the skills and expertise of DATA 2000 waived physicians in order to increase their capacity and willingness to serve more patients with addiction.
- In appropriate organizational settings, relax limits on the number of patients that can be treated by qualified clinical teams.
- Broaden the scope of DATA 2000 to allow qualified nurse practitioners to prescribe buprenorphine-containing medications.
- Develop stronger peer networks to help organizations and specialties treating patients with addiction manage care more effectively.
- Revise highly restrictive entry criteria for some medication-assisted treatment programs that add another barrier to entry for patients.
- Screen for opioid addiction in primary care settings in order to support early interventions for recovery.

2. Develop innovative strategies that connect individuals in the criminal justice system to treatment for their addiction.

- Create jail diversion programs in which non-violent offenders are assessed for addiction and referred to appropriate treatment in lieu of incarceration.
- Expand treatment to incarcerated individuals by providing Suboxone to individuals who will be in prison for more than a short period and making medication-assisted treatment (MAT) available to individuals who are waiting for sentencing.
- Avoid the indiscriminate use of naltrexone in individuals exiting the corrections system given that many individuals who are believed to be opiate-free are not, and some individuals that exit incarceration with Vivitrol are likely to never return to treatment and will be at higher risk for overdose.

3. Clinicians should individualize treatment, including decisions about medication choice, counseling, and supportive social services, according to an initial assessment of a patient’s baseline severity and unique health care needs. For most patients, medication-assisted maintenance therapy will be more effective than attempts at short-term managed withdrawal. However, short-term managed withdrawal may be a reasonable consideration for a subset of patients with relatively short-term histories of addiction and less intravenous opioid use.

- The results of a patient’s initial assessment and evaluation should determine the medication selected for treatment.
- Patients with higher opioid tolerance, longer histories of use, and unstable living situations are likely to benefit from a more structured program with methadone. Conversely, individuals with mild-to-moderate levels of dependence and greater life stability who require less treatment oversight are often considered for first-line treatment with buprenorphine-containing medications. Naltrexone may be an effective first-line treatment option for individuals with short histories of opioid use who access treatment early.
- Specialty societies, states, and other stakeholders should work together to develop evidence-based screening tools, questionnaires, or algorithms to help identify the most appropriate initial treatment based on individual patients’ unique factors.

4. Develop systems to triage patients entering treatment to the level of care most appropriate for their individual needs in order to support patient-centered treatment and allow for more capacity in the system.

- Consider developing coordinated care networks in which patients receive short-term intensive outpatient care until stabilized, and then are referred outward to other outpatient practices for lower levels of ongoing care and MAT in primary care settings or community-based practices.

5. Mandatory requirements for certain kinds of counseling can have unintended consequences and should be reconsidered to ensure they are not negatively affecting patient outcomes.

- State and health insurer medical policies that require that treatment plans provide counseling in order for patients to receive MAT should be reconsidered. Although social support and counseling are critical for many patients, there are not enough counselors to serve every patient with addiction, and therefore these policies can sometimes “bottleneck” treatment and serve as an additional barrier to care.
- Many counselors are not specifically trained in addiction and individuals with dependence may be better served through peer-led recovery support that addresses techniques for relapse prevention from a patient’s perspective.

6. Provide treatment for opioid dependence through comprehensive, team-based care with collaboration across health care providers.

- All patients should have access to comprehensive health care services that can address the full range of co-occurring clinical, social, and environmental factors surrounding dependence. Housing support, wellness services, occupational rehabilitation, transportation, reproductive counseling, parenting support, and legal support are among the social services most important for patient success.
- Treatment programs that are unable to provide the full spectrum of services that opioid-dependent patients require on-site should maintain a strong referral network with local mental health providers and other social agencies, as well as a robust case management system that tracks patients' progress and helps coordinate services for them as they access treatment.

7. Clinical strategies for dosing and tapering of medication-assisted therapy should adopt an individualized approach that engages the patient in setting goals.

- Although clinicians generally do not want to keep patients on medication indefinitely, there is little consensus on whether or how best to taper patients off maintenance therapy. Standardized treatment cut-offs are generally regarded as counterproductive.
- Some programs with success implementing a tapering strategy suggest adopting a gradual approach that slowly weans patients off medication over the course of several months. Patients should be engaged to determine their level of motivation to attempt a taper, and frequent re-assessments should be performed to decide if the taper should be halted or reversed.
- Stakeholders in Maine, where treatment programs are required to attempt to wean patients on Suboxone to a lower dose within two years as a condition for reimbursement, have found that when tapering is framed as a sign of success it boosts patients' self-confidence and engagement in their treatment plan.

8. Evidence-based insurance coverage policies for opioid dependence services should support efficient clinical practice and provide enough flexibility to help clinicians appropriately support the care needs of a diverse group of patients.

- Insurers should attempt to institute efficient prior authorization processes for Suboxone and Vivitrol to achieve intended policy goals while minimizing the burden to patients, clinicians, and pharmacists. "Fast-track" prior authorization processes for reliable prescribers should be considered.
- Insurers and providers share the burden of balancing concerns for diversion with the desire to provide a dose high enough to ensure a patient does not experience withdrawal and drop out of treatment. No standardized approach for dosing (or

tapering) will work for all patients, and therefore the level at which patients receive medication must be individualized. Mechanisms to facilitate rapid consideration of requests for dosing beyond established dosing limits should be instituted.

- Exemptions for some patients from specific coverage criteria should be considered, such as exemptions from requirements for patients with long histories of successful maintenance therapy.
- Policies for compliance monitoring and random “call backs” to prevent abuse and diversion are reasonable but as with other policies there should be some mechanism for consideration of exempting some patients demonstrating long-term adherence to treatment.
- Increases to reimbursement rates for addiction treatment in order to bring them on par with payment for other clinical services should be considered to reduce the stigma that still affects addiction medicine specialists.

9. Policymakers should develop long-term solutions to recruit, train, and retain qualified physicians to the field of addiction medicine in addition to fostering greater awareness and skills for recognizing opioid addiction among primary care clinicians.

- Require that physicians in training receive more exposure to addiction medicine in medical school and that treatment of substance abuse be incorporated as a standard part of residency training to help recruit more professionals to the field.
- Implement greater efforts to train and support primary care physicians in recognizing addiction disorder, leveraging training and physician mentorship programs from ASAM and AAAP that assist primary care providers to incorporate screening, brief interventions, and referrals to substance abuse treatment centers as a standard part of care.

10. Funders and the clinical research community should focus future study on key areas where further evidence is needed to appropriately manage patients with opioid dependence.

- Further research is needed to help clinicians identify those patients for whom abstinence may be an appropriate short, medium, or long-term goal, and how best to achieve and maintain abstinence in this population.
- Future RCTs should test the comparative effectiveness of different dosing and tapering protocols. In particular, significant questions remain in the clinical community on how best to identify patients for potential tapers who have been on treatment for many years.
- The existing literature shows promise for Vivitrol as a treatment option but more research is needed to establish its effectiveness and appropriate use compared to oral naltrexone.

1. Introduction

To make informed health care decisions, patients, clinicians, and policymakers must consider many different kinds of information. Rigorous evidence on the comparative clinical risks and benefits of alternative care options is always important; but along with this information, decision-makers must incorporate other considerations. Patients and clinicians must weigh patients' values and individual clinical needs. Payers and other policymakers must consider information about current patterns of utilization, and the impact of any new policy on access, equity, and the overall functioning of systems of care. All decision-makers, at one level or another, must also take into account the costs of care, and make judgments about how to gain the best value for every health care dollar.

The goal of the New England Comparative Effectiveness Public Advisory Council (CEPAC) is to provide a forum in which all these different strands of evidence, information, and public and private values are discussed together, in a public and transparent process. Funded by a consortium of state Medicaid agencies, private payers, and integrated provider groups, and backed by a diverse set of New England state policymakers, the mission of CEPAC is to provide objective, independent guidance on how information on comparative effectiveness can best be used across New England to improve the quality and value of health care services. CEPAC is an independent body composed of clinicians and patient or public members from each New England state with skills in the interpretation and application of medical evidence in health care delivery. Representatives of state public health programs and of regional private payers are included as ex-officio members of CEPAC. The latest information on CEPAC, including conflict of interest policies and guidelines for submitting comments, is available online: cepac.icer-review.org.

The Institute for Clinical and Economic Review (ICER) manages CEPAC and is responsible for developing evidence reviews for CEPAC consideration. ICER is a trusted non-profit organization that evaluates scientific evidence on the value of medical tests, treatments, and delivery system innovations and helps translate that evidence into action to improve patient care and control costs. By working collaboratively with patients, clinicians, manufacturers, insurers and other stakeholders, ICER develops tools to support patient decisions and medical policy that share the goals of empowering patients and improving the value of health care services. More information about ICER is available at www.icer-review.org. ICER has produced this evidence review and policy analysis in response to increasing stakeholder interest in strategies for managing opioid dependence, driven in large part by the growing opioid addiction epidemic in New England and across the country.

This report will support CEPAC's deliberation and attempts to answer some of the key issues confronting patients, providers, payers, and other policymakers. The goals of this review are to: 1) document the federal and New England state regulations affecting treatment options; 2) provide an

overview of existing clinical guidelines and payer coverage policies; and 3) summarize the evidence on the different management approaches for opioid dependence, including special considerations for adolescents. ICER's report for CEPAC also includes the results of a survey performed by ICER of treatment centers across New England in order to capture regional practice patterns, delivery system innovations, and policy opportunities to improve outcomes while controlling costs, as well as an overview of lessons learned from regional and national experts in the field of addiction medicine. ICER also developed a simulation model to explore the clinical and economic impact of various management strategies for patients with opioid dependence. The overall purpose of this report is to help enhance the use of evidence in practice and policy, and comments and suggestions to improve the work are welcome.

2. Background

Physical dependence on and/or addiction to prescription narcotics has reached a critical level in the U.S., due to the growing national epidemic of prescription drug abuse. Approximately 12 million Americans reported using prescription painkillers for nonmedical purposes in 2010, the most recent year for which data are available [National Institute on Drug Abuse (NIDA), 2014]. Heroin use is also on the rise. In 2012, the percentage of people using heroin in the past year had more than doubled since 2003 (Substance Abuse and Mental Health Services Administration, 2013). Fatal drug overdoses have more than tripled in the United States since 1999, with pharmaceutical overdoses – particularly from opioid pain medications such as oxycodone, hydrocodone, and methadone – driving the increase [Centers for Disease Control and Prevention (CDC), 2011]. In fact, death from drug overdose is now the leading cause of injury-related death in the United States, outpacing deaths from homicide, suicide, and traffic fatalities (CDC, 2013a). The problem of opioid addiction has recently received significant national and regional attention. Governors in New Hampshire, Massachusetts, Maine, and Vermont have all noted that combating growing opioid abuse is a major priority in their state, and they are searching for solutions for managing the growing affected population while addressing concerns regarding access and costs.

Several factors are cited for contributing to the escalating levels of opioid addiction in the U.S., including overprescribing and diversion of opioid painkillers, as well as the low cost, increased potency, and widespread availability of heroin. In 2010, enough prescription painkillers were prescribed in the U.S. to medicate every American adult continuously for one month (CDC, 2013b). Although most of these medications are prescribed for clinically indicated purposes, many are ultimately diverted to friends and family members without a prescription for non-medical use. Given the low cost of heroin relative to opioid painkillers, many individuals transition to using heroin once addicted to opioid medication (NIDA, 2014). The societal impact of opioid dependence is substantial in terms of costs related to treatment, lost work productivity, criminal activity, and social welfare expenditure (Hall, 2006). The total cost of illicit drug use and abuse in the U.S. was estimated to total nearly \$200 billion in 2011 (U.S. Department of Justice National Drug Intelligence Center, 2011).

Even with rising levels of opioid abuse and dependence, treatment resources are limited in the U.S. and many individuals requiring treatment are unable to access care. Medication-assisted treatment (MAT) for opioid dependence in clinic-based settings requires highly structured treatment protocols and special licensing by federal and state entities that isolate treatment from the rest of the health care system and serve as a barrier to entry for many patients and physicians (an explanation of federal and state regulations is provided in the next section). Meanwhile, federal and state regulations restrict the number of patients physicians can treat with opioid treatment medication in office-based settings. The highly restrictive treatment setting for patients with opioid dependence reinforces the stigma many people associate with treatment for substance abuse, and helps

perpetuate the misconception that opioid dependence is a willful choice and not a long-term chronic medical disorder.

Pharmacology

The goals of treatment for opioid dependence include decreased use or abstinence from illicit opioid use, reduced nonopioid drug use, decreased mortality, reductions in criminal activity, and lower incidence of overdose as well as communicable diseases common among injection drug users such as HIV and hepatitis (Thomas, 2014). Pharmacological treatment options include methadone, buprenorphine, buprenorphine/naloxone (Suboxone[®]), and naltrexone (Revia[®], Vivitrol[®]). These agents are described below, including their place in therapy as well as a discussion of their associated benefits and risks. A summary table comparing the different medications can be found on page 23.

Methadone

Methadone has been used in the treatment of opioid dependency for almost 50 years (Tetrault, 2012). As a full opioid agonist, methadone binds to cells in the brain and fully activates receptors, helping to control cravings and block the effects of illicit drugs such as heroin (Nosyk, 2013). Available as a branded (e.g., Methadose[®]) or generic medication, methadone is provided as an oral liquid for the treatment of opioid dependency (FDA, 2014). In the U.S., patients must be enrolled for treatment at a federally-licensed clinic to receive methadone, and they must go to the clinic daily for their dose (see Section 3). Advantages of methadone include documented efficacy in easing patients' cravings and feelings of euphoria, as well as blocking the euphoric effect in patients still using illicit opioids. Potential risks and adverse effects of methadone include constipation, sweating, and heart arrhythmias (Nosyk, 2013). Methadone may be used for induction therapy (initial management of withdrawal symptoms to help wean patients from illicit opioid use), or for maintenance treatment. The risk of abuse and overdose are substantial challenges with methadone treatment (Nosyk, 2013), and its use carries significant stigma as being associated with continued drug abuse (Olsen, 2014).

Suboxone[®]/Zubsolv[®] (Buprenorphine/Naloxone)

Suboxone contains buprenorphine, a partial opioid agonist/antagonist, and naloxone, an opioid antagonist in a 4:1 ratio (Suboxone[®] package insert, 2011). Like methadone, buprenorphine activates opioid receptors. However, as a partial agonist, buprenorphine's activity is diminished compared to methadone. Specifically, there is a "ceiling effect" with buprenorphine that limits its efficacy at high doses, but also limits adverse effects (Tetrault, 2012). Inclusion of naloxone deters diversion and abuse, as oral naloxone has poor absorption into the body but will cause withdrawal symptoms when injected intravenously. Suboxone is available as a branded film, taken sublingually, and as a generic

or branded sublingual tablet (Zubsolv). Patients take a single dose each day, and may receive a prescription for up to 30 days of medication. Unlike methadone, buprenorphine/naloxone may be used by office-based physicians who have obtained a special prescribing license (see Section 3) as well as in licensed treatment centers. Benefits of buprenorphine/naloxone include easing of patients' cravings with a decreased risk of overdose and diversion, as well as blocking feelings of euphoria with other opioids if used illicitly. Potential side effects include headache, sweating, and potential liver complications (Volkow, 2014); in addition, concurrent use of benzodiazepines may lead to significant respiratory depression and overdose (Tetrault, 2012). Naloxone should also be avoided in pregnancy (Tetrault, 2012). Suboxone may be used for therapy induction or stabilization as well as maintenance treatment. As with methadone use, Suboxone is viewed by some as a capitulation to drug addiction and not as a treatment for a chronic disease (Olsen, 2014). Further, while many prescribers adhere to federal prescribing regulations and treatment recommendations, other clinicians utilize Suboxone prescribing as a sophisticated cash-generating business opportunity (Sontag, 2013).

Subutex® (Buprenorphine alone)

Buprenorphine may also be used alone in the treatment of opioid dependence. Without the presence of naloxone, there is an increased risk of diversion with buprenorphine, but it may be an appropriate choice for the treatment of pregnant women (who should not receive naloxone). It is available as a generic sublingual tablet and is dosed once daily. Buprenorphine may also be used as an agent for therapy induction or stabilization as well as for maintenance treatment.

Revia®/Vivitrol® (Naltrexone)

Naltrexone is a complete opioid antagonist, producing blockade at receptors in the brain and preventing the euphoria that is a consequence of taking drugs like heroin and oxycodone (Tetrault, 2012). Available as a branded (Revia) and generic oral tablet, naltrexone was also approved in 2010 as an intramuscular depot injection (Vivitrol). Oral tablets require once-daily dosing, while the depot injection is given in a clinician's office once a month. Advantages of naltrexone include the absence of addicting or sedating effects as well as little to no potential for abuse or diversion (Volkow, 2014). The primary disadvantage is that naltrexone has relatively little effect on opioid cravings, which may precipitate addiction relapse in many patients (Dijkstra, 2007). Patients must also be opioid-free for approximately seven days before starting therapy with naltrexone. Serious adverse events include precipitation of opioid withdrawal symptoms and liver injury (Vivitrol® package insert, 2010). Other side effects include headache, stomach pain, nausea and fatigue (Tetrault, 2012). Naltrexone is used as a maintenance agent in patients who have undergone opioid management withdrawal and are not receiving opioid replacement therapy with methadone or Suboxone. Challenges to the use of naltrexone include poor adherence associated with absence of any euphoric effects, risks of overdose

in patients concurrently using illicit opioids, and the need for patient abstinence prior to therapy initiation (Tetrault, 2012).

Emerging Treatment Options

Investigational treatment options for opioid dependency include a buprenorphine implant (Probuphine®, Titan Pharmaceuticals), a naltrexone implant, and a heroin vaccine. Designed to slowly release buprenorphine over a 6-month period, Probuphine did not receive approval from the FDA in May 2013 despite a favorable vote from its Advisory Committee, as the FDA required further research regarding Probuphine's ability to mirror relevant doses of sublingual buprenorphine (Carroll, 2013). Initial studies of naltrexone implants that release medication over a 3-6 month period have demonstrated favorable preliminary safety profiles, but rigorous comparative clinical trials are still needed to investigate treatment outcomes (Lobmaier, 2011). Finally, animal studies of an investigational heroin vaccine involving antibodies to heroin and its metabolites have provided preliminary evidence of activity against the rewarding and reinforcing properties of heroin (Schlosburg, 2013).

In addition, a new buprenorphine/naloxone film (Bunavail®) has recently been approved by the FDA. Bunavail is able to be absorbed by the body faster than the Suboxone film allowing it to be administered in doses of 2.1mg, 4.2mg, or 6.3mg instead of the recommended 16mg/daily for Suboxone (Anson, 2014).

Table 1. Summary characteristics of medications for the treatment of opioid dependency.

Characteristic	Methadone	Buprenorphine/naloxone	Naltrexone
Brand name	Methadose	Suboxone, Zubsolv	Revia, Vivitrol
Class	Full agonist	Partial agonist/antagonist	Full antagonist
Administration	Oral liquid	Sublingual film/tablet	Oral tablet/depot injection
Use and effects	Taken once daily to alleviate cravings and withdrawal symptoms	Taken once daily to alleviate cravings and withdrawal symptoms	Taken once daily or by monthly injection to decrease rewarding effects of opioids
Usual effective dose	20 -100 mg/day	8-24 mg/day (Suboxone) 5.7 – 11.4 mg/day (Zubsolv)	50-100 mg/day (Revia) 380 mg/month (Vivitrol)
Prescription source	Federally regulated drug treatment clinics	Federally regulated drug treatment clinics; licensed physicians' offices	Federally regulated drug treatment clinics; physicians' offices
How dispensed	On site at federally regulated drug treatment clinics; take-home doses permitted for patients with documented compliance and negative drug urine screens	Community pharmacies; on site at federally regulated drug treatment clinics	Physicians' offices; on site at federally regulated treatment clinics
Advantages	High strength and efficacy	High strength and efficacy; eligible for prescription doses up to 1 month; avoidance of specialty clinics; decreased abuse liability	Not addictive or sedating, and without physical dependence; avoidance of daily dosing
Disadvantages	High abuse and diversion potential; requires daily visits to approved treatment clinics	Some abuse potential; risk of precipitated withdrawal with injection	Poor patient adherence; treatment requires initial abstinence
Price for 30 days of treatment (based on average wholesale price estimates)	Generic liquid: \$15	Generic tablet: \$600* Suboxone: \$500 Zubsolv: \$500	Generic tablet: \$200 Revia: \$660 Vivitrol: \$1,400

* According to Red Book Online[®], the average wholesale price for generic buprenorphine/naltrexone does not appear to be less than the current pricing for Suboxone.

Source: Volkow ND et al. Medication-assisted therapies – tackling the opioid-overdose epidemic. *N Engl J Med.* 2014;370(22):2063-2066; Nosyk B et al. A call for evidence-based medical treatment of opioid dependence in the United States and Canada. *Health Aff (Millwood).* 2013;32(8):1462-1469; Micromedex Healthcare Series. RED BOOK[®] Online. Greenwood Village, CO: Truven Health Analytics, 2014. <http://truvenhealth.com/>. Accessed May, 2014.

3. Regulations Affecting Access to Care in New England

An overview of regulations and legislative initiatives affecting treatment for opioid dependence is presented in the sections that follow. Regulations related to the prescribing of opioid medications or overdose prevention, while related to opioid dependence, are not included here in detail since they are outside the scope for this review. It is important to recognize that legislative status is an ever-changing landscape; accordingly, this section should be considered a “snapshot” of status at the time of report publication.

3.1 Federal Regulations

Opioid Treatment Programs (OTPs)

Federal law restricts the dispensing of methadone to federal- and state-approved opioid maintenance programs. OTPs, or “methadone clinics”, are licensed and accredited opioid agonist treatment programs that dispense methadone according to highly structured protocols as determined by the federal and state government, including the Department of Health and Human Services (HHS) and the DEA, and individual states (ASAM, 2004). The Substance Abuse and Mental Health Services Administration (SAMHSA) oversees the certification and accreditation of OTPs with assistance from the Center for Substance Abuse Treatment (CSAT), which is part of SAMHSA. Federal regulation passed in 2001 outlines the conditions required for authorization, including criteria for clinical environment, safety, quality control, and community involvement. Federal regulation also sets forth conditions for patient admission, program staffing, medication dosing, patient assessment, drug testing, and provision of social supportive services.

By regulation, patients receive methadone at OTPs under observation, though many patients may progress to less structured services and may eventually earn take-home medication privileges after documenting responsibility and stability to receive opioid medication unsupervised. The provision of psychosocial services is required at the main treatment facility or through formal referrals with other providers, the frequency, intensity, and scope of which vary according to each individual patient’s needs. Most OTPs only administer methadone, though following the introduction of buprenorphine some programs have expanded their services to include buprenorphine-containing products. To be admitted for treatment, adults must have a documented one-year history of opioid addiction and provide written consent (though certain exceptions apply). For adolescents the

admission criteria are stricter, requiring at least two documented unsuccessful attempts with short-term opioid withdrawal or a drug-free treatment within a year before MAT can be provided. Table 1B in Appendix B summarizes other key components of federal regulation for OTPs.

Prescribing of buprenorphine-containing medications

The passing of the Drug Addiction Treatment Act (DATA) of 2000 allowed physicians to dispense or prescribe MAT for opioid dependence in treatment settings other than the traditional OTP environment for the first time. DATA 2000 allows qualified physicians to obtain a waiver (or “X” license) to prescribe and/or dispense Schedule III, IV, and V opioid medications or combinations of such medications that the FDA has specifically approved for the treatment of opioid dependency. Buprenorphine alone and Suboxone/Zubsolv (buprenorphine/naloxone) are currently the only approved treatments by the FDA within these classifications. In order to qualify for a waiver, physicians must hold a current state medical license and a valid DEA registration number, and have adequate training with respect to the treatment and management of opioid-addicted patients. To meet this end, physicians must either be board certified in addiction medicine or other relevant specialty, have served as the principal investigator in a clinical trial for buprenorphine-containing medications for the treatment of opioid dependence, or have completed an eight hour training course on appropriate use of buprenorphine from an approved organization. Physicians with a waiver may not treat more than 30 patients with an addiction treatment concurrently, but after one year can apply for a second waiver to treat up to 100 patients at one time. Physicians must also attest that they have the capacity to refer patients to counseling and other appropriate non-pharmacological therapies as needed. The DEA maintains oversight of certified physicians and may perform random unannounced audits of physician records to ensure compliance with regulations.

Substance abuse services and the Affordable Care Act (ACA)

The signing of the ACA in 2010 established new requirements for health insurers to cover treatment for addiction and substance use disorders. The final bill includes services for mental health and substance use disorders as an Essential Health Benefit, meaning that “health insurance sold on the Health Insurance Exchanges or provided by Medicaid to certain newly eligible adults must include coverage for substance use disorders” (Office of National Drug Control Policy, 2014). The law also requires that Medicaid insurance plans and health plans on the marketplace exchange comply with standards for mental health parity and provide services for substance use disorders and mental health to the same extent as all other covered medical benefits.

3.2 New England State Regulations

Licensing requirements for substance use disorder treatment programs

Each New England state has strict criteria pertaining to the licensing and accreditation of facilities providing services for substance use disorders. Legislation in each state outlines procedures for renewal, inspections, and other approval processes, as well as conditions for safety, conflict management, patient protection, recordkeeping, and other program components. To operate in a state, OTPs and other substance abuse treatment centers must be certified and registered with all relevant state and federal authorities. The extensive set of criteria pertaining to substance abuse centers makes establishing new treatment facilities an arduous task. Some states, like Maine, require that licensing authorities first determine the need for an OTP at a particular location and hold a public forum before establishing a program in a given area.

Each New England state requires that substance abuse facilities have standardized policies and procedures in place for ongoing quality control. All facilities must have documented protocols for program evaluation; patient admission, discharge, and referral; treatment documentation and reporting; and medication administration. Patient admission protocols at OTPs or practices providing opioid withdrawal management services (“detoxification facilities”) typically follow stricter criteria than other substance abuse facilities. For example, OTPs in each state must confirm with the state that a patient is not receiving treatment at any other OTP before providing care. In Maine, OTPs may not admit more than 500 patients without a special waiver. In Rhode Island, adolescents under 16 may not be admitted for treatment without written approval from the state methadone authority, and daily reports on patient admissions, discharges, and transfers must be provided to all relevant state authorities.

As with federal regulations, substance abuse facilities in each state require that adequately licensed and trained practitioners supervise program staff. Programs providing MAT, rehabilitation, or opioid withdrawal management services in each state are required to staff a multi-disciplinary care team typically composed of a medical director, registered nurse, psychiatrist or psychologist, pharmacist, counselors, and case managers. Some states have specific requirements for clinician caseloads. For example, in Maine, counselors working at detoxification facilities or OTPs are unable to treat more than 150 patients at one time, and Rhode Island requires at least one licensed nurse per 25 patients. Most states also have standards that practitioners at substance abuse facilities receive ongoing training in addiction disorders and overdose prevention.

State licensing authorities in New England typically require that patients receive a comprehensive assessment and evaluation that informs an individualized treatment plan. Some states set standards for the frequency and interval at which practitioners must review and update treatment

plans to ensure that services continuously adapt to a patient's specific needs. Complementary social support, mental health, education, and case management services are typically required as part of the standard treatment program at all substance abuse facilities.

State treatment requirements for programs providing MAT or opioid withdrawal management generally follow federal regulations. Some states have more specific criteria for counseling and supportive care than do federal standards. For example, Maine sets minimum counseling requirements for different phases of care (e.g., 4 hours of individual counseling during first 45 days of treatment). In Rhode Island, individuals receiving care at OTPs must attend at least one hour of individual counseling monthly in the first year of treatment. The requirement is higher for patients receiving long-term opioid withdrawal management. In Vermont, regulations around MAT in OTPs also apply to physicians prescribing buprenorphine-containing medications in office-based settings. Patients receiving MAT in either setting must receive an initial psychosocial assessment or be referred for evaluation.

Many states have also enacted stricter medication requirements, particularly around random drug testing and dosing for take-home use. Federal regulations allow eligible patients to receive up to a monthly dose of methadone for take-home use after two years of continuous treatment. Rhode Island, however, requires patients to achieve four years of ongoing treatment before a monthly take-home dose can be administered. The maximum take-home dose in Massachusetts is 13 days given every two weeks following 18 months of treatment. In Maine, eligible patients may receive a take-home dose of 6 days following one year of continuous services. Maine and Massachusetts also require more frequent drug testing for patients receiving care at OTPs. Compared to federal standards of eight random drug screens a year, Maine and Massachusetts require 12 and 15, respectively.

Table 2B in Appendix B provides a more detailed overview of the various licensing criteria in the region, including staffing, treatment, and program conditions required for substance abuse facilities to operate in each New England state.

Legislative Initiatives

Table 2 on the following page provides an overview of legislative activity at the time of writing in New England states related to opioid dependence.

Table 2. Summary of New England state regulation affecting treatment of opioid dependence

State	Overdose prevention	Safe prescribing of opioid painkillers	Mandatory insurance coverage for MAT	Treatment duration limits for MAT	Increased regulation for Suboxone® prescribers	Jail Diversion programs	Care delivery reform
<i>CT</i>	■					■	
<i>ME</i>	■	■		■			
<i>MA</i>	■	■			□	□	□
<i>NH</i>		□					
<i>RI</i>	■	■	■				□
<i>VT</i>	■	■			■	■	■

Key: □ = Introduced ■ = Passed

Most legislation in New England regarding opioid dependence targets opioid prescribing and overdose prevention. States have made efforts in recent years to improve the quality of opioid prescribing for pain management in order to reduce the number of individuals addicted to opioids. States have also made efforts to reduce overdose by expanding access to naloxone, by broadening prescription and administration criteria, and providing legal immunity to persons who seek medical assistance for a drug overdose. In terms of regulation surrounding MAT and treatment for opioid dependence, some states have introduced policies regulating coverage for opioid treatment medication. For example, Maine enacted legislation in 2013 that placed treatment duration restrictions on insurance coverage for MAT. Medicaid patients receiving methadone or Suboxone for opioid dependence in Maine receive coverage for treatment for a maximum of two years, except when permitted for a longer treatment duration through prior authorization. In Rhode Island, legislators recently proposed a bill that would mandate insurance coverage for methadone, Suboxone, other forms of buprenorphine, and naltrexone. The Senate Health and Human Services committee considered the bill in April 2014 and recommended further study.

Access to MAT in criminal justice settings is rare in the U.S., but some states have made efforts to improve access to MAT and the level of care provided in prisons for individuals with opioid dependence. For example, Connecticut passed legislation establishing a jail diversion program that allows for individuals in the court system to be evaluated for addiction and appropriately referred to an addiction treatment program (Connecticut General Assembly, 2014). Massachusetts lawmakers have introduced legislation that would expand addiction treatment for nonviolent drug-dependent offenders by diverting these individuals from jail into treatment (The Commonwealth of Massachusetts, 2014). In Vermont, state legislators passed a bill requiring courts to provide pretrial screening to defendants who may benefit from substance abuse treatment. The bill also creates new programs to help divert individuals with nonviolent crimes away from traditional criminal

justice protocols to reduce the numbers of individuals with addiction in penal institutions, and establishes a pilot that allows individuals who were receiving MAT prior to incarceration to continue treatment while in prison (Vermont State Legislature, 2014).

Some New England states have also considered legislation on the regulation of buprenorphine and Suboxone prescribing. Massachusetts lawmakers recently introduced legislation that would expand the power of the Department of Public Health to oversee buprenorphine-containing medications, including the ability to establish further conditions for approval, licensure, staffing, reporting, treatment requirements, and termination of its use. Vermont recently passed legislation that would require physicians treating fewer than 30 patients with buprenorphine or Suboxone to ensure patients are assessed to determine their need for substance abuse counseling or other supportive care and are appropriately referred to services as needed. (Existing legislation in Vermont requires that physicians treating more than 30 patients in office-based settings meet federal counseling requirements for OTPs). The legislation would also allow Vermont's Medicaid agency to sanction Medicaid-participating providers who are found to have prescribed buprenorphine-containing medications in violation of state or federal requirements.

Other states have supported legislation that introduces new requirements for the delivery of opioid dependence treatment. Rhode Island recently introduced legislation that would require health care facilities providing treatment for addiction to schedule a follow-up appointment within seven days of discharge and make patient contact within 30 days of discharge to assess the patient's progress. Lawmakers in Vermont approved the implementation of a new model for care delivery called the "Hub and Spoke" program that creates an integrated care continuum for patients with opioid addiction. The Hub and Spoke model links OTPs and office-based opioid treatment programs together under one system of care and triages patients to appropriate levels of treatment based on each individual's needs (the Hub and Spoke model is described in more detail in Section 8).

Access to treatment

Current provider capacity in New England is not sufficient to meet patient need for treatment for opioid dependence. For example, data from SAMHSA's National Survey on Drug Use and Health (NSDUH) from 2009-2012 indicates that 133,000 New Englanders are abusing or dependent on opioids, of whom 70% meet criteria for treatment but are not currently receiving it (SAMHSA, 2013c). The percentage of individuals not receiving treatment includes those who think there is no problem and make no effort to seek treatment, those who acknowledge their addiction but refuse treatment, and those waiting for treatment. The NSDUH survey indicates that approximately 2,000 individuals in New England were wait-listed for treatment in 2012; interviews with regional experts and policymakers suggest that this is a conservative estimate.

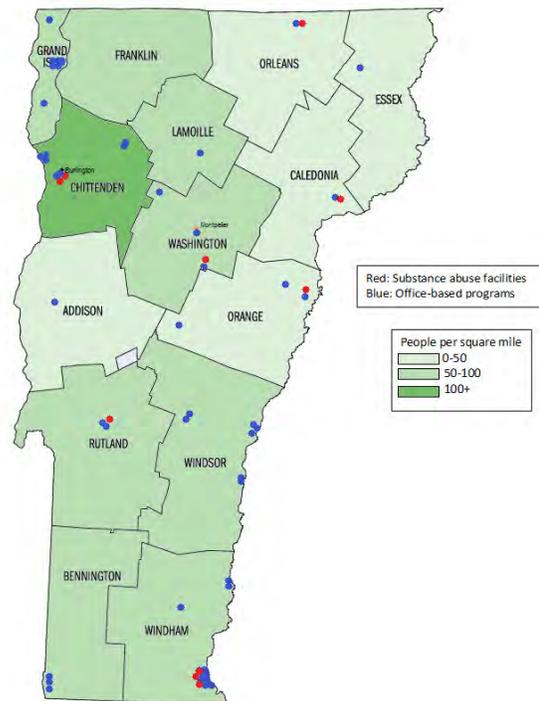
The current availability of both facility-based and office-based opioid dependence treatment falls far short of clinical need. State-based information from SAMHSA's National Survey of Substance Abuse Treatment Services (N-SSATS) shows that, in 2012, approximately 46,000 individuals in New England received at least one day of treatment with methadone or buprenorphine-containing medications in an OTP (SAMHSA, 2013b).

While information on the use of Suboxone outside of licensed facilities in New England is not publicly available, some indication of capacity for managing patients in an office-based setting is available from SAMHSA. A total of 1,193 physicians in New England who can prescribe Suboxone have voluntarily reported their status on SAMHSA's treatment program locator (SAMHSA, 2014). Most of these physicians are limited to a cap of 30 patients, but using a national benchmark, it is estimated that approximately one-third of physicians licensed to prescribe Suboxone have obtained a waiver to move from a patient cap of 30 to 100 (SAMHSA, 2013a). If this figure is applied to New England, the maximum number of patients who could be treated with Suboxone given current provider capacity is approximately 60,000. This number falls far short of the estimated 133,000 individuals in New England who have opioid dependence. And while it is theoretically possible that all 133,000 individuals could be treated by increasing the number of physicians with a cap of 100 patients, this is not a realistic outcome given that many physicians are not able to manage the care of a high number of opioid dependence patients (Gordon, 2011; Walley, 2008).

Restrictions on the availability of MAT in the U.S. criminal justice system also pose a significant barrier to treatment for many individuals with opioid dependence. In 2004, 13% of all inmates in state prisons reported using heroin or opiates regularly (Mumola, 2006). Even though the criminal justice system is regarded as the largest source of referral for substance abuse treatment, only 10% of individuals that require MAT receive it as part of their justice system supervision (SAMHSA, 2013a).

Finally, geographic barriers to access are also an important consideration across New England. For example, Figure 1 on the following page provides a map of available OTPs (in red) and office-based Suboxone programs (in blue) in the state of Vermont. As can be seen in the figure, patients in certain locations (e.g., Bennington and Franklin counties) have few or no treatment options available to them, and must therefore travel great distances for either prescriptions or daily facility-based treatment. Similar maps are available for the other New England states in Appendix C.

Figure 1. Map of available substance abuse facilities and office-based Suboxone programs in Vermont



3.3 Policy Expert Survey on Status of Treatment in New England

To help understand the status of treatment for opioid dependence in New England, ICER developed a survey instrument to profile the types of services provided to opioid dependent patients at treatment locations in the region. The survey was distributed to each facility listed in the [SAMHSA OTP directory](#) in New England, as well as to regional physicians and treatment centers included on [SAMHSA's treatment program locator](#). The survey was also sent to the leadership of each New England state chapter of the American Society of Addiction Medicine (ASAM) for broader distribution. Of the 388 treatment centers surveyed, a total of 32 unique respondents completed the instrument, of which 18 came from Massachusetts, 2 from Connecticut, 3 from Maine, 3 from New Hampshire, 4 from Rhode Island, and 2 from Vermont. Survey respondents represented federally certified OTPs, independent outpatient Suboxone and buprenorphine prescribers, detoxification centers, residential treatment providers, and outpatient counseling programs. The key survey findings are summarized in the following sections.

Description of Responding Treatment Centers

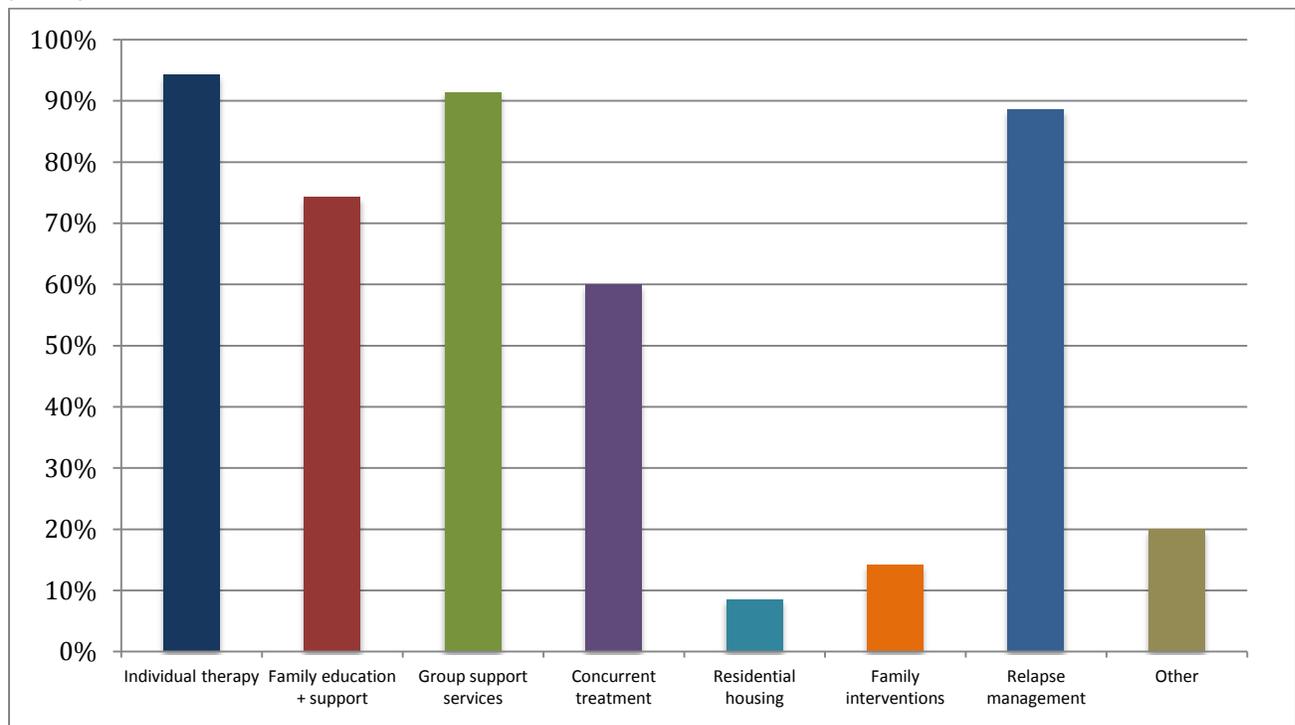
Services Provided

Of the 32 unique treatment programs that responded to the survey nearly all provided some form of MAT. Treatment programs that did not offer MAT offered short-term opioid withdrawal management, long-term abstinence-oriented recovery support, outpatient counseling and supportive services, or residential sober-living. When offering maintenance therapy, treatment programs typically provided buprenorphine/naloxone tablets and/or Suboxone. Half of the treatment programs that responded to the survey offered methadone, and half offered naltrexone. Approximately 40% of treatment programs surveyed offered both methadone and buprenorphine or buprenorphine combination therapies.

Supportive Services

All treatment centers that responded offered some form of supportive services in addition to maintenance therapy, opioid withdrawal management, and long-term drug-free rehabilitation. A summary of the supportive services typically provided is shown in Figure 2 below.

Figure 2. Survey results of supportive services provided at treatment centers in New England (n=32)



Medication requirements, protocols, and treatment choice

Of the respondents offering maintenance therapy, approximately 30% of treatment centers from across all six New England states had protocols in place that established limits on dosing and/or treatment duration. Substance abuse programs commonly limited buprenorphine or Suboxone dosing to 16 mg a day. Other practices had higher dosing limits of 24 mg or 32 mg daily. Programs in Maine had protocols for tapering and transitioning patients off treatment by 24 months, in accordance with state regulations.

Only 29% of survey respondents offering MAT had written protocols in place to support physicians in determining which treatment agent to use for drug-assisted treatment. Some practices utilize a standard set of screening criteria to assess appropriateness of buprenorphine-containing medications, methadone, or naltrexone. When patients have documented prior success with a certain medication, efforts are typically made to continue patients with that treatment option. Some practices initiate patients with mild-to-moderate levels of dependency on buprenorphine or Suboxone, and reserve methadone for individuals with higher opioid tolerance who may benefit from a more highly structured treatment regimen. However, many practices cited access questions as driving medication selection. Many patients will lack the ability -- for geographic, financial, or other reasons -- to gain rapid access to treatment with either methadone or buprenorphine/Suboxone. The treatment choice selected is usually the option that the patient can best afford and access.

Barriers to providing high quality treatment to patients with opioid dependence

Respondents cited many challenges to providing high quality health care to patients with opioid dependence. When asked to rank the extent to which different factors served as a barrier to providing treatment, respondents listed insurance coverage, efficiency of referral pathways (e.g., emergency room, court system), and regulatory structure and restrictions for practice (e.g., physician education, patient management caps for buprenorphine-containing medications, regulation of methadone clinics) as the most significant obstacles. Prominent challenges to providing treatment are listed in rank order in Table 3 on the following page.

Table 3. Barriers to providing treatment for opioid dependence in New England

Obstacle/Treatment challenge	Significant or very significant barrier
Insurance coverage for opioid treatment	57%
Efficiency of referral pathways for treatment	47%
Regulatory structure and restrictions	46%
Community reaction to placement of treatment centers	37%
Communication/coordination across different health providers	34%
Recruiting/retaining qualified staff	33%
Staff or resource levels to address co-morbid conditions	30%
Availability of time and resources to assess treatment outcomes	27%
Patient/family attitudes regarding need for treatment	23%
Tailoring treatment program to client needs	13%

Other challenges referenced by respondents included the inability to secure safe and stable housing environments for patients, insufficient transportation services, and poor coordination of services between mental health and other health care providers. One respondent mentioned that some practices are unwilling to coordinate services and have dropped patients after learning they also receive care at an OTP. Others referenced the scarcity of mental health providers in the region with whom to coordinate care and establish systems for referral.

As shown in the table above, over half of treatment centers surveyed cited insurance coverage and reimbursement as a significant or very significant barrier to care. In some states, programs mentioned that low Medicaid reimbursement rates, legislative actions to reduce funding for treatment centers, and lack of Medicare and private insurance coverage made it a challenge to remain open and continue to provide care. Others stated that underfunding of services made it difficult to maintain adequate staffing and recruit physicians to addiction medicine. Respondents also highlighted that the burdensome nature of existing prior authorization requirements for buprenorphine, Suboxone, and Vivitrol make it difficult to prescribe these therapies. The changing landscape of insurance coverage for substance abuse services due to federal regulations around mental health parity may ease some of these burdens over time.

4. Medicaid, Medicare, National and New England Private Insurance Coverage Policies

We examined publicly available policies for national payers, including Aetna, Anthem, Cigna, and UnitedHealthcare, and regional private and public payers.

Limited information is available regarding Medicare coverage of opioid dependency treatment. National Coverage Determinations describe longstanding policies regarding physician-provided, hospital outpatient, and freestanding clinic services for drug abuse treatment. Coverage is subject to general limitations applicable to these settings of care.

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=29&ncdver=1&DocID=130.5&bc=gAAAAAgAAAAAAAA%3d%3d&>

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=28&ncdver=1&DocID=130.6&bc=gAAAAAgAAAAAAAA%3d%3d&>

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=59&ncdver=1&DocID=130.7&bc=gAAAAAgAAAAAAAA%3d%3d&>

4.1 Methadone

We found a single publicly available coverage policy for the use of methadone in opioid dependence treatment. Blue Cross Blue Shield of Massachusetts (BCBSMA) explicitly requires prior authorization for methadone treatment of opiate addiction. Survey results in a report prepared for ASAM revealed that all six New England state Medicaid agencies do provide coverage of methadone treatment (ASAM, 2013), although coverage policies are not available online. Among national private payers, Anthem provides clinical guidelines for the treatment of substance abuse but the policy does not describe individual medication treatment approaches.

4.2 Suboxone/Zubsolv (buprenorphine/naloxone)

Medicaid

Use of Suboxone is generally limited in New England Medicaid programs through prior authorization and clinical criteria requirements as well as dosing and quantity limits (see Table 4 on page 39). Maine, Massachusetts and Vermont limit the allowable daily dose of Suboxone or the generic tablet to 16 mg, while Massachusetts places additional restrictions on higher doses based on duration of therapy. Use of non-preferred agents requires documentation of intolerance to preferred medication. Only Connecticut (Suboxone) does not require prior authorization. Use of Suboxone in Maine requires evidence of monthly monitoring (e.g., pill counts or urinalyses) and is restricted to a lifetime treatment limit of 24 months. Prior authorization for use beyond 24 months is contingent on patients' engagement in recovery services and documented attempt(s) at dose tapering. Vermont requires patients to designate a "pharmacy home" for all prescriptions, and the allowable maximum supply is 14 days for take-home doses. Prior authorization for Suboxone in New Hampshire evaluates whether patients have received a dependency assessment and if patients are enrolled in addiction counseling.

Zubsolv may be used in Connecticut, Maine and Massachusetts only with prior authorization.

Regional Private Payers

Among the major regional private payers, Blue Cross Blue Shield of Vermont (BCBSVT), ConnectiCare and Harvard Pilgrim Health Care (HPHC) place few restrictions on the use of Suboxone, Zubsolv and the generic tablet (see Table 5 on page 40). Conversely, BCBSMA, Blue Cross Blue Shield of Rhode Island (BCBSRI) and Tufts Health Plan require prior authorization for use of these medications with dose and quantity limits applied. Similar to Medicaid restrictions, BCBSMA limits the maximum daily dose of Suboxone and the generic tablet to 16 mg and to 11.4 mg for Zubsolv. Quantity limits based on medication strength vary widely for a 30-day prescription (generally 30 – 90 units for film strips or tablets). Criteria for approved use also include a treatment plan and enrollment in behavioral/psychosocial therapy.

National Private Payers

Aetna, Anthem/UniCare/Wellpoint, and UnitedHealthcare require prior authorization for the use of Suboxone, where documented enrollment in an outpatient treatment program may be necessary. Cigna and Aetna require step therapy for Zubsolv, where patients must initially fail therapy using Suboxone or the generic tablet. While Aetna allows for higher daily dosing limits (24 mg for Suboxone and 17.1 mg for Zubsolv), monthly quantity limits are similar across the national private

payers compared with regional groups. Anthem permits higher doses for initial therapy with lower limits for therapy beyond three months. Cigna places no dosing or quantity limits on the use of Suboxone.

4.3 Subutex (Buprenorphine alone)

Medicaid

Use of buprenorphine alone for opioid dependency treatment requires prior authorization among the New England Medicaid agencies (see Table 4 on page 39). Approved uses may include for patients who are pregnant or breastfeeding, or patients who have demonstrated intolerance to naloxone. Vermont allows a 14-day supply of up to 16 mg/day per prescription, with authorized use up to one year.

Regional Private Payers

BCBSMA, BCBSRI and Tufts require prior authorization for the use of buprenorphine, limiting its use to pregnant women, patients with a proven allergy to naloxone or as induction therapy only (see Table 5 on page 40). The maximum allowable dose is 16-24 mg/day while quantity limits range from 11 tablets/90 days (BCBSRI) to 120 tablets/90 days (Tufts).

National Private Payers

National private payers also limit the use of buprenorphine primarily to induction therapy (3-24 tablets/month). Aetna further restricts buprenorphine to patients concurrently enrolled in outpatient counseling, and UnitedHealthcare allows the use of buprenorphine if a patient is pregnant or breastfeeding while in maintenance treatment.

4.4 Revia/Vivitrol (naltrexone)

Medicaid

Among New England Medicaid policies, generic naltrexone tablets are the preferred therapeutic choice; use of branded tablets (Revia) requires prior authorization and demonstrated intolerance. Massachusetts and New Hampshire do not place restrictions on the use of Vivitrol; Vermont

requires prior authorization, with approved use limited to six months. Maine requires patients to have failed oral naltrexone, comply with psychosocial counseling, and submit a recent random urinalysis. Vermont limits the maximum monthly dose to one injection.

Regional Private Payers

HPHC and Tufts do not place restrictions on the use of naltrexone, Revia, and Vivitrol for opioid dependence. BCBSMA limits coverage to oral formulations, while ConnectiCare provides coverage of generic tablets and use of Vivitrol with prior authorization.

National Private Payers

Aetna, Cigna and UnitedHealthcare do not limit the use of naltrexone, Revia or Vivitrol for opioid dependence. Anthem/UniCare/Wellpoint restricts use of Vivitrol to patients unable to comply with daily oral dosing who are abstinent, currently enrolled in a rehabilitation program, and without liver disease.

Table 4. Coverage policies for medications used in opioid dependence treatment: state Medicaid agencies.

State	Brand: Suboxone (film), Zubsolv (tablet) Generic: buprenorphine/naloxone (tablet)	Buprenorphine (tablet)	Brand: Revia (tablet), Vivitrol (injection) Generic: Naltrexone (tablet)
Connecticut	+ (Suboxone only) • Use of any other agents requires PA	○	+ (generic oral only) • Use of any other agents requires PA
Maine	+ (Suboxone only, max dose = 16 mg) • Clinical criteria applied to Suboxone use • Lifetime limit of 24 months for use of Suboxone unless PA approved • Use of any other agents requires PA	+ (during pregnancy only)	+ (generic oral only) • Use of any other agents requires PA
Massachusetts	+ (generic tablet w/dose ≤16 mg per day) • PA required for generic tablet >32 mg/day, and doses between 16 and 32 mg depending on duration of therapy • PA required for Suboxone, Zubsolv	• PA required	+ (generic oral, Vivitrol) • PA required for Revia
New Hampshire	• PA required for Suboxone ○ (Zubsolv)	• PA required	○ (Revia and generic) + (Vivitrol)*
Rhode Island	• PA required	• PA required	• PA required
Vermont	+ (Suboxone, max dose = 16 mg/day) • PA required for generic tablet (max dose = 16 mg/day) • Clinical criteria applied to Suboxone use • Authorized use up to 1 year for Suboxone and buprenorphine/naloxone • Max days' supply for Suboxone and buprenorphine/naloxone = 14 days ○ (Zubsolv)	• PA required (max dose = 16 mg/day) • Authorized use up to 1 year for buprenorphine • Max days' supply for buprenorphine = 14 days	+ (generic oral only) • PA required for Revia • PA required for Vivitrol (max dose = 1 injection/30 days)

* Additional data regarding Medicaid coverage from American Society of Addiction Medicine (ASAM). Advancing access to addiction medicines (2013).

<http://www.asam.org/docs/advocacy/Implications-for-Opioid-Addiction-Treatment>. Accessed March, 2014.

+: coverage policy identified; ○: no coverage policy identified; PA: prior authorization

Table 5. Coverage policies for medications used in opioid dependence treatment: regional private payers.

Payer	<u>Brand:</u> Suboxone (film), Zubsolv (tablet) <u>Generic:</u> buprenorphine/naloxone (tablet)	Buprenorphine (tablet)	<u>Brand:</u> Revia (tablet), Vivitrol (injection) <u>Generic:</u> Naltrexone (tablet)
Blue Cross Blue Shield of Massachusetts	<ul style="list-style-type: none"> • PA required for all agents [max dose = 16 mg/day (11.4 mg for Zubsolv)] • Quantity limits = 30-90 units per prescription based on medication strength 	<ul style="list-style-type: none"> • PA required (max dose = 16 mg/day) 	+ (Revia and generic only) o (Vivitrol)
Blue Cross Blue Shield of Rhode Island	<ul style="list-style-type: none"> • PA required for Suboxone, buprenorphine/naloxone • Quantity limits = 30-90 units per 30 days based on medication strength o (Zubsolv) 	<ul style="list-style-type: none"> • PA required • Quantity limit = 11-12 tablets/90 days 	o
Blue Cross Blue Shield of Vermont	+ <ul style="list-style-type: none"> • Quantity limit = 90 units per prescription 	+	+ (generic only) o (Vivitrol)
ConnectiCare	+ <ul style="list-style-type: none"> • Quantity limit for Suboxone = 90 film strips/month 	+	+ (generic only) <ul style="list-style-type: none"> • PA required for Vivitrol
Harvard Pilgrim Health Care	+	+	+
Tufts Health Plan	<ul style="list-style-type: none"> • PA required for Suboxone, Zubsolv, buprenorphine/naloxone with 12-month limit on coverage 	<ul style="list-style-type: none"> • PA required (max dose = 24 mg/day) with 12-month limit on coverage • Quantity limits = 90-120 units per 30 days based on medication strength 	+

+ : coverage policy identified; o : no coverage policy identified

PA: prior authorization

5. Clinical Guidelines and Policy Statements

5.1 Methadone

American Society of Addiction Medicine (2010)

<http://www.asam.org/docs/public-policy-statements/1obot-treatment-7-04.pdf?sfvrsn=0>

ASAM considers methadone to be a significantly underutilized treatment and recommends expansion of its use to office-based settings. While OTPs provide some of the necessary structure and intensity needed for many patients who are new to treatment, ancillary services such as counseling that clinics typically provide can be offered in other treatment settings. Expanding methadone to office-based settings would give physicians the flexibility to “graduate” patients to less structured environments without having to change the type of medication that is best suited to their needs.

American Association for the Treatment of Opioid Dependence (2011)

<http://www.aatod.org/policies/policy-statements/793-2/>

AATOD recommends an outcomes-based approach for legislators and physicians to improve access to methadone-assisted treatment for opioid dependence. AATOD suggests that there has historically been a widespread problem of suboptimal methadone dosing in OTPs that leads to continued substance abuse. Efforts are needed to further educate state officials and raise awareness of the value of methadone in the treatment of opioid dependency, particularly for those in the criminal justice system.

Academy of Managed Care Pharmacy (2010)

<http://www.amcp.org/data/jmcp/S14-S21.pdf>

AMCP recommends methadone for maintenance treatment, followed by a gradual taper, for patients who have had a history of dependence of at least one year. AMCP also warns against the use of co-administering enzyme-inducing medications such as carbamazepine and St. John’s Wort because they could precipitate withdrawal symptoms in methadone-maintained patients.

American Psychiatric Association (2010)

<http://psychiatryonline.org/pdfaccess.ashx?ResourceID=243188&PDFSource=6>

The APA clinical guidelines suggest that methadone is safe and effective for use in MAT for opioid dependence and higher doses of methadone are generally associated with better retention in treatment and lower rates of illicit opioid use. Methadone-related side effects are limited, and many patients that do exhibit such symptoms develop a tolerance to them over time. The APA

recommends methadone-based maintenance treatment for patients with opioid dependence of ≥ 1 year.

National Institute on Drug Abuse (2012)

http://www.drugabuse.gov/sites/default/files/podat_1.pdf

NIDA states that methadone maintenance treatment increases patient participation in behavioral therapy and decreases drug use and criminal behavior, which are essential to recovery. NIDA guidelines suggest that patients receive methadone maintenance treatment for one year at a minimum, though treatment duration can potentially be indefinite for patients who require continued maintenance.

Substance Abuse and Mental Health Services Administration

http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf (2004)

<http://adaiclearinghouse.org/downloads/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs-51.pdf> (2006)

SAMHSA's clinical guidelines state that methadone has the greatest potential for abuse of all the drugs used in MAT, and clinicians should therefore correlate dosing with the patient's level of physical dependence on opioids. SAMHSA notes that patients desiring to be abstinent from all opioids, including MAT, have had a higher rate of success (fewer opioid-positive urines) with a longer taper (30 weeks, decreased at 3%/week) than a shorter taper (10 weeks, decreased at 10%/week). The guidelines also state that physicians should avoid involuntary tapering, if possible. SAMHSA states that patients receiving methadone may be good candidates for buprenorphine-containing medications if they can be maintained on a dose of 30mg/day. However, the guidelines recognize that achieving this transition is difficult given that opioid withdrawal symptoms typically emerge at or below 30mg/day.

5.2 Buprenorphine or buprenorphine/naloxone (Suboxone)

American Society of Addiction Medicine (2011)

<http://www.addictioninstitute.org/html/Buprenorphine%20in%20Opioid%20Addiction.pdf>

Buprenorphine efficacy is comparable to methadone, and patients can safely transfer from methadone treatment by gradually reducing their dose to 30-40mg before initiating buprenorphine/naloxone induction. ASAM acknowledges that while maintenance with buprenorphine/naloxone has been shown to improve outcomes for patients under 18, further research is needed to determine its long-term efficacy for this population. ASAM states that though buprenorphine is not recommended for patients with liver function abnormalities, it appears to be subject to fewer drug/drug interactions than methadone.

Academy of Managed Care Pharmacy (2010)

<http://www.amcp.org/data/jmcp/S14-S21.pdf>

AMCP considers office-based treatment programs a breakthrough model for the management of opioid dependence since buprenorphine and buprenorphine/naloxone have lower risks of overdose and are well tolerated in less-than-daily doses compared to methadone. AMCP suggests, however, that there is a “ceiling effect” for buprenorphine, in which there is no additional benefit by increasing the dose beyond a certain point (16-32mg depending on level of illicit opioid use).

American Psychiatric Association (2010)

<http://psychiatryonline.org/pdfaccess.ashx?ResourceID=243188&PDFSource=6>

The APA clinical guidelines recommend that buprenorphine can be effective on a less-than-daily schedule and as a bridging agent to naltrexone. Physicians should therefore administer higher, less frequent doses accordingly. Buprenorphine may be best suited for patients with less severe physical dependence. Although the overdose rate is generally low compared to methadone, death is more likely if a combination of buprenorphine and a benzodiazepine is used.

National Institute on Drug Abuse (2012)

http://www.drugabuse.gov/sites/default/files/podat_1.pdf

http://www.drugabuse.gov/sites/default/files/tib_mat_opioid.pdf

NIDA states that the availability of buprenorphine in office-based settings increases access to treatment for opioid-dependent individuals. NIDA supports further research on a long-acting (injectable) form of buprenorphine.

Substance Abuse and Mental Health Services Administration

http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf (2004)

<http://adaiclearinghouse.org/downloads/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs-51.pdf> (2006)

SAMHSA guidelines suggest that sublingual buprenorphine/naloxone seems to have comparable effectiveness to buprenorphine alone, but that buprenorphine/naloxone has less potential for abuse. If physicians use buprenorphine to initiate withdrawal or discontinue opioid-agonist treatment, naltrexone must also be administered to prevent relapse (this method is used primarily for adolescents or patients with shorter histories of abuse). SAMHSA cautions that switching from methadone to buprenorphine is complex and may not be appropriate for all patients. Typical candidates for buprenorphine maintenance include patients with a history of opioid addiction that have tried other treatment methods but are not physically dependent, those who were previously in a controlled environment, and those who have been addicted for less than one year.

5.3 Naltrexone and Vivitrol (injectable naltrexone)

American Association for the Treatment of Opioid Dependence (2013)

<http://www.aatod.org/policies/policy-statements/aatod-guidelines-for-using-naltrexone-vivitrol-in-otps/>

AATOD recommends that patients be completely opioid free for 7-10 days before starting Vivitrol treatment to prevent withdrawal. The policy statement cautions that Vivitrol should not be regarded as a type of cure for opioid addiction; rather, conventional modalities, including drug rehabilitation and counseling, should always supplement MAT. Due to Vivitrol's hypertoxicity, AATOD recommends regular clinical evaluations with serial liver function studies.

Academy of Managed Care Pharmacy (2010)

<http://www.amcp.org/data/jmcp/S14-S21.pdf>

AMCP recommends naltrexone for the treatment of opioid intoxication once acute symptoms have been resolved. Patients must be monitored closely throughout the withdrawal process, particularly in the first few hours, as there is a high risk of severe withdrawal symptoms and hypotension.

American Psychiatric Association (2010)

<http://psychiatryonline.org/pdfaccess.ashx?ResourceID=243188&PDFSource=6>

The APA clinical guidelines recommend naltrexone as a maintenance agent as it is highly effective in blocking heroin and other short-acting opioids. Retention in treatment is generally poor and has a high risk of relapse. As such, the APA states that though naltrexone is typically underutilized, the treatment option has higher efficacy with motivated patients who are participating in ancillary substance abuse services such as counseling. Voucher incentives in particular appear to improve adherence to naltrexone treatment.

National Institute on Drug Abuse (2012)

http://www.drugabuse.gov/sites/default/files/podat_1.pdf

NIDA considers naltrexone typically to be associated with poor patient compliance, and therefore has limited effectiveness in the treatment of opioid dependency. However, the guidelines suggest that Vivitrol appears to be an effective alternative for those unable to or undecided on whether to use agonist treatment.

Substance Abuse and Mental Health Services Administration

http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf (2004)

<http://adaiclearinghouse.org/downloads/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs-51.pdf> (2006)

Patients must be fully withdrawn for up to two weeks before beginning naltrexone maintenance treatment. Naltrexone is particularly effective among subgroups with strong psychosocial supports, including health care professionals, business executives, younger patients, and patients involved in the criminal justice system.

5.4 Other Treatment Requirements/Interventions

American Society of Addiction Medicine

<http://www.asam.org/docs/public-policy-statements/1obot-treatment-7-04.pdf?sfvrsn=0> (2010)

<http://www.asam.org/docs/default-source/public-policy-statements/pharmacological-therapies-for-opioid-use-disorder-2013-04-24.pdf?sfvrsn=4> (2013)

ASAM recommends collaboration between addiction medicine and addiction psychiatry organizations to provide the level of care appropriate to address patients' individualized clinical and psychological needs.

American Association for the Treatment of Opioid Dependence (2011)

<http://www.aatod.org/policies/policy-statements/793-2/>

AATOD suggests the use of prescription monitoring programs (PMPs) as a valuable clinical tool for safely and effectively treating patients, as PMP databases give OTP's access to patient data.

American Psychiatric Association (2010)

<http://psychiatryonline.org/pdfaccess.ashx?ResourceID=243188&PDFSource=6>

The APA clinical guidelines state that psychosocial treatments, such as behavioral therapies and contingency management, all have varying degrees of effectiveness in reducing opioid-abusing behaviors and retaining patients in treatment, particularly for heroin users. Although psychotherapy alone seems to yield exceptionally high attrition rates, it is particularly effective in aiding in cessation of other substances of abuse.

National Institute on Drug Abuse (2012)

http://www.drugabuse.gov/sites/default/files/podat_1.pdf

NIDA's guidelines suggest that mandatory treatment yields similarly favorable outcomes as voluntary treatment. NIDA considers it best practice to treat comorbidities simultaneously, and to

provide a continuum of services. Guidelines also state that voucher-based incentives are effective in reducing opioid and cocaine use for methadone-maintained patients.

Substance Abuse and Mental Health Services Administration

http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf (2004)

<http://adaiclearinghouse.org/downloads/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs-51.pdf> (2006)

SAMHSA's clinical guidelines suggest individualizing patient treatment to the extent possible with the resources available, screening for co-morbidities and mental disorders, and addressing the distinct needs of patients with different backgrounds. SAMHSA notes that to determine the appropriateness of office-based or other opioid-agonist treatment, a comprehensive patient assessment is crucial. SAMHSA requires psychosocial treatments to be part of any MAT plan in order to determine if a present psychiatric disorder is a primary disorder or substance-induced. The maintenance treatment model is not one-directional; relapses to drug use happen and patients should always be encouraged to remain in treatment.

6. Evidence Review

The goal of the evidence review was to evaluate the comparative effectiveness and value of MAT for the treatment of opioid dependence. The sections that follow are organized around five “framing” questions of primary interest for this review. These include (1) the comparative effectiveness of maintenance versus short-term opioid withdrawal management approaches; (2) the comparative effectiveness of different pharmacologic treatment options for opioid dependence; (3) the evidence on different protocols for medication dosing and duration; (4) identification of important components of medication-assisted treatment and their correlation with treatment success; and (5) discussion of the available evidence on alternative delivery models for opioid dependence treatment.

Given the very broad scope of this review, we did not conduct a detailed and comprehensive systematic review. Rather, we first identified several prior systematic reviews of relevant RCTs published by the Cochrane Collaboration, as listed below:

- Methadone maintenance versus no opioid replacement therapy (opioid withdrawal management) (Mattick, 2009)
- Buprenorphine versus methadone maintenance (Mattick, 2014)
- Oral naltrexone abstinence treatment (Minozzi, 2011)
- Maintenance/opioid withdrawal management for adolescents (Minozzi, 2009a&2009b)
- Psychosocial and pharmacological treatments for opioid dependence (Amato, 2011a&2011b)

To supplement these reviews, we also identified any additional RCTs, comparative cohort studies, or case series relevant to the framing questions that were published between January 2003 (the year following Suboxone approval in the U.S.) and April 2014. Case series were limited to those involving 100 or more patients; no other restrictions were placed on study selection. The focus of attention for the comparative effectiveness questions (i.e., maintenance versus short-term opioid withdrawal management, methadone versus buprenorphine versus naltrexone) was primarily on comparative studies; we nevertheless abstracted large case series relevant to these questions in order to provide additional context.

We sought published studies and systematic reviews of substance abuse treatment among all patients with dependence on prescription or illicit opioids. We further explored the evidence on adolescents as a subpopulation deemed to be of critical interest by CEPAC. We did not evaluate studies conducted specifically in pregnant women, as not all of the treatment options of interest are available to this subgroup. Interventions of interest included maintenance opioid replacement treatment with methadone or buprenorphine-containing agents (including Suboxone), dose-

tapering strategies for methadone or Suboxone resulting in opioid abstinence with or without naltrexone, use of naltrexone alone without prior stabilization on methadone or buprenorphine, and drug-free opioid withdrawal management. For the purposes of framing question 1, opioid withdrawal management was considered to be any program of treatment with opioid abstinence as a goal that was less than 30 days in duration.

Outcomes of primary interest included retention in treatment, use of illicit opioids or other drugs, relapse, and mortality. We also collected information on employment, criminal activity, and health-related quality of life where available. Further details on the literature search strategy for each framing question can be found in Appendix A.

6.1 Maintenance versus Opioid Withdrawal Management

A 2009 Cochrane systematic review of clinical trials comparing maintenance to opioid withdrawal management and other drug-free treatment for opioid dependence found consistently superior outcomes for maintenance approaches. Maintenance was associated with better treatment retention and lower rates of illicit drug use compared to patients who received short-term opioid withdrawal management as their primary course of therapy. Other studies not included in the Cochrane review have produced similar findings. While maintenance treatment appears to be effective for most opioid-dependent patients, there may be a meaningful subset of individuals who are good candidates for opioid withdrawal management. The characteristics of these potential subsets are described below.

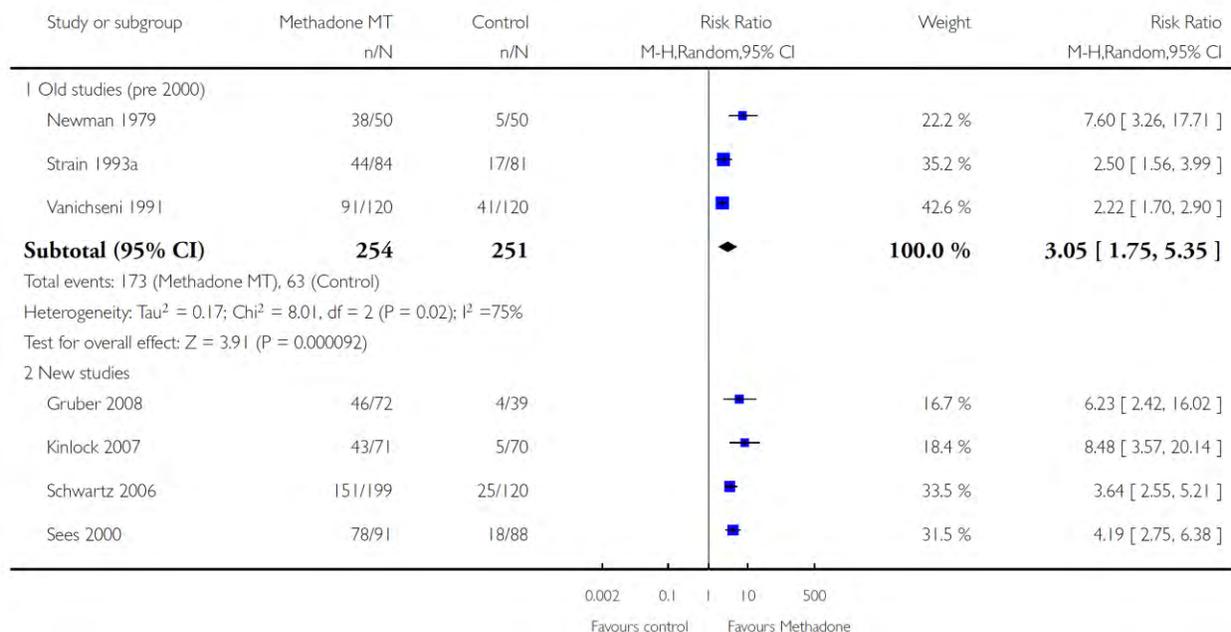
Some case series looking at opioid withdrawal management with or without use of medication have shown high completion rates of the short-term withdrawal phase. One study (Smyth, 2005) reported an 81% completion rate when methadone tapering was used over a 10-day period, while similar results were reported using Suboxone, with 68% of 234 participants successfully completing a 13-day taper (Amass, 2004). However, in this study even patients who completed managed withdrawal had poor outcomes at follow-up. Relapse to heroin use, either by urinalysis or self-reports, was identified in nearly half of participants. Another opioid withdrawal management study (Gandhi, 2003) observed that 74% of participants were using heroin 30 days after successful program completion, and <20% were retained in some form of aftercare at six months of follow-up.

However, prior studies as well as findings from a recent RCT (Sigmon, 2013) suggest that there might be a subset of patients who are more likely to have successful outcomes with short-term opioid withdrawal approaches, including those who are younger, employed, had higher levels of

education, had less severe opioid and other drug use, had fewer medical or psychiatric problems, and were not injecting drugs users.

Nevertheless, in comparing longer-term patient outcomes between opioid withdrawal management approaches and maintenance therapy, the published literature has clearly favored maintenance therapy. A 2009 Cochrane review found that methadone maintenance therapy was superior to drug-free treatment, including drug-assisted and drug-free opioid withdrawal, placebo, and wait-list control (Mattick, 2009). Although there was no statistically significant difference found in mortality between treatment approaches, maintenance therapy was found to retain a higher percentage of patients in treatment over 3-12 months of follow-up (68.1% vs. 25.1%; rate ratio [RR] 3.1; 95% CI 1.8, 5.4; $p < .001$) and had lower rates of heroin use (45.7% vs. 66.5% positive urine/hair analysis; RR 0.7; 95% CI 0.6, 0.8; $p < .001$). A forest plot of individual study results is presented in Figure 3 below. Inclusion of studies published both before and after the year 2000 yielded similar findings. It should be noted that, while both outcomes favored maintenance therapy, results were still less than optimal for maintenance approaches (i.e., nearly 50% of patients testing positive for heroin use).

Figure 3. Forest plot of methadone maintenance versus control.



Source: Mattick RP et al. Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database Syst Rev.* 2009;3:CD002209.

These findings are consistent with results from buprenorphine studies identified in our search. For example, a comparative cohort study evaluating buprenorphine for maintenance or opioid withdrawal management in 60 patients who were in a three-month treatment program found that

time in treatment was significantly shorter in the detoxification group (mean: 0.4 weeks vs. 8.5 weeks, $p=.001$) (Caldiero, 2006).

In addition, although not a direct comparison of “pure” opioid withdrawal management to maintenance therapy, the effectiveness of shorter versus longer maintenance treatment duration was evaluated in the Prescription Opioid Addiction Treatment Study (POATS) (Weiss, 2011). A total of 653 patients were treated in a two-phase study; in the first phase, patients received stabilization with Suboxone for two weeks followed by a two-week taper. Patients with evidence of illicit opioid use were invited to continue in the study’s second phase, which included three months of maintenance treatment with Suboxone followed by a four-week taper. Of those completing phase 1, the majority (93.4%) had unsuccessful opioid-use outcomes and were therefore included in the maintenance phase, which showed a program success rate of 49.2% at the completion of treatment (Weiss, 2011).

Certain factors have been found to be significantly associated with positive outcomes for patients in MAT, including absence of a family history of substance abuse, older age, and having a spouse or partner engaged in the patient’s rehabilitation (Mattick, 2009). Conversely, factors that are associated with negative treatment outcomes include heroin use (versus prescription opioid use), polydrug use (particularly cocaine and injectable drugs), participation in criminal activity, and a history of psychological problems.

We did not identify any studies comparing short-term opioid withdrawal management approaches with versus without naltrexone. We identified four case series (Bartu, 2002; Chaudhry, 2012; De Jong, 2007; Dijkstra, 2010) evaluating use of oral naltrexone after short-term opioid withdrawal management. Although the completion rates of the opioid withdrawal management phase were comparable to those in case series evaluating opioid withdrawal management without naltrexone (see above), the addition of oral naltrexone does not appear to substantially improve retention rates, which ranged between 24-30% at 2-10 months of follow-up.

Short-term opioid withdrawal management versus maintenance therapy for adolescents

The treatment of opioid dependence in adolescents represents a unique challenge to clinicians. While treatment approaches include short-term detoxification and psychosocial interventions, the risk of relapse remains high (Woody, 2008). Two systematic reviews evaluated opioid withdrawal management and/or maintenance therapy in patients age 18 years or younger (Minozzi, 2009a; Minozzi, 2009b), but found insufficient evidence to distinguish these approaches in the small set of three trials available ($n=190$). Only one of these studies directly compared maintenance versus opioid withdrawal management, an RCT ($n=152$) that compared the short-term, tapered use of Suboxone (14 days) in a managed withdrawal framework to extended maintenance use over 12

weeks of follow-up (Woody, 2008). At 12 weeks, treatment retention was significantly higher in the maintenance cohort (70% versus 21%, $p < .001$), and patients undergoing opioid withdrawal management reported significantly more illicit opioid, cocaine, and marijuana use compared to maintenance patients. A separate non-comparative case series of 100 adolescents treated with methadone maintenance found that 50% remained in treatment for more than 12 months with a drop-out rate of 32%, and 39% of patients eventually transitioned to adult clinic services (Smyth, 2012).

6.2 Comparative Effectiveness of Methadone, Buprenorphine, and Naltrexone

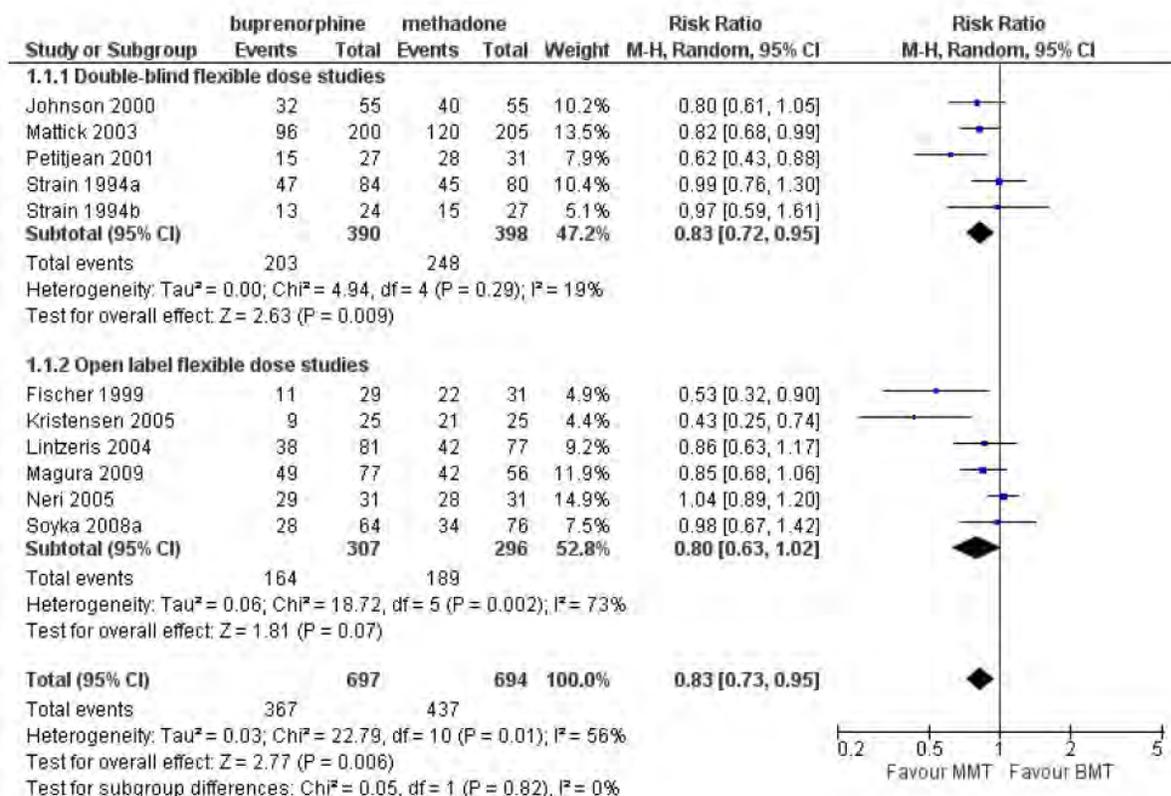
Both a recent Cochrane review as well as additional studies of maintenance treatment options consistently found that there are no major differences in mortality or illicit drug use achieved with methadone versus Suboxone or buprenorphine (in any form). However, methadone appears to be associated with greater retention in treatment compared to buprenorphine in either flexible or low, fixed doses. In contrast, naltrexone appears to be no better than placebo at retaining patients in treatment, although limited data suggest that long-acting forms (injectable or implantable) may have advantages over oral naltrexone in this regard.

Methadone versus Suboxone/buprenorphine for maintenance therapy

Findings from a recent Cochrane review comparing methadone- to buprenorphine-based maintenance treatment found no statistically-significant differences in illicit drug use, criminal activity, or mortality between treatment approaches (Mattick, 2014). Long-term follow-up from one of the RCTs included in the Cochrane review suggested that mortality rates remained comparable for methadone and buprenorphine after a mean of 8.3 years of follow-up (Gibson, 2008). Finally, while a recent RCT of 80 patients not included in the Cochrane review found a small but statistically-significant difference between methadone and Suboxone in illicit opioid use (1.5% vs. .2% for Suboxone, $p = .03$), there were no differences in opioid craving and injecting risk behaviors over five months of follow-up (Otiashvili, 2013).

Methadone maintenance does appear, however, to be associated with higher rates of treatment retention relative to buprenorphine. Findings from the Cochrane review of studies utilizing flexible doses of methadone or buprenorphine showed lower rates of treatment retention for buprenorphine (pooled rate 52.3% vs. 63.0%; rate ratio 0.83; 95% CI: 0.72, 0.95) over 3-12 months of follow-up (Mattick, 2014). Study-specific results are shown in Figure 4 on the following page. Findings were similar when maintenance treatments featuring fixed, low doses of buprenorphine (2-6 mg) and methadone (≤ 40 mg) were compared.

Figure 4. Forest plot of treatment retention in randomized controlled trials comparing methadone to buprenorphine.



Source: Mattick RP et al. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database Syst Rev.* 2014;6(2):CD002207

We identified an additional RCT of 60 patients receiving low-dose buprenorphine or flexible-dose methadone who were followed for 24 weeks (Jagsch, 2005). This RCT was not included in the Cochrane review, for unknown reasons (possibly the fixed versus flexible dose comparison). Retention in treatment at the end of the study was twice as high for methadone (71% vs. 38%, $p=.01$).

Naltrexone versus buprenorphine or methadone

We identified no head-to-head clinical studies of naltrexone versus methadone. We identified a single RCT comparing naltrexone, buprenorphine, or placebo in 126 detoxified patients (Schottenfeld, 2008) who were followed for up to 24 weeks. Buprenorphine was found to be superior to naltrexone in terms of mean days in treatment (117 vs. 84, $p=.022$), as well as mean days without heroin use (51 vs. 24, $p=.028$). In contrast, none of the key study measures statistically differed between naltrexone and placebo.

Buprenorphine versus Suboxone

We identified only two studies that assessed the comparative effectiveness of different forms of buprenorphine. One study (Lintzeris, 2013) compared the sublingual tablet and the film forms of Suboxone and found comparable drug plasma levels, clinical outcomes, and adverse-event rates, although the film version generated higher patient satisfaction scores and dissolved more quickly. Another study (Comer, 2010) found that both Suboxone and buprenorphine alone had abuse potential, but patients' self-reported desire for intravenous drug use and perception of street value was lower with Suboxone.

Long-acting naltrexone versus oral naltrexone versus placebo

A separate Cochrane review assessing six RCTs of maintenance treatment with oral naltrexone versus placebo found that retention and opioid abstinence rates were low with naltrexone (<30%) and not statistically different from rates with placebo (Minozzi, 2011). A single RCT analyzed the effectiveness of a long-acting naltrexone implant among 306 intravenous heroin users over 24 weeks of follow-up and found that the implant had significantly better treatment outcomes than oral naltrexone, including treatment retention (52.9% vs. 15.7% for oral naltrexone, $p<.001$) and negative urine tests (63.6% vs. 42.7%, $p<.001$) (Krupitsky, 2012). The implant is not currently approved for use in the U.S., however. Another placebo-controlled RCT ($n=250$) found that injectable extended-release naltrexone (Vivitrol) retained patients in treatment longer (median 168 vs. 96 days, $p=.004$), reduced rates of relapse (0.8% vs. 13.7%, $p<.0001$), and increased total abstinence rates (35.7% vs. 22.6%, $p=.022$) relative to placebo (Krupitsky, 2011). To date, however, Vivitrol has not been compared to other forms of naltrexone in any comparative study.

Methadone, buprenorphine, and naltrexone for adolescents

Limited research exists comparing opioid replacement therapies in adolescent patient populations. In a single retrospective comparative study of 61 patients aged 14-17 years, treatment with methadone resulted in significantly longer program retention compared to treatment with buprenorphine (mean days: 354 vs. 58, $p<.01$) (Bell, 2006). The use of methadone was also associated with fewer treatment drop-outs, although statistical testing was not performed.

6.3 Dosing and Duration Protocols

Studies examining dosing and duration of maintenance treatment have found both methadone (~100 mg/day) and Suboxone (16-32 mg/day) have clear dose thresholds at which clinical outcomes no longer improve. In terms of dosing frequency, daily methadone appears to produce better

outcomes than less frequent dosing, while the dosing frequency of buprenorphine appears to make little difference in outcomes. Data suggest that dose tapering regimens with either methadone or Suboxone have limited success, but that longer tapers are superior to shorter-duration tapers.

Dosage Level

Methadone

We identified nine studies, of which two were RCTs, comparing different dosing levels of methadone. One RCT (Epstein, 2009) compared the effectiveness of 70 mg/day versus 100 mg/day of methadone and concluded that 100mg was more effective at reducing illicit opioid use (42% vs. 20% for 70 mg, $p=.01$), though treatment retention did not differ. The other RCT (Kennedy, 2013) examined whether daily fixed dosing of 100 mg or daily flexible dosing over 100 mg had any impacts on treatment outcomes and determined that the flexible, high-dose group was *less* likely to produce drug-free urines; however, there were no differences in retention. Both studies found that higher doses do not reduce cocaine use, and that other treatment interventions may be required to address polydrug abusers.

Findings from selected case series also found that higher, daily doses of methadone (up to but not exceeding 100 mg) were associated with reductions in illicit opioid use and improved retention in treatment (Dunn, 2003; Fonseca, 2011; Gerra 2003). A large retrospective case series (Nosyk, 2010) evaluated 31,724 treatment “episodes” over an 11-year period from a provincial drug dispensation database and found that a higher daily maintenance dose (over 60mg/day) was positively associated with long-term retention in treatment (>3 years). Another large retrospective case series (N=301) examining a prescription database found a significant positive correlation between dose level and retention in treatment, with the best relationship found at 96mg/day (Dickinson, 2003).

Buprenorphine/Suboxone

While higher doses of buprenorphine are associated with better treatment outcomes, there may be certain thresholds at which buprenorphine reaches its maximum effectiveness. One RCT (Montoya, 2004) concluded that 16mg of buprenorphine appears to be the optimal dose for the discontinuation of illicit drug use, particularly for those who are dually dependent on opioids and cocaine. In terms of frequency of dosing, two RCTs found that less-than-daily doses of burprenorphine appear to be as effective as daily doses in preventing the use of illicit opioids and retaining patients in treatment (Marsch, 2005; Montoya, 2004).

A comparative cohort study (Fareed, 2012) examined daily dosing levels of buprenorphine greater than 16mg vs. 8-16 mg in 56 patients and found that doses higher than 32mg/day did not have any added benefits in reducing the number of positive urinalyses. Another large case series (N=979) found that maintenance doses between 12-32mg and less-than daily dosing appear to have a positive effect on treatment outcomes, including higher rates of treatment compliance, lower rates of relapse, and reduction of illicit drug use (Leonardi, 2008).

Treatment Duration Protocols

Methadone

There were no RCTs evaluating the use of tapering protocols for methadone maintenance. A large retrospective analysis of nearly 15,000 attempts at dose tapering found that rates of “sustained success”—defined as no treatment re-entry, opioid-related hospitalization, or mortality within 18 months following taper completion—were low overall (5.3%) (Nosyk, 2010). Subsequent stratification of episodes by shorter (<12 weeks) vs. longer (≥12 weeks) taper duration indicated that longer tapers were over three times as likely to result in sustained success, but absolute rates were low for both strata (18.6% vs. 4.6%, $p<.05$).

Buprenorphine/Suboxone

One RCT (Ling, 2009) found that a shorter Suboxone taper was better for patients when the goal is to discontinue treatment, with nearly half of patients in a 7-day taper group supplying opioid-free urines at the end of treatment versus 30% in a 28-day taper group. Another RCT (Weiss, 2011) evaluated a two-phase tapering regimen after maintenance on Suboxone. The study found that only 6.6% of patients assigned to a two-week taper during a 12-week initial study phase achieved self-reported opioid use of no more than four days in a month, absence of two consecutive opioid-positive urinalyses, and no more than one missing sample taken, whereas 49% of patients achieved this composite successful outcome on a longer tapering course of 12 weeks in a 24-week second study phase.

Finally, a small (n=70) RCT (Sigmon, 2013) examined prescription opioid abusers stabilized on Suboxone, then randomized to a one-, two- or four-week Suboxone taper, followed by subsequent treatment with oral naltrexone. The four-week taper group had a higher proportion of participants successfully maintained on naltrexone (50%) compared to 21% for both 1- and 2-week tapers ($p=.04$), as well as the highest rate of opioid abstinence (50% vs. 16% vs. 20%, $p=.03$) at the end of the 12-week study. The authors noted that, while this study did not involve a direct comparison with indefinite maintenance treatment, rates of retention and abstinence were similar to those seen with maintenance studies. It was also noted that these rates of success were observed in a

primarily educated and white population with dependence only on prescription opioids (heroin abusers were excluded from the study).

Adolescents

No studies of alternative dosing or duration protocols conducted specifically in adolescents were identified that included information on the outcomes of interest for this review.

6.4 Important Components of Treatment

Available evidence suggests that several types of positive incentives (e.g., contingency vouchers and rewards), as well as negative incentives (e.g., mandatory medication tapers for missed appointments), appear to improve patient retention in treatment. Evidence on the effectiveness of active, goal-oriented therapy such as cognitive-behavioral and interpersonal therapy is mixed; however, interventions to improve counseling adherence and the use of visual aids for goal-setting and tracking may improve treatment compliance. Supervised medication consumption and more frequent dispensing do not appear to improve adherence to treatment, in part because these interventions tend to be reserved for individuals with existing non-adherence patterns.

Patient compliance with opioid dependence treatment remains a significant obstacle to recovery (Brooner, 2004). Several measures have been employed to improve retention in maintenance treatment programs. The most consistent body of evidence examines the use of positive and negative reinforcement measures. For example, we identified several studies examining the impact of contingency vouchers – monetary rewards for remaining in treatment – on treatment retention and illicit drug use. In these studies, patients received vouchers that increased in monetary value with consecutive drug-free urinalyses. In an RCT of 388 patients enrolled in methadone maintenance programs across the U.S., the use of low-cost abstinence incentives (values ranged from \$0 - \$20) compared to usual care resulted in significantly more frequent submission of negative urinalyses and consecutive weeks of drug abstinence (Peirce, 2006). Schottenfeld et al. (2005) found similar results among patients receiving methadone or buprenorphine during three months of increasing voucher value; once the escalation of rewards stopped, however, benefits of incentives were not sustained. In studies examining the combined use of contingency vouchers and counseling techniques, patients receiving vouchers during the active study period were more likely to complete treatment; however, the impact was not sustained following the return of patients to standard care conditions (Brooner, 2007).

The evidence base also includes findings on the use of negative incentives, such as mandatory tapers of methadone dose with or without increased counseling following drug-positive urinalyses

and/or missed appointments. In an RCT of adaptive stepped care versus standard treatment in 127 patients, those enrolled in the adaptive stepped care treatment arm (i.e., less convenient dosing times and mandatory dose taper for missed counseling or positive urine tests) attended counseling appointments at a significantly higher rate than patients receiving standard care (83% versus 44%, $p < .001$), and had fewer poor treatment responses (46% versus 79%, $p < .001$) (Brooner, 2004). Unlike positive incentives, however, negative interventions appear to be less likely to reduce illicit drug use.

The inclusion of active, goal-oriented psychosocial approaches to counseling in the treatment of opioid dependence is legally mandated in methadone treatment (see Section 3), and has been extensively studied. Evidence on the effectiveness of these approaches is mixed, however. For example, in a systematic review of multiple counseling approaches, the impact of additional psychosocial therapy (beyond standard, mandated counseling) was not found to impact treatment retention or rates of abstinence (Amato, 2011b). In two randomized trials of cognitive behavioral therapy or specialized opioid dependence counseling in place of standard counseling and physician care, no significant differences were found in the rates of opioid abstinence or treatment retention, and outcomes were no better than for brief, clinician-provided counseling (Weiss, 2011; Fiellin, 2013). However, there is some evidence of a “dose-response” with counseling, as patients with higher rates of counseling attendance remain in treatment longer and reduce their illicit drug use (Moore, 2012; Brooner, 2007; Montoya, 2005).

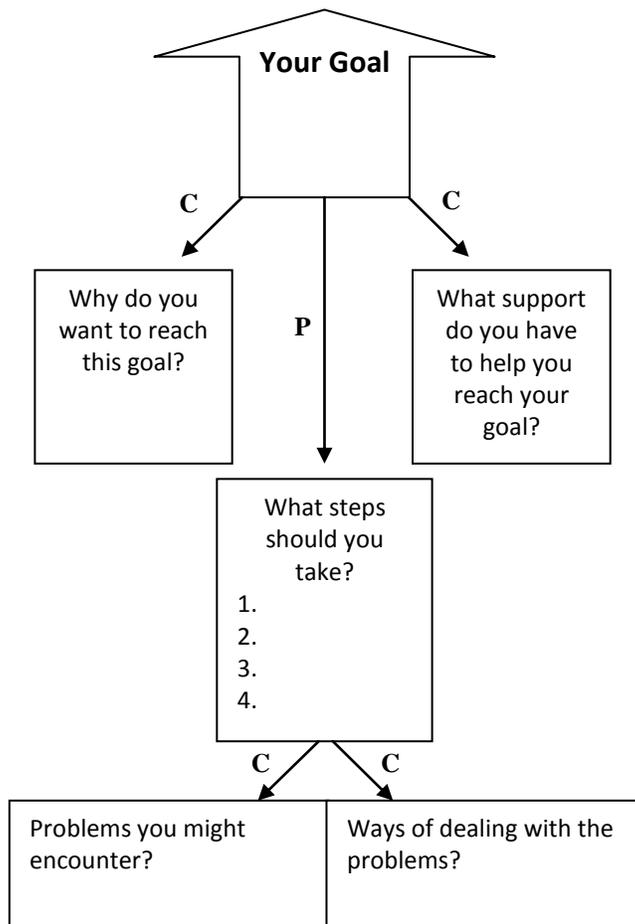
Use of other therapeutic approaches, such as addressing patient fears of withdrawal through Acceptance and Commitment Therapy (ACT), may increase abstinence rates, while innovative behavioral algorithms like the Paced Auditory Serial Addition Task (PASAT) may assist in early identification of patients at higher risk of relapse. There is limited information regarding the incremental effects of peer-to-peer sober networks on treatment outcomes, in part because these programs have historically not accepted individuals receiving opioid replacement therapy; the data that do exist suggest that 12-step programs have limited impact when compared to standard methadone maintenance with other forms of counseling (Hayes, 2004).

Other innovative approaches to opioid dependence treatment include visual treatment guides and maps designed to aid in treatment planning and progress tracking, which have been shown to improve attendance at counseling sessions and retention in treatment (Newbern, 2005). These interventions may be particularly appropriate for patients with attention deficits. An example of one of these treatment guides can be found in Figure 5 below.

Intensity of treatment for opioid dependent patients is an important consideration in care delivery. While methadone is generally dosed daily in a clinic setting, Suboxone is available for up to one month as a take-home medication, depending on patient stability. We evaluated several studies

examining the impact of different dosing approaches on treatment retention. Comparisons of outcomes for supervised and observed versus unobserved dosing yielded no significant differences in retention; however, the use of supervised dosing in patients who had already demonstrated non-adherence to treatment at baseline may have influenced these findings (Dunn, 2009). In contrast, utilization of contingency-based, take-home dosing (one week of medication provided based on demonstrated clinical stability with drug-free urine screens) appears to result in greater treatment retention and lower rates of program drop-out (Gerra, 2011).

Figure 5. Example of a visual treatment guide.



C: characteristic (counseling goal); P: part (action steps)

Source: Czuchry M, et al. Visual representation tools for improving addiction treatment outcomes. *J Psychoactive Drugs*. 2009;41(2):181-187.

6.5 Delivery Models

Alternative delivery mechanisms for counseling in opioid dependence management (e.g., telephonic coaching, group therapy by videoconference) appear to produce similar rates of treatment retention and illicit drug use relative to in-person counseling. Wait-list maintenance interventions and pilot, office-based methadone programs appear to produce outcomes comparable to clinic-based care. Provision of opioid dependence management in alternative settings (e.g., primary care, office-based clinics) with adjunct services appears to retain patients at comparable or better rates relative to standard treatment approaches.

As noted in Section 6.4, evidence is mixed on the benefits of psychosocial therapy in the management of opioid dependence. However, such counseling remains a standard component of medication-assisted treatment. Patient compliance with ongoing counseling is a major challenge, as the frequency, duration, and timing of required sessions may interfere with other treatment-related and unrelated activities (King, 2009). To address this, several studies have evaluated innovative counseling approaches such as Internet-based videoconferencing, telephonic patient support, and stepped-care approaches (Ruetsch, 2012; King, 2009; King, 2006). In these studies rates of drug-positive urinalyses and treatment adherence were comparable to those reported with the use of standard, in-person counseling at up to 12 months of follow-up, and another study reported 93% patient employment (in patients previously unemployed) following one year of treatment (Kidorf, 2004). Alternative counseling approaches appeared to work best in patients with less severe addiction and less concurrent drug use.

Incorporation of job skills training as an integral part of opioid dependence treatment addresses a crucial deficit in this patient population, as rates of employment are generally low (Magura, 2007), and employment is correlated with improved patient outcomes including treatment retention (Kidorf, 2004). Studies comparing vocational interventions such as training in job-seeking, interviewing, and problem-solving skills, demonstrated modest increases in mean days worked and significantly more paid employment (Magura, 2007; Lidz, 2004).

A central challenge for patients seeking treatment for opioid dependence is access. Extensive waiting lists further complicate already-limited access to effective treatment options (Schwartz, 2006). The impact of “bridging” approaches among patients waiting to enroll in methadone maintenance programs has been evaluated in an RCT (Schwartz, 2006). Provision of up to four months of methadone and emergency counseling (all free of charge to the patient) compared with waitlist control resulted in significantly greater patient enrollment in formal, full-scale methadone treatment programs (76% versus 21%, $p < .001$) (Schwartz, 2006). Patients in this bridging arm of the study also reported fewer days of heroin and cocaine use and fewer arrests at six months of follow-up.

Several pilot studies have investigated the use of methadone in an office-based environment with take-home dosing provided for up to one month, in contrast to the federally-mandated approach of daily observed dosing in a clinic setting. In two studies evaluating patients with demonstrated stability (no illicit drug use in prior 1-3 years, full-time employment), treatment retention was high (79-98% at 12-60 months), and illicit drug use was low (0.4-2.3%) among all patient groups (Harris, 2006; King, 2006). In the King RCT, patients receiving one month of take-home dosing initiated significantly more new vocational or social activities over a 12-month period as compared to standard treatment (81-97% versus 46%, $p < .001$). Rates of treatment retention in other pilot studies of office-based methadone are summarized by location, sample size, and retention rates in Table 6 below.

Table 6. Published studies of office-based methadone medical management.

Author, Year	Study Location	Number of Enrolled Patients	Patients Retained in Treatment (duration of observation period)
Senay, 1994	Chicago, IL	130	69% (1 year)
Schwartz, 1999	Baltimore, MD	21	71% (12 years)
Salsitz, 2000	New York, NY	158	84% (15 years)
Merrill, 2005	Seattle, WA	30	93% (1 year)

Source: Harris KA et al. A 5-year evaluation of a methadone medical maintenance program. *J Subst Abuse Treat.* 2006;31(4):433-438.

In studies of patients who were *not* clinically stable and currently using illicit drugs, treatment retention in programs featuring take-home doses appears to be comparable to or better than that in standard methadone programs, but other outcomes are inferior. For example, one study found that newly enrolled patients with unrestricted take-home methadone doses had significantly increased risks of positive urine screens, criminal activity, and self-diversion; however, in a separate group with contingency restrictions (demonstrated clinical stability and negative urinalysis) on take-home doses, rates of these outcomes were similar to standard methadone dosing (Gerra, 2011).

Other studies have evaluated alternative treatment settings for delivery of medication-assisted treatment (with Suboxone/buprenorphine), including hospital-based clinics, community-based clinics, and primary care offices. Findings from these studies suggest that flexible treatment settings may provide benefits in terms of treatment retention. In one RCT, patients (n=94) were assigned to Suboxone treatment within an opioid-treatment program (OTP), a primary care office [psychiatrist's private practice (PCS)], and a group-based cognitive behavioral therapy program

known as the manualized Matrix Model (MMM) (Miotto, 2012). Among patients remaining in treatment beyond nine weeks, OTP participants had statistically-significantly higher drop-out rates compared to PCS and MMM patients (79% vs. 67% and 48% for PCS and MMM respectively, $p=.05$). However, the number of weeks that patients were retained did not differ statistically between groups, as shown in Table 7 below.

Table 7. Treatment retention among patients receiving opioid dependence treatment in alternate settings.

	OTP (n=28)	PCS (n=33)	MMM (n=33)	p-value
Retention				
Week 9	53.6%	39.3%	54.6%	0.39
Week 20	21.4%	33.3%	51.5%	0.05
Mean # weeks retained	14	19	25	0.11

MMM: manualized Matrix Model; OTP: opioid-treatment program; PCS: psychiatrist's private practice
 Source: Miotto K et al. Comparison of buprenorphine treatment for opioid dependence in three settings. *J Addict Med.* 2012;6(1):68-76.

An additional RCT examined integration of opioid dependence treatment into HIV care at a specialty clinic (Lucas, 2010). Ninety-three HIV patients were randomized to a buprenorphine-based induction and maintenance program at the clinic or to standard case management and referral to a traditional OTP. Enrollment and retention in opioid agonist treatment at 12 months of follow-up was significantly greater for those patients receiving integrated care at the clinic compared to those referred to external opioid dependence treatment (74% versus 41%, $p<.001$) (Lucas, 2010).

Adjunct services such as education on drug risk behavior, HIV/AIDS prevention education, and family counseling improved treatment outcomes in some but not all studies. For example, in an analysis of structural-level factors correlated with success among 28 methadone maintenance programs treating a total of 560 patients, provision of at least two kinds of comprehensive services (including individual, group, and/or family counseling and skills training) was significantly but modestly associated with higher treatment retention rates (58% versus 50%, $p<.01$) (Lin, 2010); in contrast, an evaluation of individual- and group-based methadone education and skills training provided by health educators failed to reduce illicit drug use at nine months of follow-up relative to standard treatment (Li, 2013).

7. Economic Evaluation

The economic impact of treatment for opioid dependence has been evaluated across multiple settings and perspectives. While the published economic literature is too substantial to describe in detail here, findings from these studies have followed two very consistent themes. One is that MAT, whether with methadone or buprenorphine-containing agents, is highly cost-effective or cost-saving to society, particularly in analyses that incorporate costs of criminal justice, victimization, and lost productivity (Schackman, 2014; Zarkin, 2005; Zaric, 2000; Doran, 2008; Bell, 2007; Barnett, 2010; Barnett, 2001). The other is that MAT has consistently been shown to be cost-effective or cost-saving in relation to treatment *without* drug therapy (i.e., short-term opioid withdrawal management) (Polsky, 2010; McCarty, 2010; Baser, 2011; Masson, 2004).

In contrast, analyses comparing different methods of MAT have generally found very little to distinguish these approaches. For example, a comprehensive systematic review and economic evaluation conducted by the UK's University of Birmingham Health Services Management Centre (Connock, 2007) found no major differences in clinical effectiveness between methadone and buprenorphine maintenance programs other than better retention in methadone maintenance as previously described (see Section 6). Findings from the economic evaluation indicated differences in quality-adjusted life expectancy of <5 days between methadone and buprenorphine as well as minimal differences in cost.

While the findings described above have been quite consistent, we nevertheless felt it important to assess the comparative value of different approaches to treating opioid dependence with a focus on the realities of treatment in the U.S. setting, as well as to document the costs of opioid dependence in New England and the potential budgetary impact of expanding access to MAT in the region. Methods and results for the comparative value analyses are described in detail in the sections that follow. Our approach for the budgetary impact analysis is described beginning on page 70.

7.1 Cohort Model: Methods

Overview

We developed a simulation model to evaluate the comparative value of different approaches to treating opioid dependence among 1,000 hypothetical patients entering treatment. Model outcomes and costs were calculated over a two-year time horizon; consistent with methods for economic evaluation, outcomes and costs occurring in the second year were discounted using a 3% rate (Gold, 1996). Each patient could have one of four possible outcomes of treatment, as listed on the following page:

- In treatment
- Out of treatment, drug-free
- Out of treatment, relapsed
- Deceased

We adopted a societal perspective for this analysis given the potential for significant impacts of opioid dependence outside of the health care system. Costs therefore included not only those of substance abuse drug therapy and related services as well as other health care expenditures, but also “social costs” of law enforcement, victimization, and productivity loss (see “Costs” below). Cost-effectiveness was calculated alternatively as the cost per relapse averted and the cost per death averted respectively. All key model inputs can be found in Table 8 on page 62.

Treatment Strategies

We considered multiple treatment strategies for this evaluation. These included maintenance treatment with either methadone or Suboxone, stabilization with Suboxone followed by a 4-week taper to either oral naltrexone or Vivitrol, and use of oral naltrexone or Vivitrol alone for opioid withdrawal management.

Clinical Outcomes

Rates of retention in treatment for methadone, Suboxone, and oral naltrexone alone (63%, 52%, and 28%, respectively) were estimated using pooled rates of retention reported in recent Cochrane reviews (Mattick, 2014; Minozzi, 2011). We calculated retention with Vivitrol alone to be 50% greater than that of oral naltrexone based on findings from a recent placebo-controlled RCT (Krupitsky, 2011). Finally, we estimated retention with the tapering strategies based on findings from an RCT of a Suboxone-oral naltrexone approach (Sigmon, 2013). There are no published data on the use of Vivitrol as part of a tapering strategy. Because this long-acting formulation has potential adherence advantages over oral naltrexone, however, we conservatively assumed a 5% improvement in overall retention if Vivitrol was used as the opioid antagonist.

We assumed the proportion of patients “out of treatment” who were drug-free versus relapsed to be equal, based on data from a three-year cohort study of maintenance treatment outcomes (Comiskey, 2010). Importantly, we applied this to methadone as the treatment with the highest reported rate of retention. Given that 63% of patients receiving methadone were retained in treatment, we estimated that 18.5% of patients each would be drug-free and relapsed respectively (i.e., an equal division of the 37% not still in treatment at two years). However, we could not apply these proportions directly to other treatment strategies with inferior retention rates, as this would have resulted in counterintuitively higher proportions of drug-free individuals. Instead, we set the

universal “drug-free” rate based on the methadone rate (18.5%) which was reduced for each strategy by differential rates of mortality (see below). The rate of relapse for all other strategies was calculated as the proportion remaining after accounting for rates of retention in treatment, out of treatment and drug-free, and mortality.

Mortality for relapsed patients was estimated to be 1.4% annually, based on a long-term follow-up study (mean: 8.3 years) of an RCT of methadone versus buprenorphine maintenance (Gibson, 2008). We estimated annual rates of death among patients in methadone and buprenorphine maintenance treatment to be 0.2% and 0.02% based on drug overdose death rates reported among treatment enrollees in France (Auriacombe, 2004). We assumed that patients out of treatment and drug-free to be “recovered” and therefore would have no excess risk of substance-abuse related death. We assumed the same for patients in treatment with oral naltrexone or Vivitrol, given the low potential for abuse or diversion and no risk of fatal overdose with this agent.

Costs

Costs included those of drug therapy for opioid dependence, other substance abuse services, other health care services (i.e., other than for routine substance abuse treatment), and “social costs” of law enforcement, victimization, and productivity loss. We obtained costs of drug therapy and other substance abuse services for each strategy of interest from a retrospective analysis of health care claims from commercial payers and managed Medicaid plans (Baser, 2011). Costs of other health care services among relapsed patients as well as those who died were estimated to total approximately \$20,000 annually based on an assessment of the attributable costs of opioid abuse (White, 2005); we assumed these would be reduced by approximately 50% for patients in treatment based on data on drug-treated versus untreated patients in the Baser study (Baser, 2011). Patients who were out of treatment and drug-free were assumed to incur treatment costs only in the first year; health care costs in the second year were estimated using World Health Organization (WHO) figures for per-capita health care costs (WHO, 2013).

We estimated social costs of opioid dependence to total \$106,000 annually, based on an analysis of crime frequency and severity as well as employment impacts on both perpetrators and victims among 114 opioid abusers in Canada (Wall, 2000). We further assumed that law enforcement and victimization costs would be reduced by 75% among patients in treatment, consistent with reported reductions in arrest frequency and severity in a two-year follow-up study of methadone maintenance treatment (Schwartz, 2009). For all treatment strategies other than methadone, we assumed a 50% reduction in productivity loss costs, based on data on increased employment among patients enrolled in MATs (SAMHSA, 2006). We assumed no benefit for methadone in this regard given the requirements for daily in-person dosing and intensive counseling in U.S. settings.

Table 8. Key model inputs.

Parameter	Estimate	Source(s)
Retention in treatment (%):		
MMT	63.0	Mattick, 2014
BMT	52.3	Mattick, 2014
Suboxone 4 wks, oral NTX taper	50.0	Sigmon, 2013
Suboxone 4 wks, Vivitrol taper	55.0	Assumption
Oral NTX alone	27.7	Minozzi, 2011
Vivitrol alone	41.6	Krupitsky, 2011
Out of treatment, relapsed (%):		
MMT	18.5	Mattick, 2014; Comiskey, 2010
BMT	29.2	Mattick, 2014
Suboxone 4 wks, oral NTX taper	31.5	Sigmon, 2013
Suboxone 4 wks, Vivitrol taper	26.5	Assumption
Oral NTX alone	53.8	Minozzi, 2011
Vivitrol alone	40.0	Krupitsky, 2011
Out of treatment, drug-free (%)*:		
	16.9-17.7	Comiskey, 2010
Annual mortality (%):		
Out of treatment, relapsed	1.4	Gibson, 2008
In treatment, MMT	0.2	Auriacombe, 2004
In treatment, BMT	0.02	Auriacombe, 2004
Annual treatment costs (Drug therapy/ Other substance abuse services, 2013\$):		
MMT	493/9,884	Baser, 2011
BMT	3,030/5,838	
Suboxone 4 wks, oral NTX taper	1,181/3,904	
Suboxone 4 wks, Vivitrol taper	6,890/3,493	
Oral NTX alone	930/3,420	
Vivitrol alone	6,639/3,009	
Annual costs of other health care services (2013\$):		
In treatment	10,391	White, 2005; Baser, 2011
Out of treatment, relapsed	20,111	White, 2005
Out of treatment, drug-free	9,007	WHO, 2013
Annual social costs of opioid dependence (2013\$):		
Law enforcement	47,984	Wall, 2000
Victimization	50,471	
Productivity loss	7,878	

*Proportion of patients out of treatment and drug free set as constant (18.5%) based on proportion equal to relapse for methadone; reduced for each treatment strategy by rate of mortality

MMT: methadone maintenance treatment; BMT: buprenorphine maintenance treatment; NTX: naltrexone

Costs expressed in other currencies were converted to U.S. dollar amounts using prevailing exchange rates in the year in which they were reported. All costs are presented as 2013 U.S. dollar amounts; we adjusted these when necessary using the medical care component of the U.S. Consumer Price Index (Bureau of Labor Statistics, 2014).

Key Model Assumptions

Major assumptions made for this analysis, including those previously described, are noted in Table 9 below. Importantly, we assumed that all clinical outcomes were associated with the initial treatment strategy only; we did not assume switching between strategies (other than in the tapering strategy, which by definition involves a change in treatment modality), nor did we model the impact of readmission to treatment for patients who had relapsed. Both of these approaches would have necessitated complex “time-to-event” analyses for which detailed observational data are unavailable. We also did not include any information on competing mortality risks given the short-term nature of the model. Finally, we did not include any estimate of other “social” costs, such as caregiver burden, in our calculations of overall costs. Nonetheless, the components of cost included in this analysis are consistent with those of other major economic evaluations in the field.

Table 9. Key assumptions for cohort model of opioid dependence treatment.

Assumption	Rationale
<i>Outcomes driven by initial treatment strategy only</i>	<i>Lack of detailed, time-dependent data on therapy switch and/or readmission to treatment</i>
<i>Competing mortality risks (beyond those related to in- vs. out-of-treatment status)</i>	<i>Unlikely to affect outcomes in short-term model</i>
<i>Certain social costs (e.g., caregiver burden) not included</i>	<i>Cost components consistent with other published economic evaluations</i>
<i>Absolute increase in retention of 5% for taper to Vivitrol vs. oral naltrexone</i>	<i>Assumption; no available data</i>
<i>Rate of “drug-free” patients constant (modifiable only by differential rate of death)</i>	<i>Counterintuitive to assume that higher rates of treatment “drop out” would translate to higher rates of drug-free individuals</i>
<i>No benefit of methadone in reducing productivity loss</i>	<i>Assumption that need for daily in-person dosing and intensive treatment would counteract any potential for improved employment</i>

7.2 Cohort Model: Results

Two-year outcomes and costs among 1,000 hypothetical individuals entering treatment can be found in Table 10 on the following page. Model results are first presented for maintenance treatment with methadone and Suboxone as the two most common approaches, followed by alternative strategies in descending order of effectiveness.

The model results suggest that, of 1,000 initial patients, approximately 630 receiving methadone maintenance would be retained in treatment after two years versus approximately 520 for Suboxone maintenance. The naltrexone tapering strategies would retain 500-550 of the 1,000 patients. Use of Vivitrol or oral naltrexone alone produced the lowest retention rates of approximately 420 and 280 per 1,000 respectively. Consistent with the relative rankings of treatment retention outcomes, methadone maintenance produced the lowest relapse rate (~190 per 1,000), while oral naltrexone produced the highest (540 per 1,000). Rates of death were <1% for all strategies except Vivitrol and oral naltrexone alone (12-16 per 1,000), reflecting higher mortality rates associated with relapse.

Two-year costs of methadone drug therapy (~\$700) were much lower than drug costs for all other strategies except oral naltrexone alone. In contrast, costs of other substance abuse services for methadone maintenance (~\$14,000) were 2-7 times higher than costs of maintenance with other strategies, reflecting the regulated intensity of methadone-based care. This difference was counteracted somewhat by lower costs of other health care services for methadone versus all other strategies, due to greater levels of treatment retention (the costs of other health care services among patients in opioid dependence treatment are 50% lower than the costs among those out of treatment).

Putting together drug therapy costs, the costs for other substance abuse services, and the costs of all other health care services, the sum of all two-year health care costs did not substantially differ across maintenance treatment strategies (range: \$32,000 - \$39,000). Health care costs were lowest for the Suboxone-oral naltrexone taper, due to the generic availability of naltrexone, the short-term duration of Suboxone treatment, and lower intensity of other substance abuse services for patients receiving naltrexone versus continued maintenance treatment. Health care costs were highest for methadone, as reductions in the costs of other health care services only offset a portion of the higher costs of more intensive substance abuse treatment. While not reflected in the table, the two-year health care costs for relapsed or dead patients were nearly \$40,000, meaning that costs of substance abuse treatment were entirely offset with any form of treatment.

When social costs were considered as well, maintenance therapy options appeared to produce significant overall cost-savings. The two-year social costs associated with opioid dependence are estimated to be over \$200,000, 4-5 times greater than the cost of health care services for each strategy. All versions of opioid dependence treatment reduced social costs substantially compared

to no treatment, but methadone stands out with 10-35% reductions in social costs over all alternative approaches due to its higher retention rates. As a result, total (health care plus social) costs were lower for methadone maintenance (\$131,000) than for any other treatment strategy. Total costs were similar among the maintenance and tapering strategies, but were substantially higher for Vivitrol (\$157,000) and oral naltrexone (\$175,000) alone because they were the least effective. It should be noted again, however, that the total cost figures for all treatment strategies are lower than the total costs estimated for an individual with opioid dependence who is not initiated on any form of treatment.

Table 10. Two-year outcomes and costs among 1,000 hypothetical patients treated for opioid dependence.

Outcome/Cost	MMT	BMT	SUB/VIV Taper	SUB/Oral NTX Taper	Vivitrol Alone	Oral NTX Alone
Treatment outcome (per 1,000):						
<i>In treatment</i>	630	523	550	500	416	277
<i>Relapsed</i>	185	292	265	315	400	538
<i>Drug-free</i>	177	176	177	176	173	169
<i>Died</i>	8	9	8	9	12	16
Cost (\$, per patient):						
<i>Drug therapy</i>	699	3,655	8,553	1,249	6,585	665
<i>Other SA services</i>	14,017	7,043	4,146	4,297	2,985	2,446
<i>Other health care</i>	23,926	25,993	25,454	26,441	28,109	30,844
SUBTOTAL	38,642	36,691	38,153	31,988	37,679	33,954
<i>Social costs</i>	92,068	102,337	98,033	105,917	119,239	141,076
TOTAL	130,710	139,028	136,187	137,905	156,918	175,030

MMT: methadone maintenance treatment; BMT: buprenorphine maintenance treatment; NTX: naltrexone; SUB: Suboxone; VIV: Vivitrol

Table 11 on the following page summarizes our assessment of the cost-effectiveness of these opioid dependence treatment strategies, focusing on both the cost per additional relapse averted and the cost per additional death averted. The universal referent treatment was oral naltrexone alone as the alternative with the lowest retention rate; other comparisons of interest (e.g., methadone versus Suboxone maintenance) were conducted if feasible. Note that the available ratios are based on health care costs only; when total costs are considered, the most effective strategies are also the least costly, which precludes calculation of cost-effectiveness ratios.

Cost-effectiveness of different maintenance options (considering health care costs only)

Comparisons of each treatment strategy to oral naltrexone alone yielded relatively similar estimates of the cost per additional relapse averted for methadone maintenance (\$13,000), Suboxone

maintenance (\$11,000), and Suboxone stabilization followed by a taper to Vivitrol (\$15,000). The oral naltrexone taper strategy was both less costly and more effective than oral naltrexone alone. Finally, the cost per relapse averted for Vivitrol alone was approximately \$27,000, as it was approximately \$4,000 more costly and prevented fewer relapses than the maintenance and taper strategies.

Table 11. Comparative cost-effectiveness of opioid dependence treatments (selected comparisons).

Outcome/Cost	MMT	BMT	SUB/VIV Taper	SUB/Oral NTX Taper	Vivitrol Alone
Health Care Costs Only					
vs. oral NTX alone:					
<i>\$ per relapse averted</i>	\$13,000	\$11,000	\$15,000	Less costly, more effective	\$27,000
<i>\$ per death averted</i>	\$608,000	\$395,000	\$531,000	Less costly, more effective	\$927,000
MMT vs. BMT:					
<i>\$ per relapse averted</i>	\$18,000	---	---	---	---
<i>\$ per death averted</i>	\$2.5 m	---	---	---	---
VIV vs. oral NTX Taper:					
<i>\$ per relapse averted</i>	---	---	\$123,000	---	---
<i>\$ per death averted</i>	---	---	\$4.3 m	---	---
Total Costs					
vs. oral NTX alone:					
<i>\$ per relapse averted</i>	Less costly, more effective				
<i>\$ per death averted</i>	Less costly, more effective				
MMT vs. BMT:					
<i>\$ per relapse averted</i>	Less costly, more effective	---	---	---	---
<i>\$ per death averted</i>	Less costly, more effective	---	---	---	---
VIV vs. oral NTX Taper:					
<i>\$ per relapse averted</i>	---	---	Less costly, more effective	---	---
<i>\$ per death averted</i>	---	---	Less costly, more effective	---	---

MMT: methadone maintenance treatment; BMT: buprenorphine maintenance treatment; NTX: naltrexone; SUB: Suboxone; VIV: Vivitrol

Estimates of the cost per death averted were much higher (\$400,000 - \$900,000), as absolute differences in mortality were very small across the strategies. It is worth noting again that mortality estimates in this study were restricted to deaths related to substance abuse for those out of treatment and to treatment-related deaths (overdoses) for those in maintenance treatment. In addition, no excess mortality was assumed while patients were on oral naltrexone or Vivitrol.

Comparisons of methadone to Suboxone maintenance yielded estimates of \$18,000 per relapse averted and \$2.5 million per death averted, as health care costs with methadone were \$2,000 greater and relapse rates differed by ~10% in favor of methadone. Comparisons of tapering strategies with Vivitrol versus oral naltrexone yielded cost-effectiveness estimates of \$123,000 per relapse averted and \$4.3 million per death averted.

Cost-effectiveness of different maintenance options (considering total costs)

As mentioned previously, inclusion of social costs in a total cost calculation changes the picture of these comparisons. When all costs are considered, all other treatment strategies prevent more relapses, result in fewer deaths, and have lower costs than oral naltrexone alone. Methadone maintenance is also somewhat more effective and less expensive than Suboxone maintenance, and a tapering strategy using Vivitrol has better clinical results and slightly lower costs than an oral naltrexone tapering strategy.

While adolescents are clearly an important subpopulation, data were too scarce to populate a complete model focusing only on this group. Nevertheless, it seems reasonable to conclude that the economic benefits seen in this model would be increased in adolescents given that crime-based costs and long-term productivity losses may be even greater in teenagers not receiving adequate treatment.

7.3 Budget Impact Analysis: Methods

The budget impact analysis was also conducted over a two-year period. The population under consideration was limited to those individuals with opioid dependence who are either receiving treatment or who need but are not receiving any treatment (i.e., patients out of treatment but drug-free were not considered). We generated estimates of the numbers of treated and untreated patients for each New England state based on data collected in the 2009-2012 rounds of the National Survey of Drug Use and Health (NSDUH) (SAMHSA, 2013c). Information was collected for both adolescents (age 12-17) and adults (18+).

At baseline, we assumed that treated patients would receive maintenance with either methadone or Suboxone, and weighted the proportion receiving each based on 2012 data from SAMHSA's National Survey of Substance Abuse Treatment Services (N-SSATS) (SAMHSA, 2013b). Costs for treated patients were identical to those generated for the cohort model (including social costs) and were also weighted by the proportion of methadone versus Suboxone recipients. We assumed that the costs for untreated patients would be equal to cohort model costs for relapsed patients.

We also generated estimates of the number of deaths that would occur for patients in and out of treatment based on the sources used in the cohort model. Mortality rates for patients in treatment were also weighted by the maintenance modality received.

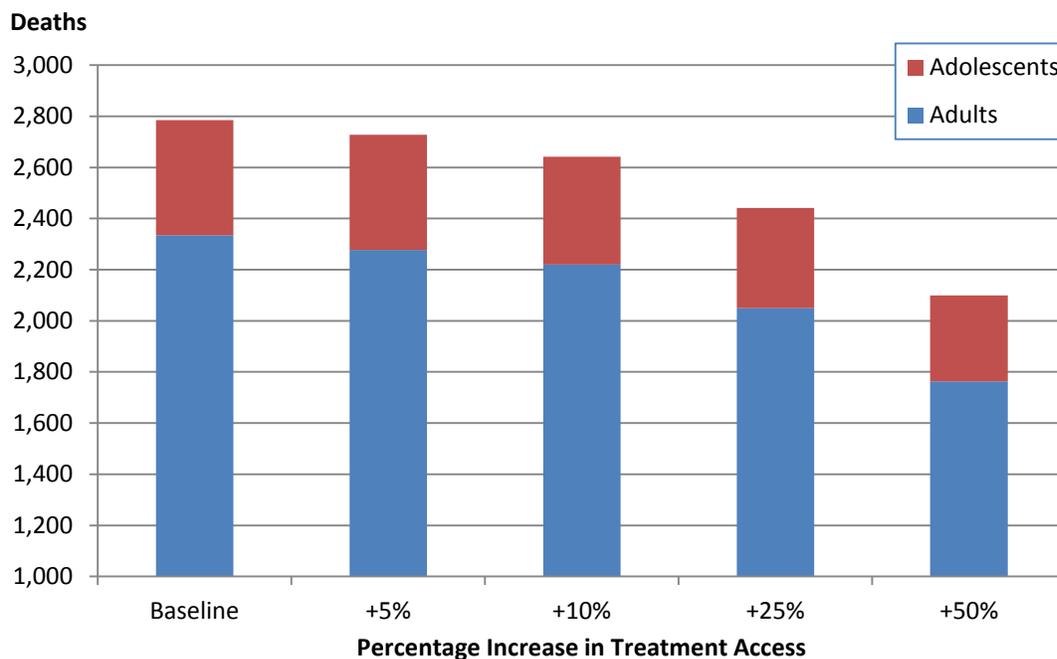
We then assessed the effects that moving untreated patients into treatment would have on deaths and total costs in the region over a two-year period. All newly-treated patients were assumed to be treated with Suboxone, as we felt that expanded access to Suboxone was more realistic than methadone expansion in the current regulatory environment. Consistent with estimates from the cohort model, slightly more than 50% of these newly treated patients would be expected to remain in treatment after two years. Rates of increase in the proportion of individuals receiving treatment ranged from 5-50%.

7.4 Budget Impact Analysis: Results

Currently, it is estimated that, of the 133,000 New Englanders with opioid dependence, 40,000 receive maintenance treatment. Moving 10% of untreated patients into treatment would increase the size of the population retained in treatment by 12%, to 45,000. Moving 50% into treatment would increase the treated population by over 60%, to 64,000.

Estimates of the numbers of substance abuse-related deaths for New England are presented in Figure 6 on the following page for adolescents, adults, and in total. At baseline, approximately 2,800 deaths would be expected to occur in a two-year period, 450 of which would be among adolescents. Expanding treatment access by 10% would reduce the death count by nearly 150 (30 of whom would be adolescents). Aggressive expansion would produce more substantial results. For example, a 50% expansion would be expected to save nearly 700 lives in two years, including over 100 adolescents.

Figure 6. Impact of expanding access to maintenance treatment on substance-abuse related deaths in New England, over a two-year timeframe.



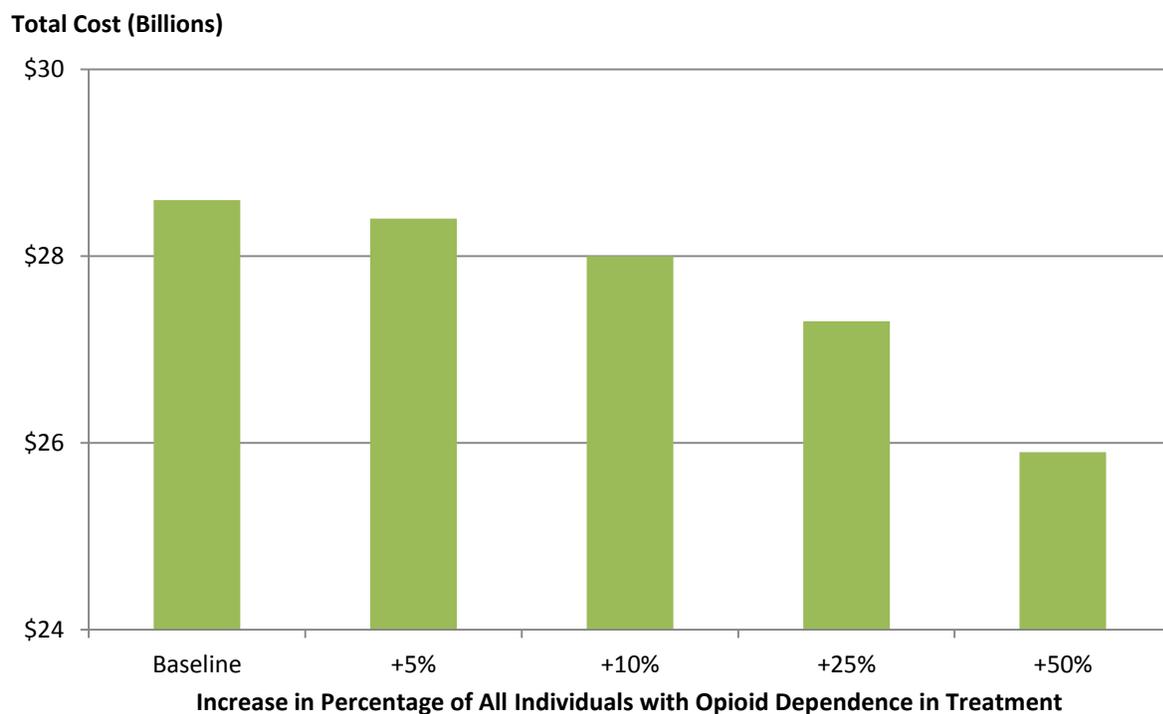
When considering health care costs alone, the additional costs associated with expanding access to maintenance treatment are essentially fully offset by savings in the cost of other health care services. Current health care costs for all individuals with opioid dependence are estimated to total approximately \$5.2 billion for the region (\$1.5 and \$3.7 billion for treated and untreated individuals, respectively). Moving 5% of untreated individuals into treatment would increase treatment expenditures by \$73 million, but result in reductions in the cost of other health care services by about \$80 million. Greater levels of expansion would result in greater net cost savings. For example, a 10% expansion would increase treatment costs by \$183 million, but reductions in the cost of other health care services of nearly \$200 million would result in net cost savings of \$15 million. A 25% expansion would more than double net cost savings to approximately \$35 million.

The effects of expanded access to maintenance treatment on *total* (health care plus social) costs are more dramatic, as presented in Figure 7 on the following page. At baseline, total costs of opioid dependence in the region are estimated to be approximately \$29 billion over two years, 81% of which is generated by dependent individuals not currently in treatment. At each level of treatment expansion, net savings are substantial, given that costs of health care services are already offset by treatment and reductions in social costs are pronounced. For example, expanding treatment by as little as 5% would decrease total costs for the entire population of individuals with opioid dependence by approximately \$220 million. A 25% expansion would decrease overall population costs by approximately \$1.3 billion, and a 50% expansion would decrease overall costs by \$2.6

billion. Put another way, each additional health care dollar spent on expanding maintenance treatment would return approximately \$1.80 in savings. Importantly, all of these savings are realized even under the assumption that only slightly more than 50% of individuals newly-accessing Suboxone treatment would remain in treatment after two years.

While the budget impact of expanding treatment was not estimated separately for adolescents versus adults, patients aged 12-17 are estimated to represent approximately 20% of the treated population in the NSDUH survey data (SAMHSA, 2013c). If cost levels are assumed to be similar for both subpopulations, a 5% expansion in the number of adolescents treated would produce approximately \$44 million in savings for these patients.

Figure 7. Total costs (health care plus social costs of opioid dependence) of persons with opioid dependence in New England, assuming different levels of increase in percentage of individuals brought into treatment. Total costs go down with each incremental increase in the percentage of patients in medication-assisted treatment programs.



7.5 Summary

The findings of the simulation model suggest that maintenance treatment with either methadone or Suboxone retains more patients in treatment over a two-year period in comparison to use of either oral or injectable naltrexone for abstinence treatment alone. Methadone and Suboxone maintenance have very similar outcomes and overall health care costs. Compared to use of oral

naltrexone alone, maintenance treatment increases the cost of health care services (i.e., substance abuse and other health care services) by \$3,000-\$5,000, but estimates of the cost per additional relapse averted are relatively low: <\$15,000 in our analysis. As a benchmark, published estimates of the cost per relapse in other mental health conditions (e.g., depression, schizophrenia) have considered estimates <\$50,000 per relapse averted to be a cost-effective use of resources (Scott, 2003; Citrome, 2014; Mihalopoulos, 2004).

When the “social” costs of law enforcement, crime victimization, and lost productivity were included in our estimates, maintenance treatment becomes both more effective and less costly than abstinence treatment with oral naltrexone. For example, methadone would still be cost-saving overall versus oral naltrexone on a societal basis even if substance abuse services were provided *free of charge*.

Our findings for strategies involving stabilization with short-term Suboxone followed by a taper to either oral naltrexone or Vivitrol are also intriguing, as these strategies are estimated to produce retention figures comparable to methadone maintenance but without requirements for continued opioid replacement. These findings should be interpreted with great caution, however, as our estimate of the effectiveness of oral naltrexone was based on a single, small (n=70) RCT (Sigmon, 2013), and Vivitrol’s retention benefits were assumed in the absence of published data on its use in a tapering strategy. However, it is important to note that treatment with any of these strategies reduces costs in comparison to no treatment. The two-year costs of untreated opioid dependence are estimated to total nearly \$250,000 per untreated individual; these costs are reduced by nearly half with maintenance treatment strategies and even by 30% with the least effective strategy considered (oral naltrexone alone).

The impact of moving untreated individuals into treatment was further confirmed by our budgetary impact analysis. The total health care plus social costs of opioid dependence are estimated to total \$29 billion annually in the region, 81% of which is generated by untreated patients. In addition, nearly 3,000 substance abuse-related deaths occur over a two-year period. Any expansion of the treated population will produce cost reductions for the region of approximately \$1.80 for every dollar invested over a two-year period. If 50% of currently untreated patients had treatment available to them, cost savings for the region would be nearly \$3 billion and nearly 700 lives would be saved, 100 of which would be adolescents. It is important to remember that estimated reductions in both the number of substance abuse-related deaths and costs occurred even with an assumed treatment retention rate for Suboxone of only slightly more than 50%.

We note some limitations of our analysis. First, we assumed that all outcomes would be driven by initial treatment; in reality, some patients experiencing relapse would re-enter treatment within the two-year period and be treated successfully. There are insufficient data on the success of retreatment for all of the strategies of interest, so any estimate would involve significant conjecture

on our part. Nonetheless, our estimates of the long-term outcomes of initial maintenance treatment are consistent with those of other cohort studies in the literature (Comiskey, 2010).

Also, as noted earlier in the report, the estimates of retention in treatment for methadone and Suboxone were obtained from a meta-analysis of RCTs that involved provision of both medications in the same treatment setting and with identical levels of available support services. This does not reflect current practice in the U.S., where methadone is delivered in a tightly-controlled environment with substantial oversight and support services available, and Suboxone is typically provided in an office-based setting with fewer controls and inconsistent levels of support. Retention in typical practice may therefore vary significantly, and treatment setting may influence this result as much or more than the medication delivered.

Our estimates of health care and social costs come from disparate sources that may not be fully generalizable to the region. For example, social costs were obtained from a landmark study, but one nevertheless conducted in Canada; this study also included an estimate of health care costs, but we chose to exclude it and focus on a U.S.-based study for that component. However, our results are robust to changes in all cost estimates. For example, reducing the social cost estimates by half does not change the order of findings for each treatment strategy, and still produces net cost savings of nearly \$900 million if treatment is expanded to 50% of currently untreated persons in New England.

8. CEPAC Votes and Deliberation

During CEPAC public meetings, the Council deliberates and votes on key questions related to the review of the evidence produced by the Institute for Clinical and Economic Review (ICER). At the June 20, 2014 meeting, CEPAC discussed and placed votes assessing the comparative clinical effectiveness and value of various treatment approaches addressed in this evidence review. The key questions are developed by ICER for each appraisal, with input from the CEPAC Advisory Board to ensure that the questions are framed to address the issues that are most important in applying the evidence to support clinical practice and medical policy decisions. Ex-officio CEPAC members participate fully in the discussion of the evidence but do not vote. The voting results are presented below, as well as key comments reflecting the considerations mentioned by CEPAC during the voting process.

When voting on comparative value, CEPAC was asked to assume the perspective of a state Medicaid program that must make resource decisions within a relatively fixed budget for care. For each question on value, CEPAC placed two separate votes: one considering only the direct medical costs associated with each intervention, and one considering both the societal and medical costs associated with each intervention. CEPAC is not given prescribed boundaries or thresholds for budget impact or incremental cost-effectiveness ratios to guide its judgment of low, reasonable, or high value. However, CEPAC did make use of a series of value categories designed by ICER to assist the Council in assigning an overall value rating (see Figure 8 below). CEPAC members who vote “no” on comparative clinical effectiveness are designated to a special “low” value vote category for lack of evidence to demonstrate comparative clinical effectiveness.

Figure 8: Value Categories for CEPAC’s votes

Low Value	Reasonable/Comparable Value	High Value
Worse outcomes; Higher or equivalent cost	Worse outcomes; Lower cost	Comparable outcomes; Lower cost
Comparable outcomes; Higher costs	Comparable outcomes; Comparable cost	Promising but inconclusive evidence of better outcomes; Lower cost
Promising but inconclusive evidence of better outcomes; Higher cost	Promising but inconclusive evidence of better outcomes; Comparable cost	Better outcomes; Lower or comparable cost
Better outcomes; Too high a cost	Better outcomes; Reasonable higher cost	Better outcomes; Slightly higher cost

Comparative Clinical Effectiveness and Value: Medication-assisted Maintenance Therapy vs. Detoxification¹

1. Is the evidence adequate to demonstrate that long-term maintenance therapy with any medication is superior to short-term detoxification for most patients with opioid dependence?

CEPAC Vote:

12 yes (92%) **1 no (8%)**

Comments: CEPAC members who voted “yes” cited the strong quality of evidence for maintenance therapy supported by the Cochrane review, as well as testimony from clinical experts that reinforced the conclusions of the research. The CEPAC member who voted “no” stated that while there is overwhelming evidence regarding the efficacy of long-term maintenance therapy, there is uncertainty of its superiority for “most” patients. The Council member noted that the existing evidence primarily looked at relatively short taper periods, and it may be that longer periods are needed for patient success than those examined. Additionally, the Council member argued that the existing evidence does not adequately identify subpopulations that might respond differently to the various treatment protocols.

2. From the perspective of a state Medicaid program, would you judge the value of long-term maintenance therapy with any medication compared to detoxification to be high, reasonable, or low?

CEPAC Vote:

Considering only direct medical costs:

10 high (77%) **1 reasonable (8%)** **1 low (8%)** **1 abstain (8%)**

Considering medical costs and societal costs together:

11 high (85%) **1 reasonable (8%)** **1 low (8%)**

¹ The terminology “detoxification” has been replaced with short-term “opioid withdrawal management” elsewhere in this document based on feedback received from the American Society of Addiction Medicine that this terminology is more clinically accurate. We retained the use of “detoxification” in this section since this was the exact wording presented to CEPAC at the time of voting.

Comments: CEPAC members who voted that long-term maintenance therapy has “high” comparative value agreed that compared to detoxification, maintenance therapy demonstrates “better outcomes at a low or comparable cost”. Council members provided the same rationale when considering only health care costs and when considering both medical and societal costs together.

3. From the perspective of a state Medicaid program, would you judge the value of expanded access to maintenance therapy with any medication versus the status quo to be high, reasonable, or low?

CEPAC Vote:

Considering only direct medical costs:

9 high (69%) 3 reasonable (23%) 1 low (8%)

Considering medical and societal costs together:

12 high (85%) 1 low (8%)

Comments: CEPAC members who voted that expanded access to maintenance therapy has “high” comparative value also categorized their vote as “better outcomes at a low or comparable cost,” both when considering medical costs alone and together with societal costs.

Comparative Clinical Effectiveness and Value: Methadone vs. Suboxone

4. Is the evidence adequate to demonstrate that maintenance therapy with methadone is at least functionally equivalent to maintenance with Suboxone in treating patients with opioid dependence?

CEPAC Vote:

12 yes (92%) 1 no (8%)

Comments: The Council member who voted “no” cited concerns that the appropriate dosing levels may not have been achieved in the available studies, as well as potential differences in treatment setting that may have confounded results.

5. From the perspective of a state Medicaid program, would you judge the value of methadone treatment compared to Suboxone treatment to be high, reasonable, or low?

CEPAC Vote:

Considering only direct medical costs:

2 high (15%) 8 reasonable (62%) 2 low (15%) 1 abstain (8%)

Considering medical and societal costs together:

3 high (23%) 8 reasonable (62%) 1 low (8%) 1 abstain (8%)

Comments: The majority of CEPAC members who voted that methadone has “reasonable” value indicated that it has “comparable outcomes and comparable costs” when compared to Suboxone, both when considering medical costs alone or medical and societal costs combined. The CEPAC member who voted that methadone is at least functionally equivalent to Suboxone but has low value reasoned that the costs of generic Suboxone will likely drop overtime, impacting the overall budget impact for this treatment.

Comparative Clinical Effectiveness: Vivitrol vs. Oral Naltrexone

6. Among patients who can be successfully tapered from maintenance therapy with any medication (e.g. Suboxone, methadone.) to opioid antagonist treatment, is the evidence adequate to demonstrate that Vivitrol is as good as or superior to oral naltrexone for patients with opioid dependence?

CEPAC Vote:

1 yes (8%) 12 no (92%)

Comments: CEPAC emphasized that this vote of inadequate evidence does not imply that Vivitrol is an ineffective treatment option, or that access to it should therefore be restricted. Rather, the strength of evidence is inadequate to determine the effectiveness of Vivitrol relative to oral naltrexone, and additional research is needed to better establish its role in the management of patients with opioid dependence.

Note: CEPAC did not place a vote comparing the value of Vivitrol to oral naltrexone since a majority of the Council did not deem the evidence adequate to demonstrate the comparative clinical effectiveness between these two options.

Broader Considerations for Equity

7. Are there any considerations related to public health, equity, disparities in access or outcomes for specific patient populations, or other social values that should also be considered in medical policies related to the use of methadone, Suboxone, Vivitrol, or oral naltrexone?

Comments: Council members emphasized that concerns for public health, equity, and disparities are major issues within this topic and policy solutions must address system capacity and access in order to better connect patients to effective treatment. Council members suggested that future research attempt to capture how patients perform with treatment over time, since it often takes individuals with addiction multiple attempts at treatment to succeed. CEPAC also cited the need for more research assessing outcomes of maintenance therapy for adolescents to determine whether or for which young adults MAT is the best choice. Council members also noted the challenge of voting on the comparative value and effectiveness of different approaches when for so many patients treatment choice is based on regulation and availability rather than evidence-based policies or decision-making.

9. Recommendations to Guide Practice and Policy in New England

Before the CEPAC public meeting, ICER staff conducted unstructured interviews with 15 policy experts to explore real world perspectives on recent practice and delivery system innovations, potential policy changes, and other opportunities to improve how patients utilize and access treatment for opioid addiction in New England. Interviewees came from each New England state and leading national organizations, with positions in OTPs, patient advocacy organizations, state agencies, clinical societies, academic institutions, and office-based addiction treatment centers.

The results from these interviews were used to frame a set of policy and practice recommendations that informed a moderated Policy Expert Roundtable discussion during the CEPAC meeting between Council members and a panel of regional policy experts. Panelists included clinical experts, health insurers, state agency representatives, and a patient advocate who discussed with CEPAC members various policy options for addressing treatment quality, health system capacity, and access to care in New England. The participants in the Roundtable discussion are shown below:

Rebecca Boss, MA	Rhode Island	Deputy Director, Department of Behavioral Healthcare, Developmental Disabilities and Hospitals (BHDDH), State of Rhode Island
John Brooklyn, MD	Vermont	Physician, Community Health Centers of Burlington
Barbara Cimaglio	Vermont	Deputy Commissioner, Alcohol and Drug Abuse Programs, State of Vermont
TJ Donovan, JD	Vermont	State Attorney for Chittenden County, State of Vermont
Kevin Flanigan, MD	Maine	Medical Director, MaineCare Services, State of Maine
John Hammel, MD	New Hampshire & Vermont	Director, Substance Abuse Services, White River Junction VA
Lisa Muré, MEd, CPS	New Hampshire	Director for Prevention, New Hampshire Center for Excellence Senior Consultant, Community Health Institute
Stacey Sigmon, PhD	Vermont	Associate Professor of Psychiatry, University of Vermont Director, The Chittenden Clinic
Jeff Simmons, MD	Massachusetts	Medical Director for Behavioral Health, Blue Cross Blue Shield of Massachusetts
Tom Simpatico, MD	Vermont	Chief Medical Officer, Vermont Department of Health Access
Jacquelyn Starer, MD, FACOG, FASAM	Massachusetts	Associate Attending Physician, Faulkner Hospital Associate Director, Physician Health Services, Inc. President, Massachusetts Chapter of ASAM
Joycelyn Woods, MA, CMA	National	Executive Director, National Alliance for Medication Assisted Recovery

Combining the insights gained from the earlier policy expert interviews with the votes on the evidence by CEPAC and the ensuing Policy Expert Roundtable discussion, the following set of recommendations are presented to guide the application of evidence to improve opioid dependence management practice and policy in New England. The discussion reflected multiple perspectives and opinions and therefore none of the recommendations should be taken as a consensus view held by all participants.

1. Coordinated efforts are needed across New England to improve access to opioid dependence treatment for the large number of individuals who lack adequate access to high quality care options.

There was sentiment among the stakeholders interviewed that restrictions in the area of addiction medicine are disproportionate to regulations in all other fields of medicine and serve to reinforce stigma and prevent the provision of high quality, responsive treatment. Experts felt strongly that regulations that isolate treatment with methadone from the rest of clinical care and place restrictions on the number of patients served with buprenorphine-containing medications must be relaxed to address the overwhelming need for opioid addiction services in New England.

Some clinical experts suggested extending methadone treatment to office-based use, as described in the King and Harris 2006 pilot studies in Section 6, as a means of expanding access to care. Some Roundtable panelists feared that the diversion risks associated with methadone made office-based methadone programs too risky politically because if implementation went poorly it could potentially discredit the progress that has been made elsewhere to expand access to this treatment. The patient advocate representative on the Roundtable emphasized, however, the importance for long-term stable patients to be able to access treatment in private settings where there is less interaction with other patients with addiction. Clinical experts on the Roundtable also stated that the vast majority of patients in treatment use medication responsibly, and that concerns for prescription abuse are secondary to concerns for access.

CEPAC and Roundtable panelists also underscored the need for more resources to develop the skills and expertise of DATA 2000 waived physicians in order to increase their capacity and willingness to serve more patients with addiction. Even with excess demand, many DATA 2000 waived physicians are not prescribing to capacity or at all. According to the experts interviewed, some practices abstain from treating more patients with addiction due to insufficient resources to address the full scope of behavioral and psychosocial needs associated with substance abuse disorder, where others fear risk of diversion and potential abuse of medications. Primary care providers in particular often feel undertrained or unsupported to take on new patients with addiction. Further dissemination of standardized guidelines and protocols is therefore needed to help physicians make use of evidence-based

practices and reduce practice variation. CEPAC members agreed with Roundtable panelists that provider organizations and clinical societies should develop stronger peer networks to help organizations and specialties treating patients with addiction manage care more effectively.

To expand access to Suboxone and buprenorphine, policy experts and CEPAC also agreed that limits on the number of patients that can be treated by qualified clinical teams should be relaxed in appropriate clinical settings. Experts acknowledged, however, that if clinical practices are allowed to increase the volume of patients receiving buprenorphine medications that measures should be taken to ensure that these practices are part of well-organized group settings that can provide adequate structure and support for physicians and other clinicians. Some clinical experts on the Roundtable also recommended that the scope of DATA 2000 be broadened to allow qualified nurse practitioners to prescribe buprenorphine-containing medications. Clinical experts interviewed for this review argued that current prescribing restrictions serve to reinforce the need for a black market for Suboxone where patients can self-medicate or at least replace the use of heroin and other long-acting drugs.

Policy experts also recognized that the highly restrictive entry criteria for some MAT programs that add another barrier to entry for patients should be revised to improve access to pharmacotherapy options. For example, in Maine some federally-qualified health centers (FQHCs) impose rules that prohibit practices from treating patients that do not already receive care within the FQHC, greatly limiting the number of providers available to patients with opioid dependence.

CEPAC agreed with policy experts that individuals should be screened for opioid addiction in primary care settings in order to support early interventions for recovery. Primary care providers should be encouraged and trained to screen for addiction during general exams, particularly when screening or diagnosing psychiatric disorders, which often present as co-morbidities of substance abuse.

Policy/Practice Option: Utilizing physician assistants and nurse practitioners to increase physician-prescribing capacity

In Massachusetts, a network of office-based addiction treatment programs called Clean Slate Centers has attempted to increase the number of DATA 2000 waived physicians prescribing at capacity. According to this model, licensed prescribers work as part-time physicians who treat patients with Vivitrol or Suboxone. In addition to prescribing treatment, these physicians review patient charts, conduct group medical visits, and answer questions from staff regarding patient management. The model also utilizes full-time clinical and supportive staff to manage all other aspects of care, allowing physicians to increase their prescribing capacity beyond their main clinic. The goal of this approach is to “remove treatment from busy, over-stretched primary care settings, and provide the infrastructure necessary for primary care physicians and psychiatrists to collaborate with behavioral health providers and experienced full-time clinicians so that patients are able to receive the comprehensive care necessary to achieve recovery.”

Policy/Practice Option: Use of technology and telemedicine to expand access to treatment

Researchers in Vermont have recently received National Institutes of Health (NIH) funding to make use of a new computerized device called the Med-O-Wheel to help patients on treatment waiting lists access some level of medication-assisted treatment. The device is for take-home use and dispenses a single dose of buprenorphine for a limited two-hour window each day, making it difficult for patients to abuse medication. The transparent back to the device also allows physicians to monitor diversion. Patients receiving buprenorphine through the Med-O-Wheel will also receive telephone-based monitoring and support that provides daily check-ins, documents patient cravings, and refers patients to other needed resources. The goal of this model is to expand patient access by offering an alternative safe delivery option for medication, thereby increasing the willingness of physicians with concerns for diversion to provide treatment.

2. Develop innovative strategies that connect individuals in the criminal justice system to treatment for their addiction.

Clinical and policy experts discussed at length during the in-person meeting the need for more efficient referral pathways for connecting individuals with non-violent addiction-related crimes to treatment. Roundtable panelists noted the challenges for patients leaving the correction system who are wait-listed for treatment at OTPs and are unable to find a primary care physician to provide treatment for their addiction, increasing the risk for recidivism. Stakeholders involved in the criminal justice system emphasized that solutions to addiction cannot be achieved in penal institutions alone and therefore stronger integration between the

criminal justice and clinical systems is required. CEPAC and Roundtable panelists recommended that policymakers establish jail diversion programs in which non-violent offenders are assessed for addiction and referred to appropriate treatment in lieu of incarceration. Some states in New England, like Vermont, Massachusetts, and Connecticut, have developed similar models and pilot programs for jail diversion.

Policy experts on the Roundtable also suggested expanding treatment to incarcerated individuals by providing Suboxone or buprenorphine to individuals who will be in prison for more than a short period and making MAT available to individuals who are waiting for sentencing. Clinical experts and patient advocates on the Roundtable noted that even though naltrexone has been recognized as an opportunity to support opioid-dependent individuals at risk for relapse who are exiting the controlled environment of the corrections system, that it should not be used indiscriminately in this population. Many individuals who are believed to be opiate-free are not, and some individuals that exit incarceration with Vivitrol are likely to never return to treatment and will be at higher risk for overdose.

Policy/Practice Option: Jail diversion for low-level drug offenses

The LEAD Model is a pilot program in Seattle, WA that diverts low-level drug offenders that meet certain thresholds into community-based support services and treatment programs instead of prison. The LEAD model is unique to other jail diversion programs in that diversion is established at the “pre-booking” stage, or prior to when offenses are charged to avoid the legal costs associated with court trials, etc. Individuals participating in the program are connected with case management and counseling services immediately. Addiction services for LEAD participants are provided through a formal contract with a community-based organization that specialized in outreach services to chronically homeless and dependent adults. The LEAD program is the result of multi-stakeholder collaborative between representatives from the criminal justice system, the legal system, local and state governments, and community organizations. The pilot is fully funded through foundation and grant support and the model for the pilot is based off of similar programs in the United Kingdom that have been employed broadly throughout the country.

3. Clinicians should individualize treatment, including decisions about medication choice, counseling, and supportive social services, according to an initial assessment of a patient’s baseline severity and unique health care needs. For most patients, MAT will be more effective than attempts at short-term managed withdrawal. However, short-term managed withdrawal may be a reasonable consideration for a subset of patients with relatively short-term histories of addiction and less intravenous opioid use.

Experts and CEPAC members agreed that the treatment needs for each patient with opioid dependence are different, and therefore clinicians must adequately assess patients to determine the level, intensity, and modality of treatment most appropriate for his or her unique circumstances. A comprehensive assessment that determines a patient's overall health risk; presence of co-morbid disorders or conditions, including chronic pain or co-occurring substance abuse; social and behavioral challenges; and extent of dependence is considered crucial to adequately refer patients to necessary services and develop a treatment plan individualized to meet the patient's needs. Clinicians providing the initial assessment should be qualified and adequately trained in addiction disorders.

Given how broadly patient expectations and treatment objectives vary, some experts suggested that treatment plans involve short-term goal setting with the patient using a structured treatment protocol designed to achieve those objectives. Experts noted that treatment plans should evolve based on a patient's level of engagement and stage of change, and therefore flexibility with treatment goals is essential.

Since opioid dependence is a chronic relapsing condition, it requires a long-term treatment approach. CEPAC agreed with clinical and policy experts that maintenance therapy is an integral component of treatment and patients rarely succeed with short-term opioid withdrawal management alone. Clinical experts on the Roundtable emphasized the danger of policies that require individuals to attempt opioid withdrawal first before receiving MAT, as patients are at very high risk of overdose once their tolerance has decreased. However, short-term managed withdrawal may be a reasonable consideration for a subset of patients with relatively short-term histories of addiction and less intravenous opioid use.

CEPAC and Roundtable panelists agreed that the results of a patient's initial assessment and evaluation should determine the medication selected for treatment. Advocates and providers noted that patients with higher opioid tolerance, longer histories of use, and unstable living situations might benefit from a more structured program with methadone. Conversely, individuals with mild-to-moderate levels of dependence and greater life stability who require less treatment oversight may be considered for first-line treatment with buprenorphine-containing medications. Some clinical experts also suggested that naltrexone may be an effective first-line treatment option for individuals with short histories of opioid use who access treatment early. CEPAC members and Policy Roundtable panelists recommended that specialty societies, states, and other stakeholders work collaboratively to develop evidence-based screening tools, questionnaires, or algorithms to help identify the most appropriate treatment based on individual patients' unique factors. Unfortunately, significant treatment capacity constraints make matching patients to medication a major challenge; instead, the treatment choice is often dictated by availability of the limited options.

Policy/Practice Option: Linking treatment success to continued coverage

A majority of Roundtable panelists and CEPAC members expressed concern that a strict time limit on treatment for all patients is not consistent with the evidence. However in Maine, where doing so is required, the state Medicaid program (MaineCare) has adopted new authorization criteria for success designed to support individualized treatment. State regulation mandates that MaineCare only cover Suboxone for a period of 24 months, after which patients must demonstrate “medical necessity,” or that a patient has had some measure of “success” with treatment, to remain on medication. Under this model, patients determine goals for treatment individually with their physician, and it is to each physician’s clinical discretion whether Suboxone is effective after the initial 24-month period in achieving treatment objectives. Criteria for medical necessity may include improvements in living stability, active employment seeking, or regained social relationships, and patients need not achieve all criteria for treatment to be authorized. According to stakeholders in Maine tasked with implementing this model, for some patients this requirement has created a positive incentive and has improved patient engagement in their treatment plan.

4. Develop systems to triage patients entering treatment to the level of care more appropriate for their individual needs in order to support patient-centered treatment and allow for more capacity in the system.

Policymakers and treatment centers in New England are considering ways to allocate resources more effectively to manage the growing numbers of opioid-dependent patients. CEPAC and Roundtable panelists discussed the importance for states and provider groups to develop coordinated care networks in which patients receive short-term intensive outpatient care until stabilized, and then are referred outward to other outpatient practices for lower levels of ongoing care and MAT in primary care settings or community-based practices. Vermont is one of the states in New England implementing this model on a state-wide basis, as described on the following page.

Policy/Practice Option: Vermont “Hub and Spoke” Model

Vermont is employing a coordinated system-wide model for triaging patients with opioid dependence to appropriate levels of care. The goal for this model is to support patient-centered treatment while more effectively distributing resources to allow for greater capacity in the system. Called the “Hub and Spoke” model, this system makes use of specialty treatment centers (“hubs”), as well as federally-qualified health centers, patient-centered medical homes, and other practices with physicians licensed to prescribe Suboxone (“spokes”). Patients begin treatment for opioid dependence centrally at the “hub,” where they receive a period of intense treatment composed of comprehensive assessment, MAT, and other supportive services for an initial stabilization period. Once stabilized, patients are referred outward to a “spoke” for ongoing care and maintenance with Suboxone. Clinically complex patients may continue to receive care at the “hub,” or are referred elsewhere for inpatient or rehabilitation services if more intensive care is deemed appropriate. Stable patients receive ongoing care at the “spoke,” which typically involves a prescribing physician, nurse, case manager, and counselor-led care team that monitors treatment adherence, provides counseling, supports contingency management, and coordinates patient access to other recovery supports as needed. This model is being implemented in stages and is not working perfectly yet, as the average spoke maintains a small number of patients and not all licensed physicians are prescribing to capacity.

5. Mandatory requirements for certain kinds of counseling can have unintended consequences and should be reconsidered to ensure that they are not negatively affecting patient outcomes.

State and health insurer medical policy often require that treatment plans meet certain criteria for counseling in order for patients to receive MAT. Though CEPAC members recognized the importance of social support and counseling for many patients, the Council and Roundtable panelists agreed that the decision for counseling should be individual rather than a blanket requirement, and therefore policies of this kind should be reconsidered. Moreover, since there are not enough counselors to serve every patient with addiction, these policies may potentially “bottleneck treatment” and serve as an additional barrier to care.

Roundtable panelists also noted that many counselors are not specifically trained in addiction and that individuals with dependence may be better served through peer-led recovery support that addresses techniques for relapse prevention from a patient’s perspective.

6. Provide treatment for opioid dependence through comprehensive, team-based care with collaboration across health care providers.

Experts agreed that patients with opioid dependence should have access to comprehensive health care services that address the full range of co-occurring clinical, social, and environmental factors surrounding dependence. Housing support, wellness services, substance abuse education, occupational rehabilitation, transportation, reproductive counseling, parenting support, and legal support are among the social services most important for patient success.

Physician-led, team-based care allows treatment centers to provide a range of services among a shared network of providers, often within the same facility, which experts noted helps improve patient retention. The multi-disciplinary care team may be composed of addiction-certified physicians, psychologists, counselors, social workers, and other complementary practitioners that coordinate care and integrate with other medical and psychiatric services, as necessary. Treatment programs that are unable to provide the full of spectrum of services that opioid-dependent patients require on-site should maintain a strong referral network with local mental health providers and other social agencies, as well as a robust case management system that tracks patients' progress and helps coordinate services for them as they access treatment.

Treatment programs across New England have adopted innovative approaches to foster collaboration and integration across providers. For example, some practices require patients to sign HIPAA release forms upon admission so that practitioners can openly communicate and discuss treatment progress for shared patients. Other programs have developed a system of communication across all treating providers, requesting that primary care physicians and pain management specialists prescribing benzodiazepines fill out information sheets that notify the addiction specialist. Finally, some practices hold weekly meetings for all care team members that discuss each patient's progress, how to prevent patient dropouts, and how services can be better integrated.

Clinical experts noted that coordinating care for patients with dependence can be difficult given how isolated this patient population is in some states, and how different treatment systems tend to function in silos. Experts also noted that the regulatory environment for substance abuse services makes it a challenge to adequately monitor and transition patients between different care systems. For example, policy experts participating on the Roundtable noted that existing federal regulations on confidentiality that are stricter than HIPAA make it difficult to share data between providers, posing a challenge at times to full care integration.

Policy/Practice Option: Use of medical homes to foster collaboration across health care providers and expand access to comprehensive, team-based services

Rhode Island is using a patient-centered medical home (PCMH) approach to provide comprehensive, team-based care to patients receiving MAT. Under this model, OTPs act as health home providers and assign participating patients to a health team, which may be specialized to meet their specific health care needs. Each patient is assigned a nurse and case manager to provide ongoing monitoring, assistance with referrals, development of care plans, recovery support, and support for transition between levels of care. The goal of this model is to support stronger, formalized relationships between OTPs, which have daily contact with patients, with community health care providers in order to provide comprehensive treatment for patients with dependence using MAT.

7. Clinical strategies for dosing and tapering of MAT should adopt an individualized approach that engages the patient in setting goals.

Experts emphasized that for patients receiving MAT, no standardized approach for dosing and tapering will work for all patients, and therefore the level at which patients receive medication must be individualized. Experts acknowledged that though clinicians generally do not want to keep patients on medication indefinitely, there is little consensus on whether or how best to taper patients off maintenance therapy. Standardized treatment cut-offs are often regarded as counterproductive and even dangerous, and experts reported that even when patients taper and attempt to withdraw from MAT, many ultimately go back on medication or relapse to illicit drug-seeking behaviors.

Patient engagement is critical to assess whether a patient is motivated and has the supports necessary to attempt tapering. Stakeholders in Maine, where treatment programs are required to attempt to wean patients on Suboxone to a lower dose within two years as a condition for reimbursement, have found tapering boosts patients' self-confidence and engagement in their treatment plan. Under this model, patients that cannot tolerate a lower dose are allowed to return to a higher dose for as long as clinically appropriate. Several Roundtable panelists cautioned, however, that mandatory tapers may have unintended results and run contrary to some existing clinical guidelines.

With patient engagement, some programs have had success implementing a gradual tapering strategy that slowly weans patients off medication over the course of several months. Ongoing re-assessment is necessary, with flexibility to halt or reverse the taper as needed. Experts shared anecdotally that tapers tend to be most successful in patients with less severe dependency who have a supportive environment (e.g., stable relationships and living

environment, active employment). Other programs have suggested that keeping patients unaware of where they are in dosing can also be helpful. Some clinical experts also highlighted naltrexone as a crucial tool for preventing relapse after a successful taper, as it blocks the patient's ability to feel "high." However, providers recognized that only a limited number of patients are good candidates for naltrexone given the requirements to be opioid-free for at least seven days and the motivation necessary to avoid the "high." Ideal candidates for taper with this therapy tend to be patients that have lower severity baseline dependence, higher psychosocial stability, and a non-using social network.

8. Evidence-based insurance coverage policies for opioid dependence services should support efficient clinical practice and provide enough flexibility to help clinicians appropriately support the care needs of a diverse group of patients.

Strict prior authorization criteria establish an additional layer of regulation that many stakeholders feel create another barrier to treatment. Clinicians interviewed underscored the need for insurers to attempt to institute more efficient prior authorization processes for Suboxone and Vivitrol to achieve the intended policy goals while minimizing the burden for patients, pharmacists, and physicians. At present, some payers require prescribing physicians to call in patient information and answer a series of questions that some clinicians interviewed feel could easily be addressed through fax. Though some experts agreed that prior authorization requirements have validity to ensure quality prescribing, many felt that they ultimately serve as another obstacle to providing high quality treatment. Many patients wait until they are down to one or two pills before refilling their prescription, and prior authorization requirements mean that some patients are unable to receive their medication when needed. Physicians suggested that payers provide "fast-track" prior authorization processes for reliable prescribers. Doing so would maintain protections against physicians that are not prescribing in good faith, but allow those with a demonstrated high quality prescribing record to treat patients as efficiently as possible. Health insurers on the Roundtable noted that prior authorization is not intended to reduce access to treatment, but rather to avoid standardized requirements or protocols that will not work for many people.

Insurers and providers share the burden of balancing concerns for diversion with the desire to provide a dose high enough to ensure a patient does not experience withdrawal and drop out of treatment. No standardized approach for dosing (or tapering) will work for all patients, and therefore the level at which patients receive medications must be individualized. Mechanisms to facilitate rapid consideration of requests for dosing beyond established limits should be instituted.

Clinicians also mentioned the need to relax other coverage criteria that serve as deterrents to care, such as regular urine testing for patients with long histories of successful maintenance therapy. Experts emphasized that strict protocols and regular testing are important in the initial phases of treatment, but they reinforce the stigmatization of opioid-dependent patients by requiring ongoing monthly testing of individuals who have been stable on treatment for many years. Payers should therefore consider exemptions for some patients from specific coverage criteria.

Given concerns for patient safety when taking MAT, many clinicians interviewed support policies for compliance monitoring and random “call backs” to prevent abuse and diversion. (“Call backs” refers to the practice of randomly selecting patients with take-home medication privileges to return to clinic and present the medication dose in its original bottle.) Though such approaches may be reasonable, as with other policies there should be some mechanism for consideration of exempting some patients demonstrating long-term adherence to treatment. Some clinicians cautioned that strict policies for MAT may serve to reinforce stigma that individuals with dependence lack self-will and are criminals.

Clinical and policy experts on the Roundtable also noted that increases to reimbursement rates for addiction treatment to bring them on par with payment for other clinical services should be considered to reduce the stigma that still affects addiction medicine specialists.

9. Policymakers should develop long-term solutions to recruit, train, and retain qualified physicians to the field of addiction medicine in addition to fostering greater awareness and skills for recognizing opioid addiction among primary care clinicians.

Recruiting and retaining enough qualified physicians to meet the demand for opioid dependence services remains one of the most significant challenges confronting New England states. According to the policy experts, federal legislation limiting the number of patients that physicians can treat with buprenorphine-containing medications, strict licensing regulations for OTPs, and public hostility to establishing new treatment centers have significantly contributed to the shortage of providers offering addiction treatment. Stakeholders emphasized the need for more targeted efforts to recruit physicians to addiction medicine. Experts suggested that medical schools require physicians in training receive more exposure to addiction medicine and that treatment of substance abuse be incorporated as a standard part of residency training to help recruit more professionals to the field.

Clinical experts and CEPAC members also recommended implementing greater efforts to train and support primary care physicians in recognizing addiction disorder, leveraging training and physician mentorship programs from ASAM and AAAP that assist primary care providers to incorporate screening, brief interventions, and referrals to substance abuse treatment centers as a standard part of care.

10. Funders and the clinical research community should focus future study on key areas where further evidence is needed to appropriately manage patients with opioid dependence.

Although there is a large body of evidence supporting the use of MAT in patients with opioid dependence, significant research gaps exist. CEPAC and Policy Roundtable panelists recognized that existing evidence demonstrates high relapse rates with short-term opioid withdrawal management, but that more research is needed to identify those patients for whom abstinence may be an appropriate short, medium, or long-term goal, and how best to achieve and maintain abstinence in this population. The Council also called for additional RCTs testing the comparative effectiveness of different dosing and tapering protocols. In particular, significant questions remain in the clinical community on how best to identify patients for potential tapers who have been on treatment for many years. CEPAC and Roundtable panelists also agreed that additional research is needed assessing the effectiveness of MAT for adolescent populations with short-term addiction histories, as well as the comparative effectiveness of Vivitrol compared to oral naltrexone.

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By Robin E. Clark, Mihail Samnaliev, Jeffrey D. Baxter, and Gary Y. Leung

The Evidence Doesn't Justify Steps By State Medicaid Programs To Restrict Opioid Addiction Treatment With Buprenorphine

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ABSTRACT Many state Medicaid programs restrict access to buprenorphine, a prescription medication that relieves withdrawal symptoms for people addicted to heroin or other opiates. The reason is that officials fear that the drug is costlier or less safe than other therapies such as methadone. To find out if this is true, we compared spending, the use of services related to drug-use relapses, and mortality for 33,923 Massachusetts Medicaid beneficiaries receiving either buprenorphine, methadone, drug-free treatment, or no treatment during the period 2003–07. Buprenorphine appears to have significantly expanded access to treatment because the drug can be prescribed by a physician and taken at home compared with methadone, which by law must be administered at an approved clinic. Buprenorphine was associated with more relapse-related services but \$1,330 lower mean annual spending than methadone when used for maintenance treatment. Mortality rates were similar for buprenorphine and methadone. By contrast, mortality rates were 75 percent higher among those receiving drug-free treatment, and more than twice as high among those receiving no treatment, compared to those receiving buprenorphine. The evidence does not support rationing buprenorphine to save money or ensure safety.

With overdose deaths from heroin and prescription pain medications increasing in the United States,¹ opioid addiction is an important concern for Medicaid programs. Medicaid beneficiaries have higher rates of opioid addiction than other insured groups,² and Medicaid programs are the largest purchasers of methadone and buprenorphine, the leading forms of opioid substitution therapy nationally. Both treatments are more effective than drug-free treatment alone.^{3,4}

Methadone is a well-established, highly regulated treatment,³ but access to licensed methadone clinics varies widely across the country. Additionally, many potential users find the

stigma and daily demands of methadone maintenance difficult. One alternative is buprenorphine, a medication for opioid addiction that received Food and Drug Administration approval in 2002.⁵ Clinical trials indicate that it is somewhat less effective than methadone in eliminating opioid abuse,^{4,6} but early treatment data suggest that it attracts a somewhat different clientele than methadone: patients who are likely to be male prescription drug abusers and who enter treatment at earlier stages of addiction.^{7,8} Early entry into treatment may improve outcomes, partially compensating for buprenorphine's lower efficacy.

Buprenorphine treatment offers several potential advantages over methadone therapy. It

carries a lower risk of overdose than stronger opioids such as methadone, and the tablets—which are dissolved under the tongue—are formulated with naloxone, an opioid receptor blocker that removes the benefit from crushing and injecting the pills to achieve a greater opioid effect.⁹ Buprenorphine is also more tightly bound to the opioid receptor than other opioids and therefore may protect patients by blocking out other opioid drugs.

The structure of buprenorphine treatment delivery also offers advantages. Federal law restricts methadone treatment to licensed programs that are often concentrated in urban areas and whose staff members are required to observe dosing of most patients daily. By contrast, the Drug Addiction Treatment Act of 2000 allows certified physicians to prescribe buprenorphine in any medical office setting, which has greatly expanded the availability of treatment.¹⁰ Patients have been more willing to participate in treatment because they can take the medication themselves at home, increasing privacy and flexibility in travel and work schedules.⁵

The cost of buprenorphine is a major concern. Average spending for the medication alone is typically more than \$300 per month—roughly \$100 more than average Medicaid payments for methadone maintenance. In several states buprenorphine is among the most expensive medications covered by Medicaid. Citing both cost and safety concerns, most Medicaid programs now require prior authorization to fill prescriptions, limit treatment duration, or impose other requirements.¹¹ For example, Washington's Medicaid program limits prescriptions to fourteen days and requires drug screening before reauthorization of prescriptions.

There is little research to guide policies about access or that assesses the impact of buprenorphine on overall Medicaid spending. This is a concern because policies focused only on the cost of a particular treatment may overlook the treatment's effects on other health care use. For example, there is ample evidence that substance abuse treatment can lower use of emergency care and hospitalization, saving money in some cases.^{12,13} Furthermore, higher treatment costs may be justified if there is a corresponding benefit from better outcomes.

To provide better information for Medicaid administrators and policy makers, we analyzed Massachusetts Medicaid (MassHealth) claims for all beneficiaries with a diagnosis of opioid addiction during the five years following the introduction of buprenorphine in 2003. Our analysis compared the impact of the alternatives of methadone maintenance, buprenorphine, drug-free treatment, and no treatment on Medic-

aid spending for all health care, on use of relapse-related services (such as hospitalization or emergency department visits related to resumption of substance abuse), and on mortality.

We found that buprenorphine was associated with more relapses but lower overall spending than methadone. Patients receiving drug-free treatment or no treatment had higher relapse rates and greater mortality than patients receiving either of the two opioid substitution treatments. Enrollment patterns suggest that buprenorphine expanded treatment access.

Study Data And Methods

Using MassHealth claims and enrollment data, we identified members ages 16–65 who had at least one diagnosis of opioid dependence between January 1, 2003, and December 31, 2007. We constructed a longitudinal database with monthly measures of total medical expenditures; service use and diagnosis-based variables for all types of health care; type of treatment received (buprenorphine maintenance, methadone maintenance, drug-free treatment, or no treatment); MassHealth eligibility status; and an indicator of whether the member died during the month. Mortality is recorded in the MassHealth eligibility file. We used Chronic Disease Payment System scores as a measure of illness burden.¹⁴

TREATMENT GROUPS We defined *buprenorphine treatment* as having an opioid diagnosis and a prescription for the medication or for the more commonly used combination of buprenorphine and naloxone. We used procedure codes to identify methadone maintenance. Patients with opioid dependence who received outpatient or residential behavioral treatment and no buprenorphine or methadone treatment were classified as receiving drug-free treatment. MassHealth members with a primary opioid diagnosis but no evidence of opioid substitution therapy or behavioral treatment throughout the study period were considered to have had no treatment.

OUTCOME MEASURES Spending included MassHealth payments for all types of care: treatment for medical conditions, psychiatric disorders, and addiction. These multiple types of care reflect the broad impact that addiction can have on medical costs through drug overdoses, higher rates of accidents and illness, poor self-care, and more complicated treatment of chronic illness.¹⁵

We adjusted spending to 2007 dollars using the Medical Care Component of the Northeast Region Consumer Price Index. We combined outpatient detoxification, inpatient, and emergency

department events with a primary diagnosis of a substance use disorder into a single outcome measure of relapse-related service use for a given month. We assumed that a treatment was more effective if it was associated with fewer relapse-related events. We calculated mortality rates within treatment episodes.

ANALYSIS To assess differences between treatment groups in spending, relapse events, and mortality, we adopted an intent-to-treat approach that began a treatment episode during the first month in which there was evidence of a particular treatment. Intent to treat, typically used in clinical trials, attributes all patient outcomes to their original treatment, even if patients switch to another treatment or drop out of treatment altogether. Our procedure was similar to a clinical trial without random assignment: Individuals were assigned to distinct treatment groups and followed for a defined period of time. Thirty-eight percent of members had more than one episode of treatment. All episodes were included in the study, except those that were already under way in January 2003.

Some physicians use buprenorphine only for detoxification, which takes about fourteen days.¹⁶ Because these cases could not be distinguished from those where longer-term opioid substitution therapy was intended but terminated shortly after treatment began, we conducted separate analyses with different beginning dates. The first analysis, combining short-term-only and maintenance patients, began in the month in which treatment started. The second analysis, eliminating short-term patients, began in the month following treatment initiation (month 2).

Both analyses followed MassHealth members for a full six months. We chose a six-month observation period because the average buprenorphine and drug-free treatment episodes were three months and two months, respectively. Cumulative spending and outcomes would be larger if patients were followed for a longer period; however, we would be less confident in attributing these outcomes to the original treatments.

We experimented with various solutions to the problem of biased selection, which may occur in the absence of random assignment. Controlling for a number of potential differences that could be measured with available data, we used propensity score matching,¹⁷ repeated measures regression, and generalized estimating equations—all of which yielded similar results. For simplicity, we report findings from generalized estimating equations.

Access to data was granted by the Massachusetts Executive Office of Health and Human Services. The study was approved by the University

of Massachusetts Medical School's Institutional Review Board.

LIMITATIONS A key consideration in this study is whether any unobserved differences in the characteristics of buprenorphine, methadone, and drug-free treatment users influenced spending and outcome measures. We were able to control for a number of important factors, such as various comorbidities, overall illness burden, and prior treatment, but it is conceivable that unmeasured factors such as motivation or family support were different across treatment groups. We cannot rule out the possibility of selection bias. However, results of our treatment comparisons are largely consistent with randomized clinical trials comparing buprenorphine, methadone, and drug-free treatment, which suggests that any remaining bias is minimal.

The administrative data used for this analysis did not allow us to define precisely the type of drug-free treatment received. It is likely that some forms may have been more effective than others. Also, our analysis was limited to Medicaid expenditures. A small number of members may also have accessed services funded separately by the Massachusetts Bureau of Substance Abuse Services; if so, this spending was not captured in our data. Finally, several studies have shown that treatment for opioid addiction reduces criminal justice involvement and spending.¹⁸⁻²¹ From a societal perspective, our analysis almost certainly underestimates the economic benefits of effective treatment in this larger sense.

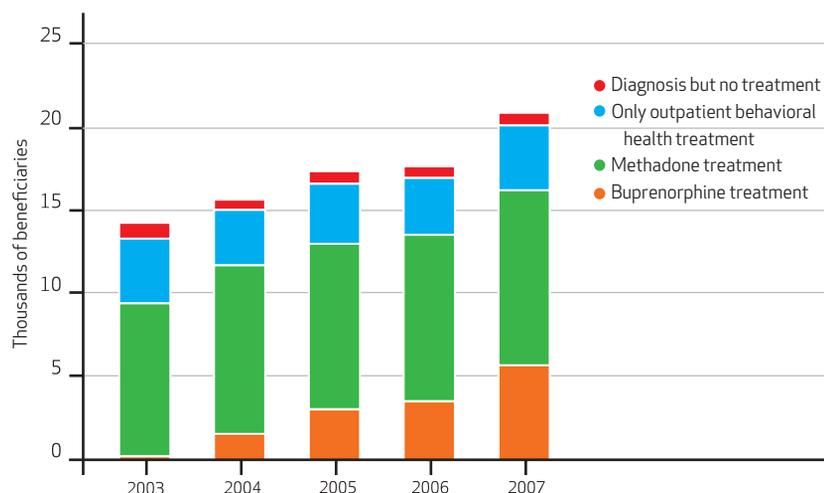
Study Results

We identified 33,923 MassHealth members who had a diagnosis of opioid dependence between January 1, 2003, and December 31, 2007, representing 53,557 treatment episodes. During that period the number of members with opioid dependence grew by 6,601: from 14,237 in 2003 to 20,838 in 2007. We found no evidence of Medicaid-funded addiction treatment for 1,955 (5.8 percent) of the 33,923 members with an opioid dependence diagnosis.

An increasing number of MassHealth members received buprenorphine treatment in the years following its introduction in 2003 (Exhibit 1). By 2007, 27.3 percent of the 20,838 members with opioid dependence were treated with buprenorphine at some point during the year. The numbers of members using other modalities remained approximately constant, with a small increase in methadone maintenance. Thus, most of the growth in opioid addiction treatment appears to be related to buprenorphine availability.

EXHIBIT 1

Opioid Addiction Treatment Among MassHealth Beneficiaries, 2003-07



SOURCE Authors' analysis of MassHealth claims. **NOTES** Each bar indicates the total number of individuals with an opioid dependence diagnosis during a given year. Individuals may be counted in multiple years.

Exhibit 2 describes characteristics of each treatment group. Those receiving opioid substitution therapy had a slightly higher overall illness burden than those who used only drug-free treatment, which suggests that more high-cost conditions are present in the opioid substitution group.

SPENDING Unadjusted results including the month of treatment initiation showed slightly higher spending for buprenorphine than methadone (Exhibit 3). Total expenditures associated with both forms of opioid substitution therapy were lower than those for drug-free treatment but slightly higher than for no treatment. Results were similar when short-term cases were eliminated. When episodes began in the second month, spending was lower for all groups, but particularly for the no-treatment group.

After adjusting for differences in characteristics of patients who entered the various treatments (Exhibit 4), spending for methadone patients was not significantly higher than for buprenorphine patients when episodes included short-term use (\$29 more per month, $p = 0.07$). Methadone patients were significantly more

EXHIBIT 2

MassHealth Patients' Characteristics, By Types Of Treatments For Opioid Dependence At Initial Enrollment

Characteristics	Treatments for opioid dependence			
	Buprenorphine (n = 10,248)	Methadone (n = 16,691)	Drug-free (n = 13,768)	None (n = 1,955)
Sex				
Female	43%	42%	43%	34%
Male	57%	58%	57%	66%
Age in years, mean (SD)	33.6 (9.9)	33.9 (9.7)	34.0 (9.9)	34.6 (10.6)
White race	66%	64%	63%	50%
Dual-eligibility	7%	2%	<1%	0%
Plan type				
Managed care	25%	28%	24%	38%
Primary care clinician plan	58%	64%	66%	45%
Fee for service	17%	8%	10%	17%
Overall Illness Burden, CDPS score, mean (SD)	0.79 (0.90)	0.82 (0.91)	0.65 (0.79)	0.64 (0.77)
No. of mental health comorbidities, mean (SD)	1.26 (1.37)	1.02 (1.28)	1.68 (1.50)	0.54 (1.01)
No. of physical comorbidities, mean (SD)	0.56 (0.91)	0.58 (0.93)	0.68 (0.99)	0.51 (0.96)
Percentage receiving other treatments, 2003-07 ^a				
Methadone	34%	100%	24%	0%
Buprenorphine	100%	21%	21%	0%
Drug-free	28%	20%	100%	0%
Medicaid coverage in the 12 months prior to treatment initiation				
12 months continuous	66%	56%	66%	62%
9-11 months	18%	20%	17%	14%
1-8 months	15%	21%	16%	24%
0 months	<1%	3%	<1%	<1%

SOURCE Authors' analysis of MassHealth claims. **NOTES** Statistical tests for differences were not conducted, as these are partially overlapping groups. Total number of patients including overlap is 42,662; total unique patients is 33,923; total number of treatment episodes is 53,557. SD is standard deviation. CDPS is chronic illness and disability payment system. ^aOther treatment categories are not mutually exclusive.

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EXHIBIT 3

Medicaid Spending, Number Of Relapse Events, And Death Within Six Months Of Treatment Initiation Among MassHealth Patients

Characteristics	Including short-term use				Maintenance treatment			
	Buprenorphine	Methadone	Drug-free	None	Buprenorphine	Methadone	Drug-free	None
No. of patients	10,248	16,691	13,768	1,955	9,927	16,458	13,513	1,402
No. of episodes	12,528	20,062	19,012	1,955	12,098	19,721	18,553	1,402
Monthly Medicaid expenditure per person ^a	\$1,220	\$1,159	\$1,516	\$1,087	\$1,101	\$1,135	\$1,292	\$734
No. of relapse events ^b	46	28	71	140	33	19	57	29
No. (percent) of deaths	29 (0.28%)	55 (0.33%)	83 (0.60%)	14 (0.72%)	31 (0.31%)	54 (0.27%)	84 (0.45%)	12 (0.86%)

SOURCE Authors' analysis of MassHealth claims. ^aInflation-adjusted to 2007 dollars using the Medical Care Component of the Northeast Region Consumer Price Index. ^bPer 1,000 member-months.

costly when episodes began in the second month (\$111 more per month, $p < 0.001$). Spending was significantly higher for methadone patients when dollar values were logarithmically transformed to reduce the influence of unusually expensive cases on overall results.

Results of the comparison between buprenorphine and drug-free treatment were mixed, with significantly higher spending for drug-free treatment using raw dollars and a nonsignificant trend toward lower expenditures in log-transformed models. No treatment was significantly more expensive than buprenorphine when episodes included short-term use and was less expensive in the model excluding short-term use. (Exhibit 4).

RELAPSE-RELATED EVENTS Frequency of relapse events, such as hospitalizations, emergency department visits, and detoxifications, was lower for methadone than buprenorphine, regardless of whether an episode included short-

term use of buprenorphine. Patients enrolled in drug-free treatment experienced significantly more relapse events than either opioid substitution treatment group. Relapse events were highest in the no-treatment group when the observation period began during the month in which the index diagnosis first appeared, but were lower than in the buprenorphine group when the period began with the month after identification.

Multivariate findings were consistent with the unadjusted results. As shown in Exhibit 5, odds of relapse-related events were 28 percent lower for methadone than for buprenorphine patients (0.72 compared to 1.00), 25 percent higher for drug-free patients (1.25 compared to 1.00), and almost three times higher for the no-treatment group than for buprenorphine patients. Differences between buprenorphine and no treatment were reversed in the model excluding short-term use of buprenorphine. Members receiving no

EXHIBIT 4

Medicaid Spending Per Person Per Month For Different Treatment Groups Within Six Months Of Treatment Initiation, MassHealth Patients

Number of episodes, by treatment group	Including short-term use (n = 53,544)			Maintenance treatment (n = 51,362)		
	Expenditure per person per month (\$) ^a	95% CI	p value	Expenditure per person per month (\$) ^a	95% CI	p value
Buprenorphine (reference)	1.0	—	—	1.0	—	—
Methadone	28.7	(-2.6, 60.1)	0.07	110.8	(77.9, 143.7)	<0.001
Drug-free	50.0	(12.7, 87.3)	0.01	-14.8	(-53.6, 24.0)	0.45
None ^b	148.5	(46.3, 250.8)	<0.001	-137.3	(-250.8, -23.7)	0.02

SOURCE Authors' analysis of MassHealth claims. **NOTE** CI is confidence interval. ^aBeta coefficients from regression analysis on total Medicaid spending using generalized estimating equations. Adjusted for age; sex; illness burden; race; number of co-occurring mental disorders and physical disorders; dual Medicare coverage; Medicaid plan type (fee-for-service, managed care, primary care clinician plan); and previous treatment episodes with buprenorphine, methadone, and drug-free modalities. All coefficients are in comparison to buprenorphine; for example, 28.7 = 28.70 more spending per month than buprenorphine. ^bFor the no-treatment (none) group, maintenance treatment refers to the six-month period beginning one month after diagnosis. Patients did not receive maintenance treatment. Full results of the model are available in the online Appendix. (To access the Appendix, click on the Appendix link in the box to the right of the article online.)

EXHIBIT 5

Deaths And Relapse-Related Service Use For Different Treatment Groups Within Six Months Of Treatment Initiation, MassHealth Patients

No. of episodes, by treatment group	Relapse-related use						Deaths					
	Including detoxification-only use (n = 53,544)			Maintenance treatment (n = 51,385)			Including detoxification-only use (n = 53,544)			Maintenance treatment (n = 51,385)		
	Odds ratio	95% CI	p value	Odds ratio	95% CI	p value	Odds ratio	95% CI	p value	Odds ratio	95% CI	p value
Buprenorphine (reference)	1.0	—	—	1.0	—	—	1.0	—	—	1.0	—	—
Methadone	0.72	0.67, 0.78	< 0.001	0.68	0.62, 0.74	< 0.001	0.91	0.60, 1.38	0.65	0.83	0.55, 1.26	0.39
Drug-free	1.25	1.17, 1.34	< 0.001	1.3	1.20, 1.40	< 0.0001	1.75	1.14, 2.67	0.01	1.52	1.00, 2.30	0.05
None ^a	2.97	2.63, 3.35	< 0.001	0.77	0.62, 0.96	0.02	2.25	1.12, 4.52	0.02	2.52	1.22, 5.24	0.01

SOURCE Authors' analysis of MassHealth claims. **NOTES** Adjusted for age; sex; illness burden; race; number of co-occurring mental disorders and physical disorders; dual Medicare coverage; Medicaid plan type (fee-for-service, managed care, primary care clinician plan); and previous treatment episodes with buprenorphine, methadone, and drug-free modalities. ^aFor the no-treatment (none) group, maintenance treatment refers to the six-month period beginning one month after diagnosis. Patients did not receive maintenance treatment. Full results are available in the online Appendix. (To access the Appendix, click on the Appendix link in the box to the right of the article online.)

treatment had about 23 percent lower odds than buprenorphine patients of relapse in analyses beginning in the month after the initial diagnosis.

MORTALITY Six-month mortality rates were 23–26 per 10,000 buprenorphine patients, 26–27 per 10,000 methadone patients, 44–45 per 10,000 drug-free patients, and 72–86 per 10,000 patients who received no treatment.

After adjustment for confounders, odds of death were 75 percent higher among drug-free treatment patients than buprenorphine patients when short-term use was included and 52 percent higher ($p < 0.05$) in long-term use. Members without treatment had 2.2 to 2.5 times higher odds than buprenorphine patients of dying during the six months after identification. There was no significant difference in odds of death between buprenorphine and methadone patients.

Discussion

After adjustments for confounding factors, total health care spending for patients using buprenorphine treatment were slightly lower than for methadone, despite more frequent relapse events for buprenorphine. Longer and more expensive hospital stays among methadone patients accounted for the largest portion of the difference. Spending for the drug-free and no-treatment groups were highly skewed but significantly less than for buprenorphine after logarithmic transformation to approximate a normal distribution.

Patients using drug-free treatment had relapse events more often than those using buprenorphine. Also, patients entering either type of opioid substitution therapy were less likely to

die during the six-month observation period than patients using drug-free treatments. Patients who received no treatment were at the greatest risk of death in the six months following identification.

Inconsistent findings for the no-treatment group in the analyses including and excluding short-term treatment may be due to a number of factors. For example, some patients could have become abstinent after a life-threatening relapse or overdose event, thus using less treatment. Others may have spent time in prison, where services are not Medicaid reimbursable. Still others may have become homeless. The lower spending and relapse rates observed in this group do not necessarily mean that its members fared better than those receiving treatment. The substantially higher death rates suggest that many in this group were in poor health and, possibly, underusing health care.

These findings were robust to various model specifications and statistical approaches. Trends remained the same when the observation period was extended to twelve months.

During the period covered by this study, buprenorphine/naloxone (Suboxone) was under patent protection. Patent protection for Suboxone has expired, but no generic version has been introduced to date. If one were introduced in the future, it would be likely to lower the cost of buprenorphine treatment, making the drug significantly less expensive than methadone and, possibly, less costly overall than drug-free treatment.

Policy Significance

BUPRENORPHINE VERSUS METHADONE Annual spending per person for buprenorphine was

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\$1,330 lower than methadone when both were used in maintenance treatment and was not significantly different when short-term use was included. Thus, the perception that savings can be obtained by restricting access to buprenorphine is not supported by this analysis. Further, unrestricted access to buprenorphine treatment does not seem to increase Medicaid enrollment, because the majority of patients receiving buprenorphine treatment were already MassHealth members in the twelve months prior to treatment initiation.

The fewer relapse events observed for methadone patients than for buprenorphine patients is consistent with clinical trials. This suggests that methadone has some clinical advantages, including the greater likelihood that patients will stay in treatment.^{4,6} These advantages must be weighed against the additional expense and, perhaps more important, the feasibility of switching from one treatment to another. Given differences in the underlying characteristics of buprenorphine and methadone users and the increased likelihood of relapse during a treatment transition, it may be difficult or even risky to induce buprenorphine patients to switch to methadone or vice versa. Only 15 percent of patients switched from one form of opioid substitution therapy to another during the study period.

BUPRENORPHINE VERSUS DRUG-FREE TREATMENT Average spending in the drug-free treatment group was lower than in the buprenorphine or methadone groups after adjusting for confounders; however, higher relapse and death rates suggest that it was less effective and riskier than opioid substitution therapy. These differences are consistent with other studies^{21,22} and may be partially explained by shorter duration of treatment—most drug-free patients dropped out of treatment in the first two months—compared with buprenorphine, for which the average length of treatment was three months (including short-term cases), and methadone, for which average treatment length extended to eleven months.

Given the potential cost in human life, drug-free treatment does not appear to be a viable alternative for opioid dependent patients, although it is effective for other forms of substance abuse.

OPIOID SUBSTITUTION THERAPY VERSUS NO TREATMENT The no-treatment group was at significantly greater risk of death during the six-month follow-up period than patients using buprenorphine or methadone. Other studies have

found significantly higher mortality rates for opioid-dependent individuals who drop out of treatment.²³

Findings for relapse were mixed due to the concentration of relapse events during the first month of the observation period. Many relapse events in the no-treatment group occurred as the result of a hospitalization or emergency department visit during the first month, which suggests the existence of a crisis related to an overdose or similar life-threatening event. Afterward, spending was significantly lower than for the opioid substitution therapy groups. This suggests that the no-treatment group was not firmly engaged with the health care system. However, relapses after the first month were more frequent in the no-treatment group than in medication-assisted groups.

Conclusions

Evidence does not support the belief that restricting access to buprenorphine lowers Medicaid expenditures or reduces mortality. Spending could actually increase if treatment shifted from buprenorphine to methadone, while a similar shift to drug-free treatment might increase relapse events and deaths. The relatively small proportion of patients who switched from one type of treatment to another suggests that patients and providers have distinct treatment preferences, or that barriers such as fear of experiencing withdrawal or difficulty in finding an alternative provider impede easy transitions from one treatment to another. Patients who find it difficult to access buprenorphine might not readily shift to methadone or drug-free treatment.

Although further studies measuring the impact of policies that restrict access to buprenorphine are needed, this analysis suggests that significant reductions in its use could have the unintended effect of increasing costs. Also, if it reduces overall use of opioid substitution therapy, a policy restricting buprenorphine use might also contribute to higher mortality among Medicaid beneficiaries with opioid addiction.

Finally, this analysis shows the importance of considering a broad range of costs and outcomes when attempting to implement targeted cost reductions. Failing to consider the impact of medications or other expensive treatments on total health care spending and outcomes could have the unintended effect of increasing costs and placing patients at greater risk. ■

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Robin E. Clark is an associate professor at the University of Massachusetts Medical School.

In *Health Affairs* this month, Robin Clark and colleagues report on how they mined Massachusetts Medicaid data to explore the relative costs and benefits of buprenorphine. The drug is a relatively new treatment for opioid addiction that, under federal law, may be prescribed to patients on an outpatient basis and taken at home. In contrast, methadone must be taken in clinics, an arrangement that some patients find inconvenient and stigmatizing.

Many states have restricted the use of buprenorphine for Medicaid patients out of the belief that it is more expensive than methadone. Yet Clark's team found that although buprenorphine costs more per dose, it is actually cheaper than methadone in the long run because its use leads to shorter and less frequent hospitalizations. The two medications had similar mortality rates and were both far better options than drug-free treatment.

"Our paper shows that the cost concerns aren't so valid if you look at everything you're spending," says Clark, adding that buprenorphine has expanded access to treatment by drawing large numbers of working people.

Clark is an associate professor of family medicine and community health and of quantitative health

sciences at the University of Massachusetts (UMass) Medical School. He is also director of research and evaluation at UMass's Center for Health Policy and Research, where he studies the economic aspects of health care interventions and policies. He focuses mainly on underserved populations, analyzing treatment patterns and costs of mental illness and substance abuse disorders among Medicare beneficiaries. Before coming to UMass in 2003, he was an associate professor of psychiatry and community and family medicine at Dartmouth Medical School.

Clark received a doctorate in social policy at Brandeis University and a master's degree in human development and family relations at the University of Connecticut.



Mihail Samnaliev is a lecturer in health economics in the clinical research program of Children's Hospital in Boston.

Mihail Samnaliev is a lecturer in health economics in the clinical research program of Children's Hospital in Boston, where he conducts cost-effectiveness analyses and other evaluations of clinical interventions and health programs. Between 2004 and 2010, he was an instructor in the Department of Family Medicine and Community Health at the UMass Medical School, where he studied costs and outcomes among people with substance abuse disorders. He

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Gary Y. Leung is a statistician at the North Carolina Central Cancer Registry.

Gary Leung is a statistician at the North Carolina Central Cancer Registry, run by the North Carolina State Center for Health Statistics. He focuses on disparities in health outcomes and quality. He coauthored this article while completing his doctorate in clinical and population health research at UMass.



Relationship Between Buprenorphine Adherence and Health Service Utilization and Costs Among Opioid Dependent Patients

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ABSTRACT

Buprenorphine-medication assisted therapy (B-MAT) is an effective treatment for opioid dependence, but may be considered cost-prohibitive based on ingredient cost alone. The purpose of this study was to use medical and pharmacy claims data to estimate the healthcare service utilization and costs associated with B-MAT adherence among a sample of opioid dependent members. Members were placed into two adherence groups based on 1-year medication possession ratio (≥ 0.80 vs. < 0.80). The B-MAT adherent group incurred significantly higher pharmacy charges (adjusted means; \$6,156 vs. \$3,581), but lower outpatient (\$9,288 vs. \$14,570), inpatient (\$10,982 vs. \$26,470), ER (\$1,891 vs. \$4,439), and total healthcare charges (\$28,458 vs. \$49,051; $p < 0.01$) compared to non-adherent members. Adherence effects were confirmed in general linear models. Though B-MAT adherence requires increased pharmacy utilization, adherent individuals were shown to use fewer expensive health care services, resulting in overall reduced healthcare expenditure compared to non-adherent patients.

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Opioid dependence is a substance use disorder characterized by compulsive opioid use typically resulting in the development of tolerance and withdrawal after a period of abstinence (American Psychiatric Association, 2000). Exposure to opioids in the United States is quite high. Americans consume 80% of the world's opioid supply despite representing only 4.6% of the global population (Manchikanti & Singh, 2008). Much of this opioid use comes from prescription opioids, which has contributed to a considerable increase in the illegitimate use of these substances (Fischer, Gittins, & Rehm, 2008; Zacny et al., 2003). It has been estimated that between 1990 and 2000, prescription opioid abuse increased as much as 400% (Substance Abuse and Mental Health Service Administration, 2003).

Opioid dependence imposes a significant economic burden on society, with annual societal costs estimated at over 55 billion dollars (Birnbaum et al., 2011). The majority of these costs are attributable to lost work productivity (46%) and health care costs (45%), with criminal justice costs (9%) making up the balance (Birnbaum et al., 2011). A hidden cost of opioid dependence is increased healthcare costs for comorbid medical and psychiatric illness. For example, among commercially insured individuals, opioid abusers have higher rates of medical and pharmacy utilization, an increased number of comorbidities including poisoning, hepatitis, psychiatric illnesses, and pancreatitis, and may incur as much as 8 times the total healthcare expenditure as non-abusers (White et al., 2005).

Studies have consistently demonstrated the positive economic impact of effectively treating substance abuse disorders (McCollister & French, 2003), including opioid dependence (Doran, 2008). Currently, there are several options available for the treatment of opioid dependence, including behavioral therapies or medication assisted treatment using full opioid agonists (i.e. methadone), partial μ -opioid agonists (buprenorphine), or opioid antagonists (naltrexone). This study focuses on buprenorphine, which is an increasingly popular treatment given that its combination with naloxone has been shown to minimize abuse and diversion while being effective to help relieve withdrawal symptoms (Johnson & McCagh, 2000). Buprenorphine-medication assisted therapy (B-MAT) has been shown to be effective in the treatment of opioid dependence both as maintenance medication and for supervised withdrawal from opioids (McCance-Katz, 2004), however it is not clear if it is more cost-effective to use buprenorphine for short term symptom relief or for long term maintenance. Under the provisions of the Drug Addiction Treatment Act of 2000, physicians can obtain a waiver to prescribe and dispense buprenorphine in an office-based setting, which also entails weekly patient visits during the initial phase of treatment, followed by an eventual reduction to monthly visits once the maintenance phase of treatment is reached (Substance Abuse and Mental Health Service Administration, 2004). Therefore, the long term use of buprenorphine will be associated with more frequent outpatient treatment visits and the increased costs of the medication. It is unclear if the additional costs of consistent, long term use of B-MAT will be offset by savings in other health care costs.

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Medication adherence has been linked to improved outcomes across a variety of chronic diseases states, (DiMatteo, Giordani, Lepper, & Croghan, 2002; Roebuck, Liberman, Gemmill-Toyama, & Brennan, 2011), and is considered a top public health priority (Bosworth & The National Consumers League, 2011). Adherence with B-MAT has already been shown to reduce the incidence of subsequent relapse among an opioid dependent sample (Tkacz, Severt, Cacciola, & Ruetsch, 2012), however little published work has examined the impact of adherence on specific healthcare utilization and expenditure. Although a more expensive ingredient, buprenorphine has been shown to result in significantly lower overall healthcare expenditure during the first 6 months of treatment compared to methadone treatment, with no difference during subsequent months (Barnett, 2009). The objective of the present study was to examine the relationship between B-MAT adherence and healthcare service utilization and costs among a commercially-insured sample of patient diagnoses with opioid dependence or abuse. It was hypothesized that B-MAT adherence would result in higher pharmacy utilization, but ultimately lower overall healthcare costs.

1. Materials and methods

1.1. Sample Selection

Aetna (Blue Bell, PA) provided medical, pharmacy and membership data for their opioid dependent commercial, fully insured HMO members during Q1 2007 through Q3 2012. All claims were de-identified, and the study was approved by Aetna's safety committee on human research protection. To identify the final study sample, the following inclusion and exclusion criteria were imposed:

1. an initial buprenorphine fill (branded or generic) on record appearing between 1/1/08 and 10/31/11 (hereafter referred to as the index date);
2. primary diagnosis of opioid dependence (304.0x), opioid abuse (305.5x) or opioid poisoning (965.0x) within 180 days of the index date; and
3. continuously and full eligibility for benefits for 6 months prior to and 12 months following the index date.

The sample attrition at each inclusion criterion imposition may be viewed in Fig. 1.

1.2. Measurement Window

The 6 months immediately preceding the index date was defined as the study pre-period, and served two purposes:

- 1) to effectively identify the first B-MAT fill, and
- 2) to generate a baseline measure of health.

The 12 months immediately following the index date served as the study post-period where the study's primary endpoints, outlined in the following section, were assessed.

1.3. Measures

Demographic variables of age, gender, and region of residence were obtained from the membership table. Health status during both the pre- and post-periods was estimated using the Charlson Comorbidity Index (Charlson, Pompei, Ales, & MacKenzie, 1987). The following health service outcomes served as the primary dependent variables, and were measured during both pre- and post-periods:

- total prescription fills (adjusted for 30-day supplies) and charges
- opioid fills, days' supply, and charges
- inpatient hospital admissions, days, and charges
- ER visits and charges

- outpatient visits and charges
- total medical charges
- total healthcare charges (medical + pharmacy charges)

A maximum of one inpatient admission and ER visit were assumed per day. Multiple outpatient visits were allowed in a single day, though they must have been associated with unique provider IDs. Persistence with B-MAT was measured as the number of days between the index date and the most recent B-MAT fill + the days supply value of the last fill. No adjustments were made for gaps in treatment. Paid amounts and allowed amounts were unavailable in the dataset, therefore charges were used as a proxy for healthcare expenditure (Lee, Balu, Cobden, Joshi, & Pashos, 2006; Salas, Hughes, Zuluaga, Vardeva, & Lebmeier, 2009; Sokol, McGuigan, Verbrugge, & Epstein, 2005).

1.4. Placement into B-MAT Adherence Groups

B-MAT adherence was estimated using the medication possession ratio (MPR), in which the total days' supply of a medication is divided by the length of the study window (Cooper, Hall, Penland, Krueger, & May, 2009). Therefore, B-MAT MPR for the current study was measured using the following formula:

$$\frac{\text{total days' supply of B-MAT in post-period}}{365 \text{ days(one-year post-period)}}$$

Members with an MPR ≥ 0.80 were categorized as adherent, while those with an MPR < 0.80 were categorized as non-adherent (Peterson et al., 2007).

1.5. Bivariate Analyses

Across the two adherence groups, means and standard deviations were reported for all continuous outcome measures, while proportions were reported for categorical measures. Chi-square tests of equality of proportions were used to assess statistically significant differences between groups on categorical variables, while and student's t-tests were used to assess group differences on age, persistence, and the Charlson Comorbidity Index. The Kruskal–Wallis test was used to measure group differences on post-period service utilization and charge measures. Additionally, analyses of covariance were conducted on all service utilization and charge measures controlling for gender, region of residence, age, pre-period value, and post-period Charlson Comorbidity Index in order to estimate adjusted means.

1.6. Multivariate Analyses

Post-period service utilization counts and charges were adjusted for gender, region of residence, age, post-period Charlson Comorbidity Index, pre-period value, and B-MAT adherence using generalized linear models. Service utilization outcomes were entered into negative binomial models, as overdispersion was present. Cost outcomes were entered into gamma models with a log-link. Marginal effects and standard errors were reported. The marginal effect of a given variable on health service and utilization outcome (dy/dx) was computed while holding all other regressors constant at their means. All data management, descriptive analyses, and bivariate analyses were conducted using SPSS v. 20 (SPSS Inc., Chicago), while multivariate analyses were conducted using STATA v.13 (StataCorp LP, College Station).

B-MAT Adherence 25

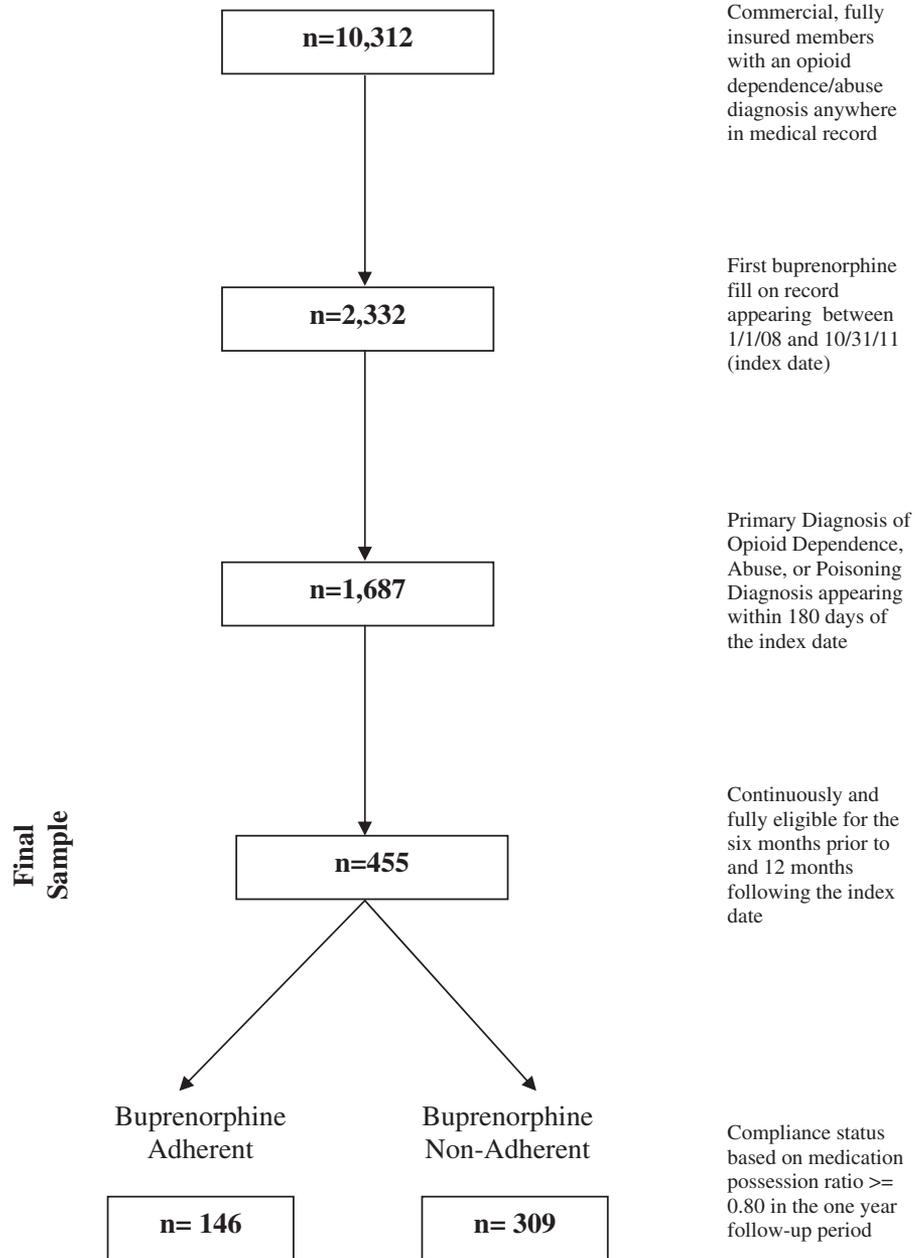


Fig. 1. Sample Attrition.

2. Results

A total of 455 B-MAT treated members met inclusion into the study. The majority of the sample were males (64.2%) living in the northeast (43.3%) and southeast (35.4%) regions of the U.S. The mean age of the sample was 33.8 ± 12.9 .

Table 1 presents descriptive statistics by adherence groups, including unadjusted mean healthcare service utilization rates and charges. A total of 146 (32%) members met criteria for B-MAT adherence, with the remaining 309 (68%) meeting criteria for B-MAT non-adherence. B-MAT adherent members were significantly older (35.8 vs. 32.8; $p < 0.025$) and were in better overall health at baseline as measured by the Charlson (0.14 vs. 0.29; $p < 0.05$), but did not differ on the remaining demographic characteristics. The average B-MAT

adherent group member filled 15.7 B-MAT prescriptions in the 1-year follow-up period, covering 367 days of therapy at a gross cost of \$4,201. The average B-MAT non-adherent group member filled 5.4 B-MAT prescriptions in the 1-year follow-up period, covering 104 days of therapy at a gross cost of \$1,094. All three B-MAT measures were significantly greater for the B-MAT adherent group ($p < 0.001$). The majority of B-MAT prescriptions filled across both groups were for the Suboxone® formulation (90.0% vs. 84.9%; $p > 0.05$).

Table 2 displays unadjusted mean health services utilization and charges. Total pharmacy use was significantly higher in the B-MAT adherence group (32.8 fills vs. 25.8; $p < 0.001$), and the associated charges were also higher (\$6,156 vs. \$3,581; $p < 0.001$). Inpatient hospital and ER utilization were also more heavily consumed by B-MAT non-adherent group members ($p < 0.001$). Total healthcare

Table 1
Sample description.

	Buprenorphine Non-Adherent			Buprenorphine Adherent			<i>p</i> ¹
	<i>n</i> = 309			<i>n</i> = 146			
	Mean	Percentages	Std. Dev.	Mean	Percentages	Std. Dev.	
Demographics							
Age	32.8		13.5	35.8		11.8	0.024
Male		63.8%			65.1%		0.785
Pre-Period Charlson	0.29		0.96	0.14		0.44	0.030
Region							
Mid-America		5.8%			8.2%		0.343
Northeast		41.4%			47.3%		
Southeast		37.9%			30.1%		
West		14.9%			14.4%		
Buprenorphine Treatment							
Fills	5.4		4.5	15.7		4.9	<0.001
Days' Supply	104		89	367		64	<0.001
Costs	\$1,094		\$1,034	\$4,201		\$1,871	<0.001
Persistence (days)	165		133	359		16	<0.001
Medication Possession Ratio	0.29		0.24	0.94		0.07	<0.001
Product							
Suboxone Only		90.0%			84.9%		0.250
Subutex Only		2.3%			2.1%		
Generic Buprenorphine Only		0.3%			0.0%		
Multiple Products		7.4%			13.0%		
Post-Period Service Utilization							
Prescription Fills	25.2		23.8	33.0		25.0	0.004
Outpatient Visits	29.8		28.3	26.3		25.3	0.306
Inpatient Hospital Admissions	1.32		3.47	0.25		0.72	<0.001
Inpatient Days	9.28		15.73	1.46		5.58	<0.001
ER Visits	1.57		3.09	0.79		1.71	<0.001
Post-Period Charges							
Pharmacy Charges	\$3,557		\$4,700	\$5,841		\$3,248	<0.001
Outpatient Charges	\$14,173		\$25,932	\$8,001		\$10,314	0.006
Inpatient Hospital Charges	\$26,043		\$61,280	\$6,003		\$21,083	<0.001
ER Charges	\$4,058		\$9,375	\$1,648		\$3,807	<0.001
Total Medical Charges	\$44,311		\$79,237	\$15,652		\$29,217	<0.001
Total Healthcare Charges	\$47,868		\$80,889	\$21,492		\$30,066	<0.001

The Kruskal–Wallis test was used to measure group differences on post-period service utilization and charge measures.

¹ Chi-square tests of equality of proportions were used to assess statistical significance of categorical variables, and student's t-tests were used for the age, persistence, and Charlson Comorbidity Index variables.

charges amounted to \$49,051 for B-MAT non-adherent members, compared to \$28,458 for B-MAT adherent members (*p* = 0.001).

Results from multivariate models of health services utilization and charges are presented in Table 3 and 4. Males utilized significantly fewer outpatient services compared to females (*p* < 0.001). Age was positively associated with pharmacy fills and charges (*p* < 0.001), but negatively associated with inpatient hospital admissions and days

(*p* < .05). Poorer health status, as measured by the Charlson Comorbidity Index, was positively associated with all outcomes (*p* < .001). Regarding the main predictor of interest, medication adherence, B-MAT adherent group members filled an average of 8 more prescriptions and incurred \$2504 greater pharmacy charges as did non-adherent group members (*p* < .001). Contrarily, B-MAT adherent members incurred \$4,793 less in outpatient charges than B-MAT adherent members (*p* < .001), although no statistically significant difference in outpatient utilization emerged. Regarding high-cost services, compared to the non-adherent group, B-MAT adherent members were significantly less likely to be admitted to both an inpatient hospital facility and the ER (*p* < .001), translating into total medical charges of \$26,226 less than the non-adherent group (*p* < .001). Overall, after controlling for demographics, prior year healthcare charges, and health status, the total healthcare charges of the average B-MAT adherent member were \$22,194 less than a non-adherent member (*p* < 0.001).

3. Discussion

Supporting the hypothesis, opioid dependent and abuse members who consistently obtained buprenorphine-medication assisted therapy (B-MAT) over the course of the year incurred significantly lower overall gross healthcare costs compared to B-MAT non-adherent members (adjusted means: \$21,492 vs. \$47,868). As expected, B-MAT adherence was associated with greater pharmacy utilization and expenditure, but reduced high-cost service utilization, including inpatient hospital and emergency room services. Results suggest that adherence with B-MAT may reduce the risk for

Table 2
Adjusted post-period means.

	Buprenorphine Non-Adherent		Buprenorphine Adherent		<i>p</i> ¹
	<i>n</i> = 309		<i>n</i> = 146		
	Mean	Std. Err.	Mean	Std. Err.	
Service Utilization					
Prescription Fills	25.8	1.0	32.8	1.4	<0.001
Outpatient Visits	30.1	1.8	27.3	2.3	0.264
Inpatient Hospital Admissions	1.41	0.20	0.52	0.26	<0.001
Inpatient Days	10.0	0.8	3.7	1.1	<0.001
ER Visits	1.61	0.17	0.78	0.22	<0.001
Charges					
Pharmacy Charges	\$3,581	\$205	\$6,156	\$269	<0.001
Outpatient Charges	\$14,570	\$1,430	\$9,288	\$1,871	0.011
Inpatient Hospital Charges	\$26,470	\$3,163	\$10,982	\$4,142	<0.001
ER Charges	\$4,439	\$547	\$1,891	\$717	<0.001
Total Medical Charges	\$45,381	\$4,047	\$22,409	\$5,298	<0.001
Total Healthcare Charges	\$49,051	\$4,108	\$28,458	\$5,376	0.001

Covariates appearing in model include gender, region of residence, age, Charlson Comorbidity index, and the pre-period value.

¹ Analysis of covariance was used to assess significant group differences.

Table 3
Marginal effect estimates from negative binomial models of health service utilization.

Predictor	Pharmacy Fills	Outpatient Visits	Inpatient Hospital Admissions	Inpatient Hospital Days	ER Visits
	b/(se)	b/(se)	b/(se)	b/(se)	b/(se)
B-MAT Compliant	7.69*** (−1.38)	−2.46 (−2.41)	−0.99*** (−0.16)	−7.52*** (−1.38)	−0.78*** (−0.18)
Male	−1.15 (−1.34)	−4.77** (−2.30)	0.07 (−0.13)	0.75 (−1.04)	−0.19 (−0.16)
Northeast Region	−1.69 (−2.64)	−0.01 (−4.63)	−0.21 (−0.25)	−5.00** (−2.16)	−0.09 (−0.32)
Southeast Region	−0.58 (−2.67)	0.32 (−4.68)	−0.40 (−0.26)	−6.85*** (−2.26)	−0.07 (−0.32)
West Region	1.68 (−2.93)	−0.17 (−5.15)	0.32 (−0.27)	−3.87 (−2.39)	0.03 (−0.35)
Age	0.16*** (−0.06)	−0.02 (−0.09)	−0.01* (−0.01)	−0.08** (−0.04)	0.00 (−0.01)
Charlson	1.88** (−0.81)	5.03*** (−1.48)	0.30*** (−0.10)	1.87** (−0.83)	0.27** (−0.12)
Pre-Period Value	0.91*** (−0.06)	0.53*** (−0.09)	0.10** (−0.05)	0.14*** (−0.06)	0.17*** (−0.04)

** $p < 0.05$.

*** $p < 0.001$.

expensive hospital-based services, and ultimately lead to a reduction in overall healthcare expenditure.

The study sample consisted primarily of males in their mid-thirties residing in the northeast and southeastern regions of the U.S. Supporting previous research, being female (Bertakis, Azari, Helms, Callahan, & Robbins, 2000) and older (Moorin, Gibson, Holman, & Hendrie, 2012) were both related to increases in specific healthcare service utilization and costs. Approximately one third of the sample ($n = 146$) demonstrated adherence with B-MAT over the course of the 1-year post-period. Analyses adjusting for case-mix revealed that B-MAT adherent group members incurred greater mean pharmacy charges (\$6,156 vs. \$3,581), but significantly lower outpatient, inpatient, and ER charges compared to B-MAT non-adherent group members. Interestingly, outpatient utilization, unlike the associated charges, did not differ between groups. These adherence effects were maintained in the general linear models, thereby ruling out demographic characteristics, prior healthcare service utilization, and current health status as accounting for group differences. Results of the multivariate analyses revealed that the B-MAT non-adherent group incurred approximately \$27,000 in greater medical charges

than the B-MAT adherent group, and over \$22,000 greater overall healthcare charges.

The treatment of opioid dependence with B-MAT has been shown to be more cost effective than no treatment (Schackman, Leff, Polsky, Moore, & Fiellin, 2012), detoxification treatment (Polsky et al., 2010), and likely equivalent to methadone treatment (Center for Health Program Development and Management, 2007). Surprisingly, only about a third of the patients in the present study exhibited good medication adherence, picking up medication on over 80% of the days in the year following treatment initiation. Strategies designed to enhance medication adherence are likely to result in even greater savings associated with B-MAT. Maximizing the use of effective pharmaceutical interventions in order to minimize use of other more expensive health care services such as hospital-based services is the most economical treatment approach. As B-MAT has already been shown to be effective in maintenance therapy (McCance-Katz, 2004), in reducing subsequent relapse to active opioid dependence (Tkacz, Severt, Cacciola, & Ruetsch, 2012), and may be suitable for both injection and pharmaceutical opioid abusers (Tkacz, Severt, Kassed, & Ruetsch, 2012), the real challenge now lies in increasing B-MAT adherence.

Table 4
Marginal effect estimates from gamma models of healthcare charges.

	Pharmacy Charges	Outpatient Charges	Inpatient Hospital Charges	ER Charges	Total Medical Charges	Total Healthcare Charges
	b/(se)	b/(se)	b/(se)	b/(se)	b/(se)	b/(se)
B-MAT Compliant	\$2504.53*** (−\$174.77)	−\$4793.49*** (−\$1485.6)	−\$21286.67*** (−\$3635.69)	−\$2451.63*** (−\$615.32)	−\$26225.80*** (−\$4382.15)	−\$22193.52*** (−\$4326.44)
Male	−\$243.56 (−\$241.86)	−\$290.67 (−\$1241.37)	−\$2736.23 (−\$2938.08)	−\$539 (−\$546.33)	−\$4413.15 (−\$3677.12)	−\$4945.87 (−\$3902.7)
Northeast Region	−\$278.52 (−\$370.94)	−\$1188.49 (−\$2131.8)	−\$2727.48 (−\$4602.26)	−\$1176.86 (−\$940.84)	−\$3156.99 (−\$5754.88)	−\$3337.9 (−\$5758.66)
Southeast Region	−\$569.92 (−\$378.41)	−\$1703.95 (−\$2166.48)	−\$11385.64** (−\$4728.09)	−\$1129.29 (−\$972.92)	−\$11203.34** (−\$5497.32)	−\$11875.16** (−\$5533.61)
West Region	−\$153.86 (−\$471.5)	\$3469.61 (−\$3323.37)	−\$1997.12 (−\$5113.45)	\$210.29 (−\$1088.72)	\$5017.44 (−\$7048.41)	\$4660.81 (−\$7425)
Age	\$33.73*** (−\$10.01)	\$24.74 (−\$45.88)	\$113.55 (−\$114.58)	\$5.42 (−\$19.78)	\$76.52 (−\$142.62)	\$128.98 (−\$146.49)
Charlson	\$490.52* (−\$275.47)	\$3130.54*** (−\$744.67)	\$9567.07*** (−\$3389.03)	\$850.65* (−\$506.43)	\$12516.63*** (−\$3834.24)	\$12731.38*** (−\$3454.95)
Pre-Period Value	\$0.66*** (−\$0.09)	\$0.24*** (−\$0.06)	\$0.09** (−\$0.05)	\$0.17*** (−\$0.05)	\$0.17*** (−\$0.06)	\$0.21*** (−\$0.07)

* $p < 0.10$.

** $p < 0.05$.

*** $p < 0.001$.

A number of methods have been shown to increase chronic medication adherence across a variety of disease states, including short message service reminders (Vervloet et al., 2012), motivational interviewing (Laakso, 2012), and behavioral feedback (Ruppar, 2010). Among opioid dependent patients in particular, participation in a telephonic care coaching program was shown to increase self-reported B-MAT medication adherence over a 1-year period (Ruetsch, Tkacz, McPherson, & Cacciola, 2012). SAMHSA (2004) has reported that comorbid psychiatric or substance abuse conditions, overall psychosocial stability, a patient's adherence history with other medications, and motivation may all potentially influence B-MAT non-adherence. Recently it was shown that early adherence to buprenorphine, lifetime abstinence from heroin, and early opioid negative urine screens were all associated with buprenorphine/naloxone treatment retention (Warden et al., 2012). Future studies are needed to examine additional causes of B-MAT non-adherence, in addition to testing new interventions aimed at ameliorating this problem. An implantable administration of buprenorphine has already shown some early promise (Ling et al., 2010). If adherence among B-MAT patients could be improved, and assuming that the present results remain in direction and magnitude across other health plans, lines of business, and from year to year, health plans may be able to experience considerable savings using B-MAT as a first line of treatment for opioid dependence supported by outpatient services such as office based providers and counselors. Hospital based services could be reserved for more severe cases or those with comorbidities that would make opioid detoxification or early treatment medically dangerous.

This study had several limitations. The primary limitation was the potential endogeneity of B-MAT adherence, meaning that there could be other unmeasured factors driving B-MAT adherence, service utilization, and/or charges, including disease severity. B-MAT adherent members were shown to be older and in better overall health compared to B-MAT non-adherent members, and it is possible that other unmeasured characteristic differences exist between groups which may partially explain the differences in adherence and healthcare outcomes. Unmeasured characteristics correlated with both B-MAT adherence and the dependent variables may lead to biased estimates. A study integrating patient surveys and/or medical charts with claims data may be able to identify predictors of B-MAT adherence. Additionally, an analysis employing pharmacy benefit design characteristics or patient proximity to B-MAT waived physicians as instrumental variables may elucidate some new effects. The identification of a true instrument for B-MAT adherence remains a challenge though, and it may simply be infeasible to correct for such endogeneity in the present database. A second limitation was the absence of the allowed amount, resulting in the use of the charge amount as a proxy for healthcare cost. Though it has been long documented that charges often do not reflect true patient costs (Finkler, 1982; Nomof, 1995), some studies investigating the effect of medication adherence on healthcare costs have continued to use charge amounts (Salas et al., 2009), and a number of organizations continue to develop more precise cost-to-charge ratios that may allow for reasonable cost estimates in the absence of such data (Dalton, Freeman, & Bragg, 2008; Healthcare Cost and Utilization Project, 2013). The parameter estimates from cost models in the present study may be viewed as overestimates of the true effects on costs; and given that the sample is comprised of patients belonging to the same diagnosis-related group (alcohol/drug dependence), these estimates are likely higher by some constant factor. Interested payers might apply their specific contractually negotiated discounts to these estimates in order to individualize the study findings. Another study limitation was the use of administrative claims data itself, which does not allow for the assessment of clinical outcomes and may include administrative coding errors (Tyree, Lind, & Lafferty, 2006). Finally, the common practice of using an MPR value of ≥ 0.80 to define adherence has recently come under scrutiny with some reporting that MPR values ≥ 0.90 may be more

appropriate (Watanabe, Bounthavong, & Chen, 2013). Sensitivity analyses around MPR, and adherence measures in general, should be conducted, and may likely differ across the various medication classes (Peterson et al., 2007).

In sum, among commercially insured opioid abusing members receiving buprenorphine treatment (B-MAT), one third demonstrated adherence during the course of a 1 year follow-up period. B-MAT adherence was associated with greater pharmacy utilization, but lower high-cost service utilization including inpatient hospital and emergency room services compared to non-adherence. Overall, after controlling for demographics, prior year service utilization, and current health status, the medical and total healthcare costs incurred by the average B-MAT adherent member was significantly less than B-MAT non-adherent members. The treatment of opioid dependence and related disorders with B-MAT may have value to health plans and providers interested in improving outcomes and containing costs. Given that a majority of members were non-adherent, future efforts should focus in increasing and maintaining medication adherence.

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Criminal justice outcomes after engagement in outpatient substance abuse treatment

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ABSTRACT

The relationship between engagement in outpatient treatment facilities in the public sector and subsequent arrest is examined for clients in Connecticut, New York, Oklahoma and Washington. Engagement is defined as receiving another treatment service within 14 days of beginning a new episode of specialty treatment and at least two additional services within the next 30 days. Data are from 2008 and survival analysis modeling is used. Survival analyses express the effects of model covariates in terms of "hazard ratios," which reflect a change in the likelihood of outcome because of the covariate. Engaged clients had a significantly lower hazard of any arrest than non-engaged in all four states. In NY and OK, engaged clients also had a lower hazard of arrest for substance-related crimes. In CT, NY, and OK engaged clients had a lower hazard of arrest for violent crime. Clients in facilities with higher engagement rates had a lower hazard of any arrest in NY and OK. Engaging clients in outpatient treatment is a promising approach to decrease their subsequent criminal justice involvement.

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1. Introduction

By focusing on arrests after treatment for substance use disorders, the goal of this study is to add to the emerging literature on the association of engagement in treatment (a process measure) and outcomes. Both process measures focused on the treatment that clients receive and outcome measures describing client status are important in monitoring the delivery of treatment for substance use disorders. Process measures offer two advantages: they are more immediately actionable and they are often more useful for identifying specific areas of care that may require improvement (Horgan & Garnick, 2005; Krumholz, Normand, Spertus, Shahian, & Bradley, 2007; McLellan, Chalk, & Bartlett, 2007). However, only processes of care that have a strong foundation of research showing an association with improved clinical outcomes should be used as performance measures (Chassin, Loeb, Schmaltz, & Wachter, 2010; Harris, Kivlahan, Bowe, Finney, & Humphreys, 2009).

We focus on the treatment engagement measure (described in the next section) developed over a decade ago by the Washington Circle (Garnick et al., 2002) which has been widely adopted, endorsed and adapted for use in various settings (Garnick et al.,

2011; Harris, Humphreys, Bowe, Tiet, & Finney, 2010; National Committee for Quality Assurance, 2010; National Quality Forum, 2009). It is important to study the outcome considered here—criminal justice involvement—because of its high cost to society and individuals (Harwood, 2000; Office of National Drug Control Policy, 2004; Zarkin et al., 2012). Criminal justice involvement also is a well-established outcome measure for substance abuse treatment (Gossop, Trakada, Stewart, & Witton, 2005; McLellan, Cacciola, Alterman, Rikoon, & Carise, 2006; Prendergast, Podus, Chang, & Urada, 2002). Nearly half of those arrested meet the criteria for an alcohol or other drug disorder (Kubiak, Arfken, Swartz, & Koch, 2006) and these disorders are prevalent in the prison population (Belenko & Peugh, 2005).

The purpose of this study, therefore, was to examine how adults' engagement in outpatient treatment in the public sector relates to subsequent involvement in the criminal justice system in the year after beginning treatment. Specifically, using treatment and criminal justice systems data from four states (Connecticut, New York, Oklahoma and Washington), we explored the following:

- The extent to which individual client and facility-level engagement in outpatient specialty treatment is associated with any arrest or specifically drug related arrests or property or violence related arrests

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- Whether the predictive relationships between client engagement in outpatient specialty treatment and criminal justice outcomes are affected by the client's pre-treatment criminal justice involvement.

1.1. Measure of treatment engagement

Treatment engagement is an important performance measure because it is highly associated with the longer term continuation in treatment that is often clinically recommended for success (Garnick, Lee, Acevedo, et al., 2009). Moreover, it can be measured in a short enough time period to target efforts to contact non-engaged clients and encourage them to receive treatment on a timelier basis. Therefore, more than a decade ago the Washington Circle (Garnick et al., 2002; The Washington Circle, n.d.) focused its initial efforts on developing measures that assess provision of timely substance abuse services at the start of an outpatient treatment episode. Currently used by the National Committee for Quality Assurance (NCQA) and Department of Veterans Affairs and endorsed by the National Quality Forum (NQF) (Harris, Humphreys, & Finney, 2007; National Committee for Quality Assurance, 2012; National Quality Forum, 2009), individuals are initiated if they receive treatment through an inpatient alcohol or other drug admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis. Individuals are engaged if they have initiated and also received two or more additional services with a diagnosis of alcohol or other drug dependence within 30 days of the initiation visit.

In 2004, the Washington Circle formed a workgroup, including the four states reported on here as well as eight other states, to evaluate the suitability of these measures for publically funded treatment. This Workgroup recommended that performance measures be calculated separately by level of care because of differences in treatment approach and client severity in specialty care in public sector settings (Garnick, Lee, Horgan, Acevedo, & Washington Circle Public Sector, 2009; Garnick et al., 2011). For public sector outpatient treatment:

- Initiation is defined as receiving another treatment service within 14 days after the beginning of a new outpatient or intensive outpatient treatment episode.
- Engagement is defined as receiving two additional services within 30 days after the initiation service.

Thus, the engagement measure reported on in this paper differs from the widely accepted measures of initiation and engagement in two ways: only outpatient or intensive outpatient treatment can begin the episode and only specialty treatment is included.

1.2. Criminal justice outcomes

The cost of crime to society is enormous. Substance abuse treatment is an intervention that not only has the potential to improve individual lives but also to benefit society by bringing about a reduction in drug-related crimes (McCollister, French, & Fang, 2010). Many individuals who have a substance use disorder also have criminal justice involvement (Belenko & Peugh, 2005; Greenfield & Weisner, 1995). A high proportion of arrestees have been found to have a problem with drug dependence (National Institute of Justice, 2003). Webster and colleagues found that having one or more lifetime arrests for driving under the influence (DUI) was associated with use of illegal drugs and these individuals have more criminal activity than individuals without a history of DUI (Webster et al., 2009). Among a nationally representative sample of non-institutionalized individuals, adults who had been arrested in the past year for a serious violent or property offense were more likely to have used illicit substances than those who had not been arrested for a serious offense (Substance Abuse and Mental Health Services Administration, 2005). The association between alcohol use and criminal activity has been well documented. About 40% of violent offenders in state and local jails

across the country had been drinking at the time of the offense for which they were incarcerated and about a quarter of state prisoners are alcohol dependent (Martin, 2001).

Prior criminal justice involvement probably makes it more difficult to bring about positive outcomes. Individuals who were recently arrested were less likely to engage in treatment as were those with a diagnosis of drug dependence (Brown, Bennett, Li, & Bellack, 2011). Indeed, the most consistent and most powerful predictors of poor criminal justice outcomes have been shown to be pretreatment measures of those same variables (Calsyn, Yonker, Lemming, Morse, & Klinkenberg, 2005; Easton, Babuscio, & Carroll, 2007; Luchansky, He, Krupski, & Stark, 2000; Luchansky, Krupski, & Stark, 2007).

At the same time, individuals with a recent criminal justice history may be more likely to enter and remain in specialty substance abuse treatment because of being mandated to treatment as a condition of parole or probation supervision. In fact, criminal justice involvement has been associated with receiving substance abuse treatment and the criminal justice system is the largest referral source for treatment admissions reported to state treatment agencies, accounting for more than a third of treatment referrals (Cook & Alegria, 2011; Substance Abuse and Mental Health Services Administration, & Office of Applied Studies, 2009). In addition, most studies have found reduced recidivism through drug courts, in which judges mandate clients to treatment, monitor how well they follow the rules of the court and impose rewards or sanctions (Wilson, Mitchell, & MacKenzie, 2006). Recent results reported from a study supported by the National Institute of Justice, the Multi-Site Adult Drug Court Evaluation (MADCE), showed that 83% of drug court offenders received at least some treatment during the initial 6 months although more than a third of the comparison sample also reported receiving at least some treatment (Rossman et al., 2011). Moreover, in the first 6 months of follow up, drug court offenders were significantly less likely than the comparison group to self-report engaging in any criminal behavior (28 versus 40%), but the differences in re-arrest rates were not significant.

1.3. Association of treatment engagement and criminal justice outcomes

Most previous studies of the association of treatment and criminal justice outcomes have not focused on treatment engagement. Substance abuse treatment has been shown to result in fewer arrests (Luchansky, He, Longhi, Krupski, & Stark, 2006; Luchansky, Nordlund, et al., 2006), lower risk of felony convictions (Luchansky, He, et al., 2006; Luchansky, Nordlund, et al., 2006), declines in self-reported illegal activities (Hubbard, Craddock, & Anderson, 2003), lower re-arrests among clients participating in treatment in lieu of incarceration for drug-related offenses (Evans, Huang, & Hser, 2011), lower conviction rates (Gossop et al., 2005), and lower arrests for both all types of crimes and specifically property and drug-related crimes (Evans, Li, & Hser, 2008).

The few studies that did relate engagement and criminal justice outcomes show lower arrests and incarcerations in Oklahoma (Garnick et al., 2007), lower arrest rates in Washington state (Campbell, 2009) and improved individual level legal outcomes and reduced substance use among outpatients in the Veterans Administration (VA) (Harris et al., 2010). Among adolescents in outpatient treatment, however, those engaging did not have significantly lower likelihoods of reporting trouble controlling behavior or illegal activities at 6 months after beginning treatment (Garnick et al., 2012).

This study expands previous research on the association of treatment engagement and criminal justice outcomes in three ways. First, we explore the generalizability of previous findings that used data only from Oklahoma in 2001 by including an additional three states that were involved in the Workgroup that adapted the engagement measure for the public sector, as well as updating the results for Oklahoma using 2008 data. Second, we refine our analyses

of treatment engagement's influence on the likelihood of arrests by using any arrest as our outcome and examining the effect on arrests in general, but also examining specific categories of arrests. Third, we create both client-level and facility-level measures of treatment engagement, and use them to examine two separate aspects of treatment engagement: the effect of an individual client's engagement on likelihood of arrest and the effect of the facility's rate of treatment engagement.

2. Methods

2.1. Data

This study focused on adult clients who received publicly-funded substance abuse treatment in specialty settings in 2008 in the states of Connecticut, New York, Oklahoma, and Washington. Substance abuse treatment data for treatment clients were linked by matching with arrest and incarceration data from each state's criminal justice agencies. This included data from the states' Department of Corrections (Washington and Oklahoma), state patrol (Washington), Division of Criminal Justice Services (New York), Department of Public Safety (Oklahoma), State Bureau of Investigation (Oklahoma), and Administrative Office of the Courts (Washington). In Washington and Connecticut, the Link King software was used for matching (Campbell, Deck, & Krupski, 2008). In Oklahoma probabilistic matching was used based on last name, first name, social security number, date of birth, gender, and race. In New York deterministic matching was used including date of birth, gender, and parts of the social security number. After matching, the resulting merged, integrated datasets in each state were stripped of all personally identifying information before being provided to the study's analytic team. Except in New York which did not provide data on individual encounters, the substance abuse treatment data generally included both admission intake information such as client demographics (e.g., age, gender, race/ethnicity), living situation, treatment referral source, and self-reported substance use, and encounter data which included dates and types of services the client received.

2.2. Sample selection

The study sample was made up of adult clients (ages 18+) who began a new outpatient substance abuse treatment episode in 2008. A new outpatient treatment episode is triggered by receipt of outpatient treatment (called the index), which follows a period of at least 60 days, during which no treatment services are received. Under this rule, detoxification services were not considered treatment and could occur during the intervening period of at least 60-days. In Connecticut and Oklahoma, the index was based on the date of the first documented service while in New York and Washington the index was based on the date of an outpatient treatment admission following a no service period. Treatment admission was used as the index date for New York because it does not collect encounter data and thus date of first treatment service was not recorded and for Washington because a therapeutic activity usually takes place on the same date as the outpatient treatment admission. To avoid possible correlations from multiple episodes within the same subject, in all states, if a client had more than one outpatient treatment episode during the year 2008, only the first episode was used in the analyses.

A total of 120,381 adult clients across the four states had a new treatment episode in 2008 (Table 1). We excluded clients admitted for over 2 days to a residential treatment program within 45 days of the outpatient index as their outpatient treatment service would not be indicative of the beginning of an outpatient treatment episode. Due to data and modeling considerations, we also excluded clients who did not have an admission record within 30 days around the index date, were incarcerated after the index without an arrest because they were

Table 1
Information on clients in analytic file.

	Connecticut	New York	Oklahoma	Washington
Clients with new OP episode in 2008	7978	89,750	13,195	9458
Residential stay LOS > 2 first 45 days	69	1728	704	437
Incarceration after index without arrest	492	–	61	–
Incarceration within 45 days of index, LOS > 30	20	190	0	16
Admission data > 30 days from index	0	0	3767	0
Arrest before time 0	245	1231	122	244
Death after index	8	79	25	8
Missing data on independent variables	1806	1127	575	548
Only one client in agency after other exclusions	23	4	2	17
Final sample used in regressions	5324	85,211	7939	8188
Mean number of days to arrest ^a	310.7	349.0	320.9	294.0

^a Means based on truncated information. Clients not arrested within year after discharge are assigned values of 365 days.

likely to have been incarcerated due to previous involvement with the criminal justice system (e.g., for violation of probation or parole), had missing data in any of the variables of interest, died within the year after discharge, or were the only client with a new treatment episode in 2008 at their facility after other exclusions. In addition, rather than considering the incarceration period to be a timeout as we do for shorter confinements, we also dropped from our study all clients who were incarcerated for 30 days or more within 45 days after their index dates. Clients in such controlled environments could not engage in treatment during their incarceration due to circumstances beyond their control, and incarcerations of 30 days or more were considered long enough to undo any benefit from the short amount of treatment before the incarceration began. Finally, to avoid an important, but often overlooked bias that could impact our estimates, "immortal time bias" (Suissa, 2007), we also excluded clients who were arrested before they had a full opportunity to engage or not engage. After these exclusions, the final analytic sample consisted of 106,662 clients (CT = 5324, NY = 85,211, OK = 7939, WA = 8188).

2.3. Variables

2.3.1. Outcome variables

The main outcome variable was time to an arrest as measured by the number of days between time 0 (defined in section 2.3.4 below) and the client's first arrest, censored at 365 days for those without an arrest in the following year. In order to examine arrests in more detail, we also examined time to arrests for specific type of crimes: substance-related (e.g., drug trafficking and possession, DUI), and property (e.g., theft, burglary, destruction of property) or violent (e.g., assaults, homicides, rape). Classification of arrests into these three categories was performed in accordance with the Bureau of Justice Statistics' codebook for the 2004 Survey of Inmates in State and Federal Correctional Facilities (U.S. Department of Justice, n.d.). Property and violent crimes were combined because of relatively low numbers of arrests for violent crimes. We did not use incarceration as an outcome because incarceration is highly subject to differences across states, local courts and race/ethnicity in the extent of plea bargaining and because it proved difficult to determine if an incarceration after treatment related to new criminal activity or to past events (Alexander, 2010; Guerino, Harrison, & Sabol, 2011; Human Rights Watch, 2009).

2.3.2. Treatment engagement

We used the Washington Circle (WC) public sector specifications for initiation and engagement (Garnick, Lee, Acevedo, Horgan, & Washington Circle Public Sector Workgroup, 2009; Garnick, Lee, Horgan, et al., 2009) to create the analytic variable indicating whether a client engages in outpatient treatment or not. A client who receives at least one service within 14 days after the index is considered to have initiated treatment. Treatment engagement is then defined as receiving at least two additional services within 30 days after the initiation visit. New York does not collect encounter data, but facilities report at discharge the total number of treatment visits provided to each client during the treatment episode. Thus, a client was considered engaged if providers reported that the client had had at least four treatment visits and either their length of stay, defined as the number of days between admission and discharge, was longer than 30 days or had another treatment admission within 30 days of the first admission. To test the sensitivity of New York's measure, encounter data from Washington state were used to determine clients' engagement status by both New York's and the Washington Circle's definitions of engagement. The results showed that using the two definitions of engagement, there was a match in engagement status for 83% of the clients.

We also included in our models a facility-level variable for the proportion of outpatient adult clients (before exclusions) admitted in 2008, who engaged in treatment. Facility engagement rates were calculated by dividing the number of 2008 clients in the facility who met the engagement criteria by the total number of 2008 clients in the facility.

2.3.3. Covariates

Our theoretical framework for regression analyses is the Behavioral Model of Health Services Use (Andersen & Davidson, 2007), which suggests that the relationship between health services utilization and outcomes is further influenced by additional individual and contextual factors. Covariates used in our models consist of client variables (demographic characteristics and substance use and treatment referral source) and facility factors (prevalence of use of hard drugs and prevalence of prior year arrest or incarceration among clients).

Unless noted, the data used to determine the client characteristics were collected by staff at the treatment facilities at treatment admission and are based on client self-report. To continue receiving Federal Block Grant funding, states are required to include these data in their annual reports to the Substance Abuse and Mental Health Services Administration (SAMHSA). These data allow for meaningful comparisons of common benchmarks among the states, although some variation by state in level of detail does remain. As a result, SAMHSA in consultation with the agency staff of each individual state has developed a crosswalk to collapse the state's original coding schemes into uniformly recognized categories. For example, Connecticut and Oklahoma collect information on years of formal education, whereas New York and Washington collect information on level of education with answers noting final obtained degree (e.g., high school, associate's, or bachelor's), "some college", or years of education if less than high school graduate (New York only). Thus, "13 or more years" of education in Connecticut or Oklahoma was categorized as "more than high school", as were "some college", and associate's or higher degrees from the other states. To avoid certain bias issues for regressions which use covariates with very small categories, we required that all categories of all variables have at least 5% representation and combined categories into "other" to meet this requirement (e.g., American Indian in New York or Addiction Service as referral source in Oklahoma and Washington).

2.3.3.1. Client demographics. Demographic variables included gender, age, race/ethnicity (Non-Hispanic White, Non-Hispanic Black, His-

panic/Latino, American Indian, Other race/ethnicity), education (less than high school, high school degree, more than high school), homelessness (yes/no), marital status (married/living as married versus unmarried), and employment status (unemployed/not in labor force versus employed). Connecticut had high rates of missing data in the marital status and employment status variables, and thus we excluded these variables in our models for this state. We also linked each client's zip code of residence to its corresponding Rural Urban Commuting Area Code (WWAMI Rural Health Research Center, 2007) to create an indicator for whether the client resided in a rural or urban area. Our models also included a covariate for clients' criminal justice involvement in year prior to treatment defined as clients for whom the data from state criminal justice agencies showed an arrest or incarceration at any point in the 365 days prior to their index. Because we were interested in testing whether predictive relationships between engagement and criminal justice outcomes are moderated by clients' pre-treatment criminal justice involvement, our models also included the interaction between these two variables.

2.3.3.2. Substance use and treatment referral. Two covariates were created to reflect the client's substance use: first, a set of indicators for whether they reported using substances in particular groups within the month prior to treatment admission, and second, the earliest age of use of substances within the groups. We also included referral source with categories for self/family, community agency or group (e.g., child protective services), addiction service (e.g., another substance abuse treatment program), other health professional (e.g., mental health or medical provider), criminal justice system (e.g., department of corrections, drug court), and other (e.g., employer, school personnel, clergy). Referral source was excluded in Connecticut because a high proportion of clients were missing data on this variable.

2.3.3.3. Client characteristics aggregated at the facility level. In addition to a variable for the engagement rate at the facility where the client received treatment, we also included the proportion of clients at the facility who had an arrest or incarceration in the year prior to the index and the proportion of clients at the facility whose admission records indicated use of hard drugs in the prior month (i.e., drugs other than alcohol and marijuana). Proportions were calculated prior to the client exclusions noted in Section 2.2. In order to reduce the possible effect of multi-collinearity between client-level variable and the facility-level variables, client-level engagement and client-level prior year arrest or incarceration were centered around their respective mean facility-level proportions. We did not create a centered variable for hard drugs, because the facility variable is a composite of the specific drug variables and is not highly correlated with any of the individual level drug variables.

2.3.4. Analysis

Following examination of the characteristics of the clients and the facilities where they were treated, we utilized shared frailty models (Therneau & Grambsch, 2000), which are the survival analysis equivalent of random effects models, to examine the relationship between outpatient engagement and three time-to-event outcomes related to arrest: days to any arrest, days to a substance-related arrest, and days to a property/violent arrest. We conducted analyses to examine substance abuse arrests and property or violent arrests as separate outcomes since our main independent variables are performance measures for substance abuse treatment. We wanted to examine the specific effects of meeting the performance measures on substance-related arrests. Furthermore, there was a relatively low number of arrests for violent crimes in our data set, thus they were combined with arrests for property crimes.

One key decision in our time-to-event survival analyses concerns identification of the starting time, or "time 0". It would seem simple

and reasonable enough to choose each client's index date as "time 0" in our models, as it would measure each time to arrest from beginning of treatment. However, such a choice would also provide a basis for "immortal time bias" (Lash & Cole, 2009; Levesque, Hanley, Kezouh, & Suissa, 2010; Suissa, 2008; Zhou, Rahme, Abrahamowicz, & Pilote, 2005). Immortal time refers to the time during which "death" cannot occur for a client under study. For a time-to-event analysis to be fair, the immortal times for clients in the two groups, engaged and non-engaged, need to be balanced. For our particular choice of starting time, the immortal time between the two groups will not be balanced, because engaged clients cannot be arrested until they are engaged (which could occur up to 45 days after index), while non-engaged clients can be arrested immediately. The lack of balance in immortal times between our two groups will bias results. Even if engagement provides no true benefit to clients, selection alone will make non-engaged clients appear to have shorter average times to arrest, and thereby increasing the possibility of rejection of the null hypothesis. In light of the many factors for and against various starting times for our study, we chose the earliest time at which each client's engagement status could be determined (Zhou et al., 2005). This depends on their index dates, and initiation and engagement status: (1) for clients who did not initiate or engage, time 0 was chosen to be day 14 after the index (because if client had not initiated by then, he/she would not have been able to engage); (2) if a client had initiated only, time 0 was 30 days after the initiation (to allow for possible engagement); and (3) for clients who engaged, time 0 was the time of the visit that met the engagement criteria. As a sensitivity test, we also ran our analyses defining 'time 0' as 45 days after index date, the latest date by which engagement status can be determined. Results of these parallel analyses were quite similar—the only difference was that engagement's effect on arrest for violent crime lost significance for one state, Washington. As such, only results of our main analyses are provided.

For the most part, when no arrest was found for a client within 365 days of the starting time, the client's time-to-event was censored at 365 days. The exception concerns clients who, due to incarceration (without corresponding arrest) or admission to residential substance abuse treatment during the year, have their likelihood of arrest temporarily curtailed. In those cases, the days in residential treatment or incarceration that are under 30 days is considered a "time-out," and their total is not included in the time-to-event value. In consideration of the "time out" periods, the follow-up is expanded by the same number of days, so that the maximum time-to-event for clients remains 365 days (marked as 'censored', however, if the client was not arrested during the expanded time period). In cases where the new follow-up period necessitated by time in a controlled setting did not allow for 365 days between the origin and December 31, 2009, the last day for which data are available, the clients' times-to-event were censored at December 31, 2009. For clients whose length of stay went beyond December 31, 2009, the times-to-event were censored at the beginning of the incarceration or residential stay.

The shared frailty models we use for our analyses represent a version of multivariate Cox proportional hazards regression (Therneau & Grambsch, 2000), which examines the effect of treatment engagement status on the hazard of arrest, after accounting for potential clustering of outcomes by facility and adjusting for other confounding covariates at both the client and facility levels. The facility-level variables in our models include percentage of clients engaging in treatment, percentage having prior arrest or incarceration, and percentage using hard-core drugs other than marijuana. The traditional Cox model, which assumes independence of survival times among all clients, will ignore any potential correlations among clients from within the same cluster. This may lead to exaggerated significance and the potential for drawing incorrect conclusions. The shared frailty model, on the other hand, accounts for clustering of outcomes among clients from the same facility, by introducing an additional parameter into the hazard rate function to reflect the

assumption that clients within the same facility have a component of shared risk of arrest.

3. Results

3.1. Descriptive and bivariate results

Characteristics of clients beginning new episodes of treatment are shown for each state in Table 2. For some demographic characteristics, states were similar. For example, in all states clients were predominantly men and the most prevalent age group is 31–44 with about 20% or more over age 45. Also, in all states except Connecticut, where marital status and employment were excluded from the analysis due to missing data, about a quarter of clients were married and unemployment rates were high, almost 60% or more. The distributions of other important client characteristics, however, varied extensively across the four states. In New York, for example, White clients

Table 2
Client characteristics at beginning of new episode of outpatient treatment by state (%).

Characteristic	Connecticut (n = 5324)	New York (n = 85,211)	Oklahoma (n = 7939)	Washington (n = 8188)
Engagement rate	45.4	78.0	50.0	71.1
Client demographics				
Female	30.7	27.0	37.5	37.3
Age				
18–20	9.0	8.8	6.6	9.3
21–25	18.2	16.3	19.6	17.7
26–30	15.9	14.9	19.6	16.6
31–44	34.5	34.4	34.9	34.2
45+	22.5	25.7	19.4	22.2
Race/ethnicity				
White	56.5	48.7	66.5	58.6
Black	20.2	28.9	16.2	8.4
Latino	21.3	19.2	4.0	11.4
American Indian	–	–	12.1	14.0
Other	2.0	3.2	1.2	7.6
Education				
< High school	30.5	32.3	33.0	31.9
High school degree	50.3	37.7	50.0	56.2
> High school	19.3	30.1	17.5	12.0
Homeless	4.1	4.8	0.8	8.3
Married	–	21.5	24.8	23.8
Unemployed	–	59.6	60.2	70.8
Rural	10.4	11.2	44.1	18.6
Arrest or incarceration in prior year	52.5	17.7	46.7	50.6
Substance use and treatment referral				
Substance(s) used in past month ^a				
Alcohol	33.8	37.7	29.9	28.9
Marijuana	19.4	25.8	20.8	16.2
Cocaine	9.0	14.7	6.3	5.9
Opiates	4.0	7.8	8.6	5.7
Methamphetamines	–	–	7.7	5.2
Other drug	2.7	4.5	5.6	2.0
Age of first use ^b				
≤ 10	5.0	6.3	7.7	12.6
11–14	28.6	29.3	29.7	36.4
15–17	36.1	35.7	32.5	31.4
18–20	16.7	16.6	15.0	11.5
21+	13.0	12.1	15.1	8.1
Referral source				
Self/individual	–	19.1	28.4	9.1
Community	–	13.8	17.3	20.8
Criminal justice	–	47.5	50.3	55.9
Addiction service	–	6.1	–	–
Health prof.	–	5.8	–	–
Other	–	7.8	4.0	14.2

^a Substance was listed as a primary, secondary, or tertiary drug and frequency of use was one or more times in the past month.

^b Earliest age of first use of any of the substances reported as primary, secondary, or tertiary substance of abuse.

Table 3
Variables aggregated at the facility level.

Variable	Connecticut (n = 58)	New York (n = 457)	Oklahoma (n = 81)	Washington (n = 187)
Facility engagement rate				
25th percentile	0.00	0.74	0.33	0.56
50th percentile	0.42	0.79	0.52	0.71
75th percentile	0.63	0.86	0.72	0.88
Proportion of clients with prior year arrest or incarceration				
25th percentile	0.36	0.08	0.31	0.33
50th percentile	0.50	0.16	0.45	0.45
75th percentile	0.60	0.25	0.55	0.56
Proportion of clients reporting use of hard drugs at start of new episode of treatment ^a				
25th percentile	0.04	0.11	0.08	0.02
50th percentile	0.12	0.18	0.16	0.10
75th percentile	0.25	0.30	0.28	0.20

^a Hard drugs includes any substance other than alcohol or marijuana.

represented a lower proportion of clients than in the other states, while Black clients represented a substantially higher proportion. Oklahoma had the highest proportion of White clients among the four states. In Oklahoma and Washington there were much higher proportions of American Indian clients than in New York and Connecticut. Across all four states, about a third of clients did not finish high school. In New York, however, the remaining clients split almost evenly between high school and more than high school, while in the remaining states the ratio was closer to 3:1 or more. There was a higher proportion of homeless clients in Washington (8.3%) compared with the other states, while in Oklahoma far more clients lived in rural areas (44.1%). During the year prior to their new episode of outpatient treatment for substance abuse, about half of the clients in Connecticut, Oklahoma and Washington, but only 17.7% of clients in New York had a prior arrest or incarceration.

As self-reported on admission, across all states a third of clients had used alcohol and about a quarter had used marijuana in the past month. More clients in New York reported using cocaine (14.7%) than in the other states and methamphetamines were reported by a substantial proportion of clients only in Oklahoma (7.7%) and Washington (5.3%). Age at first use of any substance was most common during adolescence with 15% or less of clients reporting first use at age 21 or older. About half of clients were referred from the criminal justice system.

Regarding facility level variables, the median client engagement in a new episode of outpatient treatment for substance abuse was higher in New York and Washington, although there was considerable range across facilities in all states (Table 3). The proportion of clients with arrest or incarceration in the year prior to treatment was lower in New York and the median proportion of clients using hard drugs was lower in Connecticut and Washington than the other states.

Table 4
Client outcomes in year following a new episode of outpatient treatment by state and engagement status.

Outcome	Connecticut (n = 5234)		New York (n = 85,211)		Oklahoma (n = 7939)		Washington (n = 8188)	
	Clients not engaged	Clients engaged	Clients not engaged	Clients engaged	Clients not engaged	Clients engaged	Clients not engaged	Clients engaged
n	2908	2416	18,747	66,464	3969	3970	2363	5825
Any arrest (%)	25.9	24.9	6.5	5.0**	24.4	18.5**	33.0	30.5*
Arrest for substance-related crime (%)	9.3	8.1	2.8	2.3**	14.5	11.7**	12.2	13.2
Arrest for property/violent crime (%)	13.7	12.7	3.4	2.4**	13.4	9.4**	14.1	12.5

* Differences by engagement status of proportions significant at $p < .05$.

** Differences by engagement status of proportions significant at $p < .01$.

As shown in Table 4, in all states clients who engaged had lower rates of any arrest in the year following a new episode of outpatient treatment, although the difference was not significant in Connecticut. In addition, in both New York and Oklahoma clients who engaged had significantly lower rates of arrests for a substance-related crime or for a property or violent-related crime than clients who did not engage.

3.2. Survival analysis results

3.2.1. Engagement, prior year arrest or incarceration, and their interaction

Table 5 shows the results of the time-to event survival analysis for the any arrest outcome. For each state, engaged outpatient treatment clients had a significantly lower hazard of an arrest than non-engaged outpatient treatment clients (Connecticut hazard ratio = 0.82; 95% confidence interval [95% CI] = 0.71–0.94, New York HR = 0.78; CI = 0.71–0.87, Oklahoma HR = 0.73; CI = 0.65–0.82, Washington HR = 0.83; CI = 0.76–0.92). Thus, at any point in time after beginning outpatient treatment in New York, clients who had not yet been arrested had 22% less likelihood of arrest if they were engaged, than if they were not engaged. Similarly, Connecticut clients who engaged had 18% less likelihood of arrest, Oklahoma clients who engaged had 27% less likelihood of arrest, and Washington clients who engaged were at 17% less risk of arrest than clients who did not engage.

Being treated in New York or Oklahoma facilities with higher proportions of engaged clients also predicted lower hazards of arrest (New York HR = 0.56; CI = 0.35–0.91 and Oklahoma HR = 0.54; CI = 0.32–0.90). These coefficients imply, for example, that compared to being treated in a New York facility with a 60% engagement rate, clients treated in a New York facility with a 70% engagement rate have a 5.6% lower hazard of arrests in the year following treatment.

Similarly, being engaged predicts a significantly lower hazard of an arrest for a property or violence-related crime (Table 7), and in New York and Oklahoma for a substance-related crime (Table 6). The facility-level engagement rate is significant in Washington for substance-related arrests (Table 6) and in Oklahoma for property or violence-related arrests (Table 7).

Table 5 also shows that for each state, the strongest predictor of arrests after treatment was arrest or incarceration in the year prior (Connecticut HR = 3.01; CI = 2.65–3.42, New York HR = 9.66; CI = 9.05–10.32, Oklahoma HR = 1.85; CI = 1.66–2.06, Washington HR = 2.18; CI = 1.99–2.39). In New York, clients with arrest or incarceration in the prior year have a 9.6 times higher hazard of arrest than those without this prior criminal justice involvement. Being treated in a facility with a higher proportion of clients with arrest or incarceration in the prior year also predicts a significantly higher likelihood of any arrest in Connecticut, New York and Washington. For outcomes involving substance-related arrests (Table 6) or property or violence-related arrests (Table 7), clients' arrests or incarceration in the prior year were always significant predictors of higher hazards of arrests, while facility-level proportions of clients with this prior

criminal justice involvement were also significant in Connecticut, New York and Washington.

Focusing on the interaction between the client-level variables for engagement in treatment and prior arrest or incarceration, our models show that in New York, this interaction provided additional protection against any arrest. In particular, compared with the estimate of hazard of arrest based only on the main effects of engagement in treatment and prior year arrest or incarceration, the interaction in our model for New York predicts an additional 17% reduction in hazard of arrest for clients who have both characteristics. Together with the main effect of 22% lower hazard of arrest, which all New York clients should enjoy if they engage, New York clients who had a prior year arrest or incarceration should expect an additional 17% lower hazard of arrest if they engage in treatment, compared with similar clients who do not engage. This additional protection from the interaction between client-level variables, however, is not observed in models of the separate outcomes of substance-related arrests or

property or violence-related arrests (Tables 6 and 7). These non-significant results are probably due to fewer arrest outcomes in these latter analyses.

3.2.2. Other characteristics predicting arrest

Other client characteristics which significantly affected the hazard of arrests were sex, education, and marital status. Being female predicted a lower hazard of any arrest than being male in New York, Oklahoma and Washington. Similarly, having a high school degree or higher education and being married in New York and Washington states predicted a lower hazard as well (Table 5). Compared with clients aged 45 and over, all the younger age groups had a significantly greater hazard of arrests as did those who were homeless and unemployed in New York and Washington states. The impact of a client's race or ethnicity varied across states. Black clients had a higher hazard of arrest in Connecticut (HR = 1.29; CI = 1.11–1.49), New York (HR = 1.14; CI = 1.05–1.24) and Washington (HR = 1.52;

Table 5
Time-to-event survival analysis of any arrest following a new episode of outpatient treatment.

Variable	Connecticut (n = 5324)		New York (n = 85,211)		Oklahoma (n = 7939)		Washington (n = 8188)	
	H.R.	(95% CI)	H.R.	(95% CI)	H.R.	(95% CI)	H.R.	(95% CI)
Engagement and prior year arrest or incarceration								
Engagement ^a	0.82**	(0.71, 0.94)	0.78**	(0.71, 0.85)	0.73**	(0.65, 0.82)	0.83**	(0.76, 0.92)
Prior year arrest or incarceration ^a	3.01**	(2.65, 3.42)	9.66**	(9.05, 10.32)	1.85**	(1.66, 2.06)	2.18**	(1.99, 2.39)
Engagement × prior year arrest or incarceration	1.08	(0.81, 1.43)	0.83*	(0.72, 0.96)	1.01	(0.80, 1.28)	0.91	(0.74, 1.12)
Facility engagement rate	1.28	(0.93, 1.77)	0.56*	(0.35, 0.91)	0.54*	(0.32, 0.90)	1.25	(0.98, 1.60)
Facility proportion of clients with prior year arrest or incarceration	3.74**	(1.91, 7.30)	10.37**	(6.69, 16.09)	1.32	(0.72, 2.44)	5.51**	(3.98, 7.63)
Client demographics								
Female	0.84*	(0.74, 0.95)	0.58**	(0.53, 0.63)	0.70**	(0.62, 0.78)	0.72**	(0.66, 0.78)
Age (reference: 45+)								
18–20	1.69**	(1.35, 2.11)	2.13**	(1.89, 2.41)	2.52**	(2.03, 3.12)	1.60**	(1.36, 1.89)
21–25	1.53**	(1.27, 1.85)	1.88**	(1.70, 2.10)	1.91**	(1.60, 2.28)	1.48**	(1.29, 1.70)
26–30	1.28**	(1.05, 1.55)	1.73**	(1.56, 1.93)	1.84**	(1.56, 2.19)	1.42**	(1.24, 1.63)
31–44	1.38**	(1.17, 1.62)	1.46**	(1.33, 1.60)	1.50**	(1.28, 1.76)	1.38**	(1.23, 1.55)
Race/ethnicity (reference: White)								
Black	1.29**	(1.11, 1.49)	1.14**	(1.05, 1.24)	1.11	(0.97, 1.28)	1.52**	(1.33, 1.74)
Latino	1.07	(0.92, 1.24)	1.00	(0.91, 1.10)	1.02	(0.81, 1.30)	0.95	(0.83, 1.10)
American Indian	–	–	–	–	0.96	(0.83, 1.13)	1.31**	(1.15, 1.48)
Other	1.12	(0.77, 1.62)	0.95	(0.79, 1.14)	1.13	(0.75, 1.68)	1.23**	(1.07, 1.41)
Education (reference: no high school degree)								
High school degree	0.90	(0.79, 1.01)	1.04	(0.97, 1.11)	0.86**	(0.77, 0.95)	0.91*	(0.83, 0.99)
More than high school	0.82*	(0.69, 0.98)	0.79**	(0.73, 0.86)	0.77**	(0.66, 0.90)	0.83*	(0.71, 0.96)
Homeless	1.44**	(1.11, 1.87)	1.40**	(1.22, 1.60)	1.26	(0.75, 2.13)	1.25**	(1.10, 1.43)
Married	–	–	0.87**	(0.80, 0.95)	0.92	(0.81, 1.03)	0.87**	(0.79, 0.96)
Unemployed	–	–	1.45**	(1.35, 1.55)	1.10	(0.99, 1.22)	1.21**	(1.11, 1.33)
Rural	1.25*	(1.02, 1.53)	1.15**	(1.04, 1.28)	1.04	(0.91, 1.20)	0.82**	(0.73, 0.93)
Substance use and treatment referral source								
Substance(s) used in past month ^b								
Alcohol	1.04	(0.92, 1.17)	0.88**	(0.82, 0.93)	1.00	(0.90, 1.13)	1.06	(0.97, 1.16)
Marijuana	1.15*	(1.00, 1.33)	1.13**	(1.06, 1.21)	1.00	(0.88, 1.13)	1.00	(0.90, 1.12)
Cocaine	1.31**	(1.09, 1.57)	1.57**	(1.44, 1.71)	1.15	(0.94, 1.40)	1.30**	(1.11, 1.53)
Opiates	1.36*	(1.05, 1.77)	1.57**	(1.42, 1.74)	1.06	(0.87, 1.28)	1.29**	(1.09, 1.52)
Methamphetamines	–	–	–	–	1.45**	(1.23, 1.72)	1.80**	(1.55, 2.10)
Other drug	1.13	(0.81, 1.56)	1.08	(0.93, 1.26)	1.07	(0.88, 1.31)	1.04	(0.78, 1.38)
Facility proportion of clients reporting use of hard drugs	1.78	(0.89, 3.57)	1.22	(0.91, 1.65)	1.06	(0.54, 2.09)	1.77*	(1.09, 2.88)
Age of first use ^c (reference: 21+)								
≤ 10	1.16	(0.89, 1.51)	1.40**	(1.21, 1.63)	1.15	(0.92, 1.44)	1.29**	(1.07, 1.55)
11–14	1.15	(0.95, 1.39)	1.30**	(1.15, 1.46)	1.14	(0.96, 1.35)	1.12	(0.95, 1.32)
15–17	0.87	(0.72, 1.05)	1.08	(0.96, 1.21)	1.11	(0.93, 1.31)	1.09	(0.92, 1.29)
18–20	0.92	(0.75, 1.14)	0.91	(0.80, 1.03)	0.97	(0.80, 1.17)	1.00	(0.82, 1.21)
Referral source (reference: self/individual)								
Community organization/agency	–	–	1.14*	(1.02, 1.28)	0.99	(0.81, 1.20)	1.08	(0.91, 1.28)
Criminal justice	–	–	0.98	(0.90, 1.07)	1.03	(0.88, 1.21)	1.18*	(1.01, 1.39)
Addiction service	–	–	1.13	(0.98, 1.31)	–	–	–	–
Health prof.	–	–	0.91	(0.76, 1.08)	–	–	–	–
Other	–	–	0.90	(0.78, 1.04)	0.65*	(0.47, 0.91)	0.96	(0.80, 1.16)

^a Engagement and prior year arrest or incarceration are centered around the facility mean.

^b Substance was listed as a primary, secondary, or tertiary drug and frequency of use was one or more times in the past month.

^c Earliest age of first use of any of the substances reported as primary, secondary, or tertiary substance of abuse.

* $p < .05$.

** $p < .01$.

Table 6
Time-to-event analysis of arrest for a substance related crime following a new episode of outpatient treatment.

Variable	Connecticut (n = 5324)		New York (n = 85,211)		Oklahoma (n = 7939)		Washington (n = 8188)	
	H.R.	(95% CI)	H.R.	(95% CI)	H.R.	(95% CI)	H.R.	(95% CI)
Engagement ^a	0.82	(0.65, 1.03)	0.83**	(0.73, 0.95)	0.74**	(0.64, 0.86)	0.92	(0.79, 1.09)
Prior year arrest or incarceration ^a	2.37**	(1.92, 2.94)	8.20**	(7.45, 9.03)	1.85**	(1.61, 2.12)	2.07**	(1.79, 2.39)
Engagement × prior year arrest or incarceration	0.96	(0.59, 1.55)	0.88	(0.71, 1.09)	0.81	(0.60, 1.10)	1.08	(0.75, 1.57)
Facility engagement rate	0.85	(0.50, 1.45)	0.58	(0.29, 1.14)	0.73	(0.40, 1.32)	1.82*	(1.13, 2.93)
Proportion of clients with prior year arrest or incarceration	4.52**	(1.44, 14.20)	9.19**	(4.96, 17.03)	1.56	(0.76, 3.19)	4.26**	(2.31, 7.84)

Notes: Controlling for other client-level covariates included in Table 4.

* $p < .05$.

** $p < .01$.

^a Engagement and prior year arrest or incarceration are centered around the facility mean.

CI = 1.33–1.74) compared with White clients. In Washington, clients who were American Indians had a higher hazard of arrest (HR = 1.31; CI = 1.15–1.48) compared with White clients. Clients living in rural areas had a higher hazard of arrest in Connecticut (HR = 1.25; CI = 1.02–1.53) and New York (HR = 1.15; CI = 1.04–1.28) but a lower hazard of arrest in Washington (HR = 0.82; CI = 0.73–0.93) compared with clients living in urban or suburban areas.

The impact of substances used at admission, facility proportion of clients reporting using hard drugs at admission, and referral source also varied by state. While the significance levels varied, reporting each of the substances as either a primary or other drug at admission as well as using the substance in the past month, compared with not reporting use of that specific substance in the past month always showed a higher hazard of arrest. Being treated in a facility that treated a higher proportion of clients reporting using hard drugs at admission only significantly predicted higher hazard of arrest in Washington state. Across all states, clients reporting younger age at first use had higher hazards of arrest compared with those reporting first use at age 21 or over. Finally, referral source only predicted a higher hazard of arrest for those referred by a community organization or agency in New York compared with self-referral.

4. Discussion

4.1. Impact of treatment engagement on criminal justice outcomes

Across four states, our analysis shows that being engaged in treatment predicts a lower hazard of arrest following the beginning of an episode of outpatient treatment. Moreover, the magnitude of this effect is substantial, ranging from 17% to 27% across states. These results confirm the findings of prior studies in Oklahoma and the Veterans Administration (Garnick et al., 2007; Harris et al., 2010). However, the results varied across states when we examined different types of arrests and compared client-level with facility-level specification of treatment engagement. Thus, both the development of

process-focused performance measures and the testing of the relationship of process measures and outcomes should be conducted using a variety of settings, use a range of outcomes, and include both individual and aggregate levels of the process measures.

The results for substance related arrests and property or violence related arrests vary across states, however. The influence of engagement on substance related arrests is statistically significant only in New York and Oklahoma while the influence of engagement is significant for property or violence related arrests in all four states. These findings justify our decision to analyze the data for each state separately, a decision made because we knew there are differences across states in their treatment systems, law enforcement procedures and data procedures.

Including facility-level engagement is key, both to focus on the question of whether it makes a difference in outcomes to be treated at a higher performing facility, as well as to avoid bias (Finney, Humphreys, Kivlahan, & Harris, 2011). In two of the four states, New York and Oklahoma, being treated in a facility with a higher engagement rate also matters, conferring additional protection from subsequent arrest.

These robust results suggest that state agencies and treatment facilities can use the performance measure of treatment engagement to monitor provision of services to their clients, include the measures in continuous quality improvement activities, and consider them for incentive programs. Currently, the state agency in Oklahoma includes engagement as part of a standard provider performance report for all public behavioral health providers. Focusing on individual clients, providers might take steps to get clients who are at risk of not becoming engaged in treatment to return for more treatment during the early stage of a treatment episode. One action that they can take, for example, is making follow-up phone calls to clients. At the facility level, lower engagement rates may indicate that the facility needs to examine why engagement is low and try to improve its rates. Improvement collaboratives under the NIATx model suggest interest circle calls, clinic-level coaching, and learning sessions as ways to

Table 7
Time-to-event survival analysis of arrest for a property/violent crime following a new episode of outpatient treatment.

Variable	Connecticut (n = 5324)		New York (n = 85,211)		Oklahoma (n = 7939)		Washington (n = 8188)	
	H.R.	(95% CI)	H.R.	(95% CI)	H.R.	(95% CI)	H.R.	(95% CI)
Engagement ^a	0.71**	(0.59, 0.87)	0.71**	(0.63, 0.81)	0.71**	(0.61, 0.83)	0.84*	(0.72, 0.98)
Prior year arrest or incarceration ^a	3.18**	(2.64, 3.82)	10.41**	(9.47, 11.44)	1.91**	(1.65, 2.21)	2.21**	(1.92, 2.55)
Engagement × prior year arrest or incarceration	1.65*	(1.10, 2.47)	0.91	(0.74, 1.11)	1.23	(0.89, 1.69)	1.21	(0.88, 1.67)
Facility engagement rate	1.34	(0.94, 1.91)	0.75	(0.41, 1.40)	0.50*	(0.26, 0.94)	0.93	(0.58, 1.48)
Proportion of clients with prior year arrest or incarceration	2.54*	(1.19, 5.43)	7.18**	(3.99, 12.91)	1.17	(0.55, 2.48)	4.82**	(2.59, 8.96)

Notes: Controlling for other client-level covariates included in Table 4.

* $p < .05$.

** $p < .01$.

^a Engagement and prior year arrest or incarceration are centered around the facility mean.

increase treatment access (reducing waiting time, and increasing the number of clients) and retention (defined similarly to engagement). A recent study indicates that some of these components are helpful in significantly increasing treatment access, although not significantly improving treatment retention (Gustafson et al., 2013).

While our results related to treatment engagement and arrests are consistent across states, we recognize that whether a client is arrested may be biased by race/ethnicity (Alexander, 2010; Eith & Durose, 2011; Human Rights Watch, 2008; Kochel, Wilson, & Mastrofski, 2011). According to Human Rights Watch's analysis of arrest data obtained from the FBI, Blacks' arrest rates nationwide for drug charges are higher than White arrest rates relative to their proportion in the population, although Blacks and Whites engage in drug offenses at roughly comparable rates (Human Rights Watch, 2009). In the states we studied, the Black to White ratio of drug arrests in 2006 ranged from 2.6 in Oklahoma and New York, to 4.5 in Connecticut and 5.1 in Washington state (Human Rights Watch, 2009). In addition, recent studies have identified law enforcement's use of racial profiling to determine who is searched for drugs during traffic or pedestrian stops is well-documented (Birzer & Birzer, 2006; DeLisi, 2011). Once stopped, Blacks are more likely to be searched and arrested (Human Rights Watch, 2008).

4.2. Impact of prior criminal justice involvement

Our results corroborate earlier findings in the literature that history of prior arrests or incarceration is the strongest predictor of arrest in the time period following substance abuse treatment (Calsyn et al., 2005; Easton et al., 2007; Luchansky et al., 2000; Luchansky et al., 2007). However, among outpatient treatment clients in New York, engagement provides additional protection for those with prior arrests or incarcerations. In other states, treatment engagement was not strong enough to have an additional impact on criminal justice outcomes among this population. In addition, being treated in a facility with a higher proportion of clients who also had prior arrest or incarceration was associated with a higher hazard of arrests (with the exception of Oklahoma). These two complementary results are particularly important, because half of the clients treated in the public sector in three states had a prior arrest or incarceration history in the year before they began their episode of treatment.

For clients with prior criminal justice involvement, engagement may not be enough to bring about positive changes and sustain outcomes. These clients may need more resources as they transition back to the community, such as relapse prevention, employment services, vocational training, housing, and connections to social networks of non-users. To address the high costs associated with incarceration and the high rates of recidivism among ex-offenders once released, many states have implemented reentry initiatives that usually entail collaborative relationships between correctional institutions and partnering community service providers who provide varied health and supportive social services to individuals transitioning from incarceration back into the community. Currently, Connecticut has several programs in place designed to assess and address inmates' substance abuse, mental health and medical treatment service needs prior to release, as well as to coordinate appropriate aftercare with community partners upon their release from incarceration. In New York, the full impact of amendments to the Rockefeller Drug Laws in April 2009 that expanded judicial discretion to offer drug court alternatives for certain addicted nonviolent offenders are still being studied (Division of Criminal Justice Services, 2012).

4.3. Study limitations

Working collaboratively, the state and academic co-authors were able to take advantage of the rich opportunity for research offered by linking information from the substance abuse treatment agencies and

the criminal justice agencies. As previously reported by other researchers, despite the best efforts of everyone involved and our previous collaboration through the Washington Circle Public Sector Workgroup (Garnick et al., 2011; Garnick, Lee, Acevedo, et al., 2009; Garnick, Lee, Horgan, et al., 2009), the data sharing process was difficult and time consuming (Hser & Evans, 2008). Within each state, we had to take into account each agency's Institutional Review Board, data sharing agreements, and security procedures. On average, it took over a year from the initial data request for merged files to be transmitted to the academic co-authors. Despite the rich information we obtained from this serious investment of effort, we recognize several limitations to the analytic databases that we built.

First, there may be some missing data on arrests or incarcerations from the administrative sources, and this issue may vary in magnitude across states. Clients new to the state treatment system (e.g. recently moved to the state) may have incomplete prior year treatment or criminal justice data. The four states differed in the level of detail about arrests that they could make available for this study. Particularly, in New York, only the "top charge" was listed for each arrest whereas in other states multiple charges were coded for each arrest. This results in lower rates of specific types of arrests for New York.

Moreover, although we used the best possible methodology for linking administrative data, we cannot claim that all matches between state treatment systems and state criminal justice systems were entirely correct. Issues in the underlying data such as missing data on key matching variables, the use of multiple identifiers (social security numbers) by some clients, and errors in the data (e.g., misspelling or partial information for names) existed for all states to some degree. Of particular concern was New York's linkage algorithm which had to rely on more limited data and probably had lower accuracy. Washington State research suggests that New York's lower accuracy may, in part, explain its higher hazard ratio for prior arrest or incarceration. To test the impact of linkage accuracy on analytic results, a Washington State researcher conducted "what if" analyses under a variety of scenarios, including one similar to our particular model (Campbell, 2009). If a variable for a prior status is included as a predictor of a subsequent status, such as the status of criminal justice involvement as in our case, and if the source for the status relied on the same linkage and thus often miscoded the same subjects in both the pre and post time periods, it would produce biased results (i.e., hazard ratios of large magnitude). Furthermore, if an independent source was used to determine the prior status, results were far less biased. To test the sensitivity of our results to this issue, we re-ran the analyses for NY, using self-reported criminal justice involvement in the past 6 months instead of arrest status based on administrative data. As suggested by Campbell (2009), the hazard ratio for the self-reported prior criminal justice involvement, while still significant, was much lower in the model and the interaction between individual engagement and self-reported criminal justice involvement was no longer significant. Perhaps most importantly, however, the hazard ratio for individual engagement, our key variable of interest, remained the same.

Second, this study used information on arrests obtained from linking to states' criminal justice agencies. Thus, we examined the impact of treatment engagement on official encounters with the criminal justice system, but did not measure the impact on criminal behavior itself. In particular, we were not able to link arrests with their adjudication, so we do not know if clients who were arrested were later found not culpable of any crime, and of course, we were unable to use criminal behavior that was unrecorded. Also, by using a one year period for prior history of arrest or incarceration, we did not make use of criminal justice involvement from a more distant prior period. We selected a one year period because of concerns about not being able to differentiate between those with no real criminal justice activity from those not residing in the state.

Third, as in other non-randomized, observational studies, there may be unobserved or uncollected variables that, if included in the models would influence both engagement and outcomes. For example, clients with stronger motivation at entrance to treatment may have both higher engagement and better outcomes. The potential effect of unobserved variables on outcomes is probably lessened because the study included a substantial collection of clients' clinical and behavioral characteristics in the regression models. The variables we used were consistent with the Behavioral Model of Health Services Use (Andersen & Davidson, 2007) which posits that a rich array of individual and contextual characteristics may influence health services use.

4.4. Implications for use of treatment engagement as a performance measure

Performance measures, such as engagement in substance abuse treatment, are a starting point in improving the quality of treatment of people who are not receiving adequate treatment for their addiction problems. The acceptance of measures that focus on process of care, such as engagement in substance abuse treatment, often rests on their association with outcomes. Previous research on the effect of treatment engagement on outcomes generally has focused on its ability to reduce substance use. Client's own engagement in outpatient treatment was shown to be associated with reduced substance use in the Veterans Administration (Harris et al., 2010). Similar measures (two to six visits in the first month of treatment among veterans) were associated with both individual and facility-level positive outcomes at outpatient and intensive outpatient clinics for patients with alcohol use disorders (Harris et al., 2009). Among adolescents in public sector treatment, those engaging in outpatient treatment had significantly lower likelihoods of reporting any substance use, alcohol use, heavy alcohol use, and marijuana use, although facility-level engagement rates were not significantly associated with any outcomes (Garnick et al., 2012). In Washington State, engagement as a main effect was not significant for employment outcomes; however, for clients with prior criminal justice involvement, engagement was associated with both having any employment and with higher wages following treatment (Dunigan et al., in press).

Results of the current study add to existing research by identifying a significant association between engagement in specialty outpatient treatment in public sector settings in four states and criminal justice outcomes. These results are particularly important in an environment where there is a renewed focus on performance measures driven, in part, by recent legislative initiatives such as the 2010 Patient Protection and Affordable Care Act, which may open up treatment for substance use disorders for more Americans; and the 2008 Mental Health Parity and Addiction Equity Act, which expands benefits for mental and substance use disorders. Moreover, performance measures play a key role in incentive-based approaches to paying for treatment services. With this focus on performance measures, therefore, further studies are crucial to better understand if the associations between improvements in process-based performance measures and improvements in clients' outcomes extend to other populations and types of outcomes.

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White Paper

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August 2010

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I. INTRODUCTION

The Center for Substance Abuse Treatment (CSAT), Division of State and Community Assistance and Division of Pharmacologic Therapies, invited representatives of 12 Single State Authorities for substance abuse services—plus the National Association of State Alcohol and Drug Abuse Directors (NASADAD), NAADAC, the Association for Addiction Professionals, and the State Associations of Addiction Services—to discuss and share their experiences and challenges in implementing medication-assisted treatment (MAT). The final participant list is included as appendix A.

Participants shared program, funding, regulatory, and other strategies and discussed lessons learned. Appendix B includes a list of MAT resources that participants shared, and the following sections summarize participants' insights. There was uniform agreement that MAT is effective, and there was uniform support for its expanded use. While participants also clearly pointed out that MAT faces challenges, the substance abuse field, including MAT, is moving steadily toward integration—with mental health, developmental disabilities, and ultimately mainstream medicine. Such integration reflects the growing strength and integrity of the substance abuse field and recognition that achieving important outcomes requires providers to put individual client needs first in service planning and delivery. MAT and medication-assisted recovery occupy an important place in this process and in the recovery-oriented continuum of care.

II. MEETING SUMMARY

A. What is MAT?

The treatment of substance use disorders (SUDs) has advanced from the days when disulfiram (Antabuse) was the only medication used to promote long-term recovery in alcohol-dependent clients and methadone was the only medication used to promote long-term recovery in opiate-dependent clients. In discussing the concept of MAT, participants noted that the term has been defined differently. Today, MAT refers to a range of pharmacotherapy that encompasses a variety of medications that are available to detoxify and medically manage clients and treat addiction, including prescription drug, alcohol, and tobacco addiction. This broader definition of MAT reflects an important change because it sets the stage for a new vision of substance abuse treatment and the role that medications can play in client recovery and in the quality of care that substance abuse providers deliver.

B. Vision for MAT Implementation

States are in different stages of implementing MAT, with a wide range of plans envisioned for future development. (See “Appendix C: Brief Examples of State MAT Implementation.”) With a broad spectrum of activities already underway, participants discussed both a long-term perspective as well as immediate developmental strategies for MAT.

In the long term, participants envision full integration of addiction treatment and MAT with primary health care. Based on this vision, MAT becomes part of the mainstream health care system and takes its place as a means of addressing disease conditions and restoring the health and well-being of substance-dependent and addicted individuals. States are moving toward this long-term vision through various strategies. Some are implementing pilot projects in which they introduce MAT incrementally through regulatory, contractual, and workforce changes. For example, one State has collaborated with its drug courts to begin offering Vivitrol (naltrexone) to clients, while another State has begun dispensing buprenorphine through its outpatient treatment clinics. Still other States are reaching out to local medical societies and physician communities, educating these professionals about MAT to begin normalizing addiction as part of the human condition. Participants agreed that MAT for SUDs must become part of mainstream medicine, particularly as more medication options become available. Primary care physicians, and newer physicians in particular, need training to understand that, as a disease, SUD treatment requires an integrated team of specialists and medications like the treatment of many other diseases. Physicians also need to recognize that effective tools and knowledgeable substance abuse treatment professionals need to be an active part of the care team.

C. Importance of Strategic Partnerships

The importance of forming strategic partnerships emerged as a core theme and strategy for MAT implementation. States are effectively creating and expanding partnerships with other systems, such as child welfare, corrections, and primary health care, to coordinate planning and priorities and to advance understanding and acceptance of MAT. In many States, substance abuse provider organizations are in place and strong partnerships with these groups have proven especially valuable in the following ways:

- Securing legislative support for MAT
- Supporting and implementing regulatory changes
- Encouraging use of patient-centered, evidence-based practices
- Removing barriers to opening opioid treatment programs (OTPs) in communities
- Encouraging openness to MAT within and across multiple levels of care (e.g., drug courts, outpatient clinics, and residential treatment centers)
- Promoting coordination within the field

Some States have also established clinical provider and consumer advisory groups to obtain guidance and valuable feedback on specific MAT policies, review patient care issues, and improve performance of clinicians and provider organizations.

With substance abuse as a factor for a significant number of persons involved in the justice system, States have recognized the importance of reaching out to educate drug courts and judges about MAT, dispelling myths, emphasizing the benefits of MAT for clients, and encouraging drug court acceptance of MAT clients. Intensive, one-on-one efforts to establish relationships with correction officials have culminated in introducing methadone into a State prison for the first time, and, in another instance, adding a methadone clinic to a detention center. These and other efforts are promoting the seamless transfer of adjudicated individuals back into the community and linking them to treatment. A participant also reported that in 2010, the Department of Justice, under its Second Chance Act initiatives, authorized \$15 million to strengthen collaboration between the substance abuse and criminal justice fields and to introduce pharmacological treatment into prisons.

States are addressing the needs of underserved populations through partnerships with organizations such as the Veterans Administration. In one State, a new initiative focuses on assessing traumatic brain injury and comorbid drug problems among veterans. Due to the increase in availability of opiates and consolidation of drug cartels in some border areas and tribal lands, States now recognize that stronger partnerships with tribal leaders are also essential.

Participants identified the recovery community as an important partner for MAT providers and clients. States are encouraging individuals receiving MAT to engage with recovery support services in the community; and educating these service providers about using MAT and the outcomes achieved for clients is now part of effective MAT delivery. State efforts to communicate with and train members of the recovery community about MAT have also led to more openness about this treatment approach among groups at the national and local levels, such as Narcotics Anonymous, that previously have rejected medication treatments for SUDs.

Participants said that forming linkages with federally qualified health centers (FQHCs) and community health centers is an important but challenging strategy for States and MAT implementation. Nevertheless, several States are successfully reaching out to and collaborating with FQHCs around MAT. As a result, there have been opportunities for increased integration with primary health care, enhanced support for medication monitoring, and increased likelihood that FQHC clients are effectively linked with substance abuse treatment providers for counseling and other essential support services.

Despite these ongoing and positive efforts, participants agreed that States must forge additional strategic partnerships and strengthen and expand existing ones. Participants clearly stated that developing partnerships with primary care physicians is extremely important. They generally agreed that sometimes poor coordination exists between primary care physicians and MAT providers. A range of strategies and initiatives are underway to address this issue. For example, several States are now engaging primary care physicians in substance abuse screening and brief interventions through the CSAT-funded Screening, Brief Intervention, and Referral to Treatment (SBIRT) training grants. Other States have successfully engaged medical societies to educate their members on substance abuse, particularly MAT. In one State, physicians at several medical schools received training through a large grant to introduce substance abuse material within the primary care curricula. Also, trained substance abuse staff members are working alongside physicians and nurses in emergency departments to provide screening, brief interventions, and referrals to treatment.

In addition, participants agreed that the time is right to educate members of Congress about MAT. Current interest concerning prescription drug abuse is high among these elected officials, providing an opportunity for briefings by representatives of the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, States, and providers, who are focused on MAT and its capacity to enhance the quality of life for constituents and help reverse the consequences of prescription drug abuse.

D. Need for Workforce Development Measures

All States are paying considerable attention to workforce development. A primary workforce development goal is to ensure that competent, trained professionals deliver MAT, and States recognize that substance abuse clinicians and physicians have knowledge and skill deficits in delivering and monitoring MAT. A second goal is to ensure that substance abuse providers integrate MAT into their programs and collaborate effectively on behalf of clients with existing OTPs, prescribing physicians, and others.

States reported that training has reduced the considerable resistance to MAT among some treatment providers. Relevant topics for training of substance abuse providers have included addiction neuroscience; craving; pharmacological actions of the various prescribed medications, including methadone, Vivitrol, and buprenorphine; attitudes regarding MAT; the stigma attached to clients and use of MAT; and the complexities of co-occurring disorders. Also, participants said this is an educational priority: the need to foster a culture of competency by educating providers about their new level of responsibility and accountability as medications are introduced into the treatment environment.

One State is now requiring physicians in its treatment programs to be certified by the American Society of Addiction Medicine (ASAM) within a few years and is collaborating with ASAM to offer relevant courses and mentoring opportunities. States have also recognized that primary care physicians are often poorly informed about medical interventions for addiction, safer opioid prescribing, and the stigma associated with substance abuse in general and MAT specifically.

States identified other workforce development issues, including poor retention of trained staff and the difficulty of attracting qualified personnel to underserved and rural communities. The low pay structure for provider staff members remains part of the problem, leading to high turnover, staff vacancies, and a workforce with limited MAT knowledge. To address this challenge, one State petitioned its licensure body to waive certain licensing requirements so that a broader, nonlicensed group of individuals could be considered for employment.

Participants identified a range of strategies they employ to address workforce development needs, including the following:

- **E-learning.** States reported using this learning methodology to conveniently disseminate content on a range of topics to dispersed groups. For example, States also reported that e-learning tools are used to educate physicians and other emergency department personnel, such as nurses and social workers, on SBIRT. Groups of individuals with similar learning needs and interests have formed collaboratives to enhance their learning experience. In another instance, a substance abuse agency is collaborating with a mental health agency to fund e-learning systems and continuing education courses.
- **Videoconferencing.** States are using this capability to bring together clinical, medical, and other groups of professionals and to connect those located in different areas of a State to discuss various topics and practices, provide supervision, and offer case presentations for review and discussion.
- **Learning Thursdays.** Substance abuse professionals who require certification and/or a license to practice must routinely participate in continuing education activities and courses. One State supports its workforce to obtain such educational units by sponsoring biweekly webinars—“Learning Thursdays”—with free educational credits. These 1- to 2-hour webinars feature clinical guidance, patient stories, information sharing on MAT, tobacco cessation approaches, and related topics.
- **Cross-agency training.** In one jurisdiction, the Office of Public Health (OPH) requested and received training on addictions because it operated shelters with clients who often had SUDs and co-occurring disorders. The jurisdiction developed protocols linking the systems of care for

addictive and co-occurring disorders, and is conducting quarterly videoconferencing on MAT and addiction treatment conducted for OPH and mental health personnel.

- **Governor’s Institute on Alcohol and Drug Abuse.** This institute in one State provides training and technical assistance in such areas as MAT and opioid prescribing for physicians; supports safer opioid prescribing training; and has successfully partnered with local medical societies to encourage physicians to participate in training. Institute training workshops have also focused on the State-controlled substances reporting system, and the institute distributes a monthly online newsletter to physicians, nurses, and other providers. A new institute project is to provide training for drug courts on MAT, initially focusing on attitudes about addiction.

E. Role of Statutes, Regulations, and Policy in MAT

States identified several examples that illustrate the role that statutes, regulations, and policies play in delivering MAT. For instance, States have revised their statutes to allow use of general funds to establish an MAT program and to expand the range of services that substance abuse providers must offer. The expansion in the number of for-profit OTPs has caused some States to review how they should regulate these providers. Many States require all providers to be licensed; in other States, regulations apply only to providers receiving public funds. In other instances, contractual requirements ensure that program and client data reporting occurs, that programs address standards regarding delivery of counseling as well as medications, and that sanctions are in place.

States are using regulatory and other reforms to address discriminatory practices toward MAT clients. Some States have instituted regulations prohibiting non-MAT providers who receive public funds from discriminating against methadone patients. When one State changed regulations to merge MAT with its outpatient system of care, resistance to serving MAT clients surfaced. Thus, the State revised provider contracts, requiring that providers offer clients an opportunity to receive MAT, either on site or through a memorandum of understanding. Based on the effectiveness of this approach, other States are considering a similar solution to end the practice of providers turning away MAT clients. Another jurisdiction—to address community restrictions on establishing new MAT programs to expand capacity—implemented mobile service units that did not require zoning changes.

As the overall substance abuse treatment field moves toward the chronic disease model and availability of MAT expands, participants suggested that States may need to reexamine their statutes or regulations regarding the size of clinical caseloads. The large caseloads of many clinicians have typically included multiple, long-term MAT clients, and clients who require more intensive services need some of these slots. Reducing clinicians’ caseloads to respond to these needs may require statutory or regulatory revisions that support a better balance between clients who are in the early phases of treatment versus those in the later phases.

States have a range of laws in place to stipulate who delivers MAT. For example, one State requires that a certified professional perform client assessments, while another State requires all prescribing physicians in substance abuse treatment programs to be ASAM certified. The professional licensing requirements of still other States are limited. At a minimum, a physician must be licensed and trained to prescribe and monitor medications, and State medical directors are typically engaged in training, mentoring, and providing oversight for the MAT medical staff.

Participants said confidentiality regulations are often misunderstood, hindering collaboration among substance abuse, mental health, and primary health care providers. Some States viewed the need to maintain compliance with Federal confidentiality regulations (Title 42 of the Code of Federal Regulations, Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records) as supporting client protections and ensuring appropriate communication with and effective monitoring of clients who are receiving MAT, particularly those with comorbid conditions and clients in emergency environments. Other States indicated that, typically, counselors obtain written releases from clients and that counselors generally secure required releases to facilitate the exchange of client information. There was a mentioned need for continuing assistance with establishing agreements and interpreting the regulations.

States are using statutes, regulations, and policies to ensure that best practices are in place. From a practical perspective, States are writing regulations and policies to ensure that programs, such as mobile units, store and dispense medications appropriately. Because MAT linked with counseling is a best practice that has been shown to improve client outcomes, some State statutes require counseling as part of treatment. Participants, however, voiced some concern that, as States move toward integration with mental health and primary health care, they are no longer linking counseling consistently to MAT.

F. Use of Technology

Participants acknowledged that technology is a valuable and integral part of a fully developed system of care for MAT clients. As already noted, States in varying degrees use such technologies as webinars, videoconferences, and e-learning tools for staff training and information sharing. A few have formed multidimensional learning systems to strengthen education and training within and across systems.

Participants identified the following examples of additional technologies that their States employ to improve MAT access and quality:

- **Telepsychiatry and e-counseling.** The development and use of telepsychiatry addresses the severe shortage across the country of addiction psychiatrists trained to provide MAT and other behavioral health services. Using online systems, these specialists can efficiently extend their reach to programs and clinics, especially in rural and medically underserved areas. One State that has implemented this service worked with its Medicaid office and made statutory, policy, and procedural changes to authorize delivery of psychiatric services, including involuntary commitments under specific circumstances. Participants agreed that using telepsychiatry and nurse practitioners in areas with few physicians will expand in the future.

Closely resembling telepsychiatry, e-counseling offers client access to trained clinicians regardless of location, time of day, mobility, or other factors. At least one State indicated an interest in creating regulations to allow for delivery of and payment for e-counseling.

- **Central patient registry.** States are using central patient registries to track residents receiving methadone treatment across a State. The registry helps in authorizing appropriate doses of methadone for clients during emergencies such as Hurricane Katrina.
- **Prescription drug monitoring system.** Multiple States have implemented this system, which supports improved quality of care, by giving physicians ready access to information about prescriptions that clients may be receiving and on which critical treatment decisions are based. While many physicians have access to a prescription drug monitoring system, some do not consistently use it. One State also reported that the Veterans Administration prohibits its physicians from accessing the prescription monitoring system.

G. Role of Medical Directors

Since 1993, the Substance Abuse Prevention and Treatment Block grant regulations have required States to employ a State medical director. Over time, the medical directors have assumed different roles and responsibilities within States, and, in some areas, multiple medical directors with assigned specialty areas are in place. States that have involved their medical director in the implementation of MAT services have found it to be an effective practice.

A consistent role for medical directors responsible for substance abuse and mental health is developing policies and procedures. For instance, in States with combined substance abuse and mental health organizations, the medical director has worked with the addictions staff to develop policies and procedures regarding such issues as using methadone and benzodiazepines, managing drug interactions, prescribing during emergencies, and overseeing pilot projects that explore new dosing protocols with pain management patients. Regarding mental health, medical directors have also

developed policies and procedures regarding delivery of psychiatric services and operation of psychiatric hospitals. In addition, medical directors have been engaged in efforts as diverse as helping to secure Medicaid reimbursement for substance abuse services and educating legislative staff on MAT issues and benefits.

State medical directors are also starting to focus on a second key area: workforce development. With workforce issues prominent in many States, medical directors have been instrumental in encouraging training on evidence-based practices and in working with patients with co-occurring disorders. Medical directors have led efforts to develop protocols for cross-system training on MAT for child welfare and corrections staff members, and they worked to develop linkages with entities such as hospital emergency departments, community mental health centers, and FQHCs.

State medical directors have played an important role in guiding and supervising clinical treatment directors in OTPs and in substance abuse treatment programs. For instance, they have conducted regular meetings with program personnel, providing direction on implementing policies, regulations, and best practices. Other medical directors make OTP site visits or mentor providers via teleconferences.

H. Physicians and Buprenorphine

Physicians are increasingly prescribing buprenorphine for detoxification and treatment of opiate addiction. While multiple States dispense the medication through their outpatient programs, hundreds of individual primary care physicians in private practice settings in many States are certified to prescribe and monitor patients receiving buprenorphine.

Despite intensive efforts to certify primary care physicians as prescribers of buprenorphine, State after State reported that significant numbers of these physicians are not prescribing the medication. Participants could not say for sure why physicians spend the effort to become certified and then do not follow through with client treatment, but they offered the following possible explanations:

- First, the buprenorphine training that physicians received may have caused them concerns about their ability to effectively manage induction and maintenance with a potentially challenging client population.
- Second, a recent letter from the Drug Enforcement Administration that referred to inspections of physician offices also may have contributed to physicians' reluctance to become buprenorphine prescribers.
- Third, there is often a lack of support for the physicians or a lack of effective linkages to counseling and other services that are needed to support recovery.
- Finally, participants considered the low level of Medicaid reimbursement to likely be a strong disincentive for physicians in private practice to prescribe buprenorphine.

States have made efforts to introduce and expand buprenorphine use to treat opiate addiction. Initiatives to train physicians, including using local medical societies, have helped. Another resource for physicians is ASAM's (American Society of Addiction Medicine) Physicians Clinical Support System (PCSS). States have contemplated engaging other service professionals, such as social workers, to support prescribing physicians in the community. At least one State is exploring special induction centers, since this is the phase of MAT that appears to cause physicians greatest concern. Participants suggested that a brief online survey of certified physicians could help identify barriers to the prescribing of buprenorphine and lead to targeted strategies for removing the barriers.

I. Health Disparities—Equity and Engagement Issues

Participants acknowledged that health disparities continue to exist within State systems of care and that these disparities include and extend beyond issues of access to treatment or a failure to achieve cultural competency within treatment environments. Participants said that States also need to understand health disparities within the context of equity and engagement for underserved populations, especially adolescents, women, African Americans, Native Americans, and Hispanic individuals.

Participants suggested several strategies to address a lack of equity for and engagement of target populations who could benefit from MAT. Optimally, substance abuse providers need to link with FQHC and community health centers to provide information, discuss these issues, and identify practical solutions. Participants also suggested finding and encouraging indigenous community leaders who are trained and engaged as substance abuse treatment clinicians and administrators. These clinicians will help build trusting relationships with clients, optimize engagement within the first few critical visits, and retain clients in treatment. As administrators, they will be able to listen deeply to community and client voices, help programs to focus more on the individuals they are serving, and achieve greater equity and engagement for underserved populations. The peer recovery support approach offers a good model for how to listen and engage others. Participants identified the Network for the Improvement of Addiction Treatment (NIATx) as another proven approach that requires constant examination of methods and outcomes so that “one size fits all” programs will become history. Another suggestion to help address health disparities included translation of documents into Spanish and other target languages.

J. Pain Management and Addiction

Some evidence indicates that more people are becoming addicted to opioid medications prescribed for pain management. In a few communities, for instance, physicians are sending these individuals to methadone programs for treatment. States agreed that pain management transcends the scope of MAT and requires physicians with specialized skills. At the same time, an individual’s clinical picture is not always clear. Persons with substance use disorders may also have chronic pain, and individuals prescribed pain management medications may have addiction issues. MAT providers are addressing these concerns by developing good working relationships with pain management clinics and providers in their communities. In at least one State, educational forums on dosing and pain management for OTPs were conducted. Participants also suggested that States need guidelines and procedures for substance abuse providers regarding addiction and pain management to achieve enhanced collaboration with other health professionals.

K. Enhanced Performance Measures

States face a common challenge of developing relevant performance measures for MAT. Participants agreed that capturing only admission and discharge data or using National Outcome Measures (NOMs) are not adequate or meaningful enough for MAT. While participants acknowledged that they continue to struggle with identifying and designing meaningful measures for MAT, they suggested the following as possible performance measurement candidates:

- Access to care
- Client progress through phases of treatment/levels of care
- Change in status
- Retention in treatment
- Client satisfaction
- Frequency of substance use (reduced number of drinks, days of drinking, etc.)
- Cost effectiveness
- Level of functioning (particularly for clients with co-occurring disorders)
- Utilization of services, including overuse
- Post-treatment engagement with peer recovery support
- Reduced symptom severity (e.g., using ASAM criteria)

- Implementation of a model with fidelity

States are at different stages in assessing performance of their MAT providers. There are States just starting on the journey, using NOMs while exploring detoxification, relapse, and other measures. Some States are conducting regular client satisfaction surveys, including use of separate instruments for adolescents and adults. Collaborating with providers, other States have developed provider report cards that include MAT, producing scores that focus on access, retention, and followup. Some States are interested in measuring practice fidelity at the clinical level as well as outcomes, and then assessing if the two are connected. Participants acknowledged that the needs for performance data can vary among clinicians, program administrators, and state and Federal officials.

A participant identified five quality indicators that this individual's State is using. These indicators include time from first contact through assessment, detoxification, and treatment; linkages; polypharmacy issues; cost-effectiveness; and trends in occurrence of sentinel events at regional and provider levels (e.g., suicides). Further, NASADAD is now compiling the medical literature on performance measures. While there are consistent performance measures in health care (Healthcare Effectiveness Data Set, National Quality Forum, etc.) that are widely used and accepted, the use of various adaptations of these measures for performance contracting is less consistent. Given recent work in the area of performance measures (e.g., Veterans Administration, Washington Circle) and the growing body of work in the area of performance contracting for substance use treatment, it appears promising that the substance abuse field will be able to develop a host of performance measures that are on par with those in medicine. The following are overall objectives of the NASADAD research effort:

- Identify criteria for effective substance abuse performance measures
- Determine the specific measures to implement
- Test the validity of the selected measures

III. CONCLUSION

MAT is among a number of key approaches and practices that can lead to an improved quality of life for many individuals with SUDs. States are advancing toward full integration of substance abuse, mental health, and developmental disabilities with primary health care services based on individual client needs—and MAT is an integral part of the continuum of care. States are implementing MAT with integrity, using different approaches but reflecting the common vision of full integration with the primary health care system.

States are developing effective strategies to address and persistently challenge barriers to MAT implementation. These key barriers include provider resistance to using medications to treat addiction, the lingering stigma attached to substance abuse, the urgent need for workforce development, and reluctance of other systems (e.g., corrections) to accept or incorporate MAT for their clients.

States have developed and are consistently employing certain approaches to strengthen MAT implementation and effectiveness. These common approaches include developing strategic partnerships; creating internal and cross-agency training opportunities; developing and advocating for changes to statutes, regulations, and policies; creatively using technology; attending to issues of equity and engagement; preparing guidance on pain management issues and expanding use of buprenorphine; and fully engaging the skills and knowledge of medical directors.

States are urgently searching for valid measures of organizational performance and client success to more fully integrate MAT within their programs and broader systems of care. MAT now plays a significant role in the continuum of care and client recovery, as evidenced by the use of continuous quality improvement and NIATx, implementation of pilot projects to demonstrative cost-effectiveness, and the resetting of performance measurement criteria in multiple States. With valid and reliable outcome data, States will be better able to improve existing MAT delivery systems and expand the reach of this life-saving and life-enhancing treatment.

APPENDIX A

**The Substance Abuse and Mental Health Services Administration
(SAMHSA)**

presents

Implementing Medication-Assisted Treatment Statewide

**Hyatt Regency Bethesda Diplomat/Ambassador
Bethesda, Maryland
March 11–12, 2010**

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APPENDIX B

MAT RESOURCES

NAADAC, The Association for Addiction Professionals—www.naadac.org

NAADAC is a membership organization serving addiction counselors, educators, and other addiction-focused health care professionals who specialize in addiction prevention, treatment, recovery support, and education. With 10,000 members and 43 State affiliates, NAADAC's network of addiction services professionals spans the United States and the world.

NAADAC's Life-Long Learning Series

Medication Management for Addiction Professionals: Campral Series

Published June 2006

Project Leader: Tom Freese, PhD

NAADAC, in partnership with Forest Laboratories, Inc., is pleased to introduce its Life-Long Learning Series with "*Strengthening the Will to Say No*" Medication Management for Addiction Professionals – Campral Series.

NAADAC's Life-Long Learning Series has evolved from NAADAC's long history of providing quality education courses led by counselors and other addiction-related health professionals who are trained and experienced in both pharmacology and clinical application of therapies. These seminars are aimed at NAADAC's 11,000 members, consisting of doctors, nurses, psychologists, social workers, counselors, prevention specialists and those who work in various clinical settings.

Campral is a pharmaceutical developed by Merck Santé s.a.s., a subsidiary of Merck KGaA of Darmstadt, Germany, and is licensed to Forest Laboratories, Inc. for use in the United States. Campral is designed to help clients stay alcohol free and is intended for people who are alcohol dependent, who have decided to stop drinking entirely, and are prepared to participate in counseling. Campral has been approved by the Federal Drug Administration and has been used for more than a decade in Europe.

Campral works differently than other medications for alcohol dependence. Campral is not intended to cause illness if the person drinks alcohol nor is it meant to block the "high" associated with drinking alcohol. Instead, it focuses on reducing symptoms of distress once the patient has become alcohol free. Clinical trials of Campral showed that patients on Campral are three times more likely to stay alcohol free than people taking placebo tablets. This is thought to occur by reducing the symptoms of withdrawal (anxiety, sweating, difficulty sleeping) which often lead alcohol dependents to drink again.

Counselors are in a unique position to work with others in the addiction related health care profession. As the people who know clients best, counselors can assess treatment plans and help determine if Campral is appropriate for their clients.

This distinct seminar on medication management is specifically designed for the addiction treatment professional. The education and training program will consist of dynamic workshops, which both challenge the participant to apply the knowledge to their existing skills as clinicians, while engaging addiction professionals in case studies and peer discussion.

Participants will be provided with a comprehensive reference guide and will be able to use this curriculum in their clinical practice. Following in the tradition of NAADAC's previous educational seminars, the handbook will also contain chapters regarding the relationship between physicians, counselors and clients and an appendix that will contain elaborate assessment worksheets.

Pharmacotherapy: Integrating New Tools into Practice

Published March 2007

Project Leader: Tom Freese, PhD

Alcohol abuse and dependence affects millions of Americans each year. The Substance Abuse and Mental Health Services Administration (SAMHSA) estimates that alcohol abuse affects 9.7 million people and alcohol dependence touches 7.9 million people. In the addiction profession, bio-psycho-social treatment traditionally has been the mainstay of alcohol and drug treatment programs, but more and more, there has been a growth in the availability of medications that may be able to supplement traditional treatment.

The goal of NAADAC's Life-Long Learning Series *Pharmacotherapy: Integrating New Tools into Practice* is to bring together addiction professionals from many backgrounds to discuss pharmacotherapy in a way that challenges ideas and perceptions, and to present unbiased information that can be used to assess the best possible treatment for patients.

This educational program will discuss the four facets of alcohol dependence and addiction (biological, psychological, social and spiritual), will discuss addiction as a disease and the scientific evidence to support this claim, will compare of FDA-approved pharmacotherapies for alcohol dependence, focus on overcoming treatment obstacles, apply strategies to match patients to the most appropriate therapy and plans to motivate patients in treatment.

New Innovations with Opioid Treatment: Buprenorphine

Published March 2008

Project Leader: Tom Freese, PhD

The goal of NAADAC's Life-Long Learning Series *New Innovations with Opioid Treatment: Buprenorphine* is to bring together addiction professionals from many backgrounds to discuss medication-assisted treatment in a way that challenges ideas and perceptions and to present unbiased information that can be used to assess the best possible treatment for patients.

This educational program will discuss the four facets of opioid dependence and addiction (biological, psychological, social and spiritual), addiction as a disease and the scientific evidence to support this claim, three FDA-approved medications for opioid dependence, applying strategies to match patients to the most appropriate therapy, methods of motivating patients in opioid dependence treatment and building cooperative relationships between addiction professionals and prescribers.

New Horizons: Integrating Motivational Styles, Strategies and Skills with Pharmacotherapy

Published August 2008

Project Leader: Carlo DiClemente, PhD

The goal of NAADAC's Life-Long Learning Series *New Horizons: Integrating Motivational Styles, Strategies and Skills with Pharmacotherapy* is to educate participants on various motivational approaches to help alcohol dependent clients make positive behavior change in their lives. This educational program will discuss how addiction counselors and other helping professionals can utilize a motivational style in addiction treatment, as well as how to integrate appropriate motivational strategies and skills to help the alcohol dependent move through the Stages of Change. This educational program will provide an introduction to open-ended questions, reflective listening, affirmation, summarizing, eliciting change talk, asking permission, giving advice, providing a menu of options, rolling with resistance and the four FDA-approved pharmacotherapies for alcohol dependence.

Integrating Treatment for Co-occurring Disorders: An Introduction to What Every Addiction Counselor Needs to Know

Published February 2010

Project Leader: Mary Woods, RNC, LADC, MSHS

Integrating Treatment for Co-occurring Disorders: An Introduction to What Every Addiction Counselor Needs to Know is a skill—based training program that will help addiction counselors improve their ability to assist clients who have co-occurring disorders, within their scope of practice. This educational program will discuss the many myths related to mental illness treatment, barriers to assessing and treating co-occurring disorders, relevant research and prevalence data, commonly encountered mental disorders, applicable screening and assessment instruments and issues surrounding medication management and coordinating with other mental health professionals. This education program will also introduce the integrated model of mental health and addiction treatment services, outlining how to utilize current substance abuse treatment best practices when working with this population. Through the use of case studies, video clips and interactive exercises, participants will feel more comfortable and competent in addressing mental health issues with clients who have co-occurring disorders.

Michigan

http://www.michigan.gov/documents/Treatment_Policy_05_Enrollment_Criteria_for_Methadone_145925_7.pdf

Michigan's policy for enrolling clients for services with methadone.

http://www.michigan.gov/documents/Treatment_Policy_04_Off-Site_Dosing_147368_7.pdf

The policy that assists with the regulation of off-site dosing and take-homes for methadone.

http://www.michigan.gov/documents/mdch/TA-T-06_Counseling_Requirements_206190_7.pdf

A guidance document established to help methadone programs understand the requirements involving a change in the administrative rules for how counseling should be provided to clients receiving methadone.

http://www.michigan.gov/mdch/0,1607,7-132-27417_27655_30419---.00.html

This webpage contains all of the documents required for establishing a new treatment program in Michigan.

http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=32514401&Dpt=&RngHigh=32599408

Specific rules and regulations for methadone treatment programs in Michigan.

New York

<http://www.oasas.state.ny.us/Admed/index.cfm>

The New York State Office of Alcoholism and Substance Abuse Services (OASAS) maintains a robust Addiction Medicine Web site. Sections include Addiction Medications, Drugs of Abuse, Prescription Drug Abuse, Medical Consequences, and Physician Resources. Through this Web site, OASAS also offers a free Addiction Medicine Educational Series.

New Jersey

<http://www.state.nj.us/humanservices/das/feefor/forms/NETI%20App.doc>

New Jersey's fee-for-service (FFS) Medication-Assisted Treatment Initiative (MATI) Network application. Interested providers need to complete this application to join the network of approved FFS providers for this medication-assisted treatment FFS initiative. The application includes the qualifying criteria.

<http://www.state.nj.us/humanservices/das/feefor/descriptions/Standardized%20Service%20Descriptions%20Jan%202009.doc>

The link on the Web site to treatment service descriptions, which includes medication services as well as STR, LTR, etc.

<http://www.state.nj.us/humanservices/das/treatment/neti/index.html>

The Web site link to background information on the MATI. The MATI consists of five mobile medication sites, one fixed site, six corresponding office-based services sites, outreach to the syringe exchange programs and community-based agencies, two intensive supportive housing providers serving 62 individuals with wrap-around services, the creation of ten enhanced sub-acute detoxification beds, vouchers for additional treatment services in a fee-for-service network of 28 providers, and an evaluation of the entire initiative conducted by CASA at Columbia. The site also includes links to our biannual reports to the Governor and Legislature on this pilot initiative.

<http://www.state.nj.us/humanservices/das/information/AB-Buprenorphine.pdf>

The Web site link to the administrative bulletin on buprenorphine, which details guidelines for its use in New Jersey substance abuse treatment facilities.

The State of New Jersey also provided the following documents (included in this appendix):

- Annex As for New Jersey's MATI, which are similar to contractual terms and conditions to which providers must adhere. These documents are just one component of New Jersey's contract package, and they include descriptions of deliverables for the services.
- The Request for Proposal Nondiscrimination language for clients using MAT.
- A brief description of New Jersey's quarterly medical directors' meetings.

Methadone Maintenance Treatment Annex A

In addition to the General Requirements stated in Annex A-Sections I and II, the contractee shall comply with the following requirements and all services provided and/or referred shall be documented in the clients' file.

***DAS reserves the right to amend this document as necessary during the contract period.**

A. Contract Specific Requirements

1. The contractee shall accurately complete the New Jersey Substance Abuse Monitoring System (NJ-SAMS). The NJ-SAMS admission and discharge screen forms shall be completed for all clients to ensure participation in the National Outcome Measures (NOMS).
2. The contractee shall ensure that upon admission each client shall be assigned to a substance abuse counselor, with assignment documented in the client's treatment file.
3. The contractee shall ensure a minimum of (150) methadone clients at all times.
4. The contractee shall ensure clients being referred by the mobile unit for methadone maintenance and requiring office-based services be accompanied by mobile unit staff, ensuring that client's receive the recommended level of treatment.
5. The contractee shall ensure that during all hours when medication is being administered, there shall be at least one registered professional nurse (RN) present in the mobile unit for 150 or fewer active clients and at least one additional licensed nurse present in the mobile unit for each additional 150 or fewer active clients.
6. The contractee shall provide priority treatment to the following in this order: Pregnant injecting drug users, pregnant drug users, injecting drug users, and all other drug users.
7. The contractee shall ensure that all pertinent and required documents shall be visibly posted, including priority treatment for pregnant women and IV drug users, DAS license, DAS complaint hotline, and how to request for sign language interpreter services.

B. Clinical Services

1. The contractee shall ensure that appropriate assessments are completed on each client including a completed New Jersey Substance Abuse Monitoring System (NJSAMS), Addiction Severity Index (ASI), Diagnostic Statistical Manual (DSM) IV Diagnoses (all 5 Axes), American Society of Addiction Medicine (ASAM) Level of Care Index, and medical clearance and evaluation.
2. The contractee shall ensure that each substance abuse counselor's caseload does not exceed 50 clients.
3. The contractee shall ensure that group therapy includes no more than 12 clients per session.
4. The contractee shall ensure that all individual, group, and didactic sessions shall be a minimum of 45 minutes in duration regardless of the modality of treatment.
5. The contractee shall ensure that clients have been educated about the Phase system of methadone maintenance and what they must do in order to progress through the Phases.

6. The contractee shall ensure that all outpatient methadone detoxification programs shall provide a minimum of one counseling session per week to each client during the first four months after initiation of treatment and at least one counseling session every two weeks thereafter until discharged.

7. The contractee shall ensure that their outpatient methadone maintenance program(s) assign each client to one of the following Phases and provide counseling to the client in accordance with the following schedule:

Phase I. At least one counseling session per week with at least one individual session per month, for a total of four sessions per month.

Phase II. At least one counseling session every two weeks with at least one individual session, for a total of two sessions per month.

Phase III. At least one individual counseling session per month.

Phase IV. At least one individual counseling session every three months.

Phase V. Clients who have had twenty-four consecutive months of negative drug screens and meet other program criteria for treatment progress shall receive counseling services at a frequency determined by the multidisciplinary team and program policy.

Phase VI. Clients who have had thirty-six consecutive months of negative drug screens and meet other program criteria for treatment progress shall receive counseling services consistent with their clinical needs and the documented recommendations of the multidisciplinary team.

Phase I-A. Clients in Phase I, for a period of at least twelve (12) months, who have failed to progress in treatment despite documented efforts by the program to intensify treatment services and where referral to supplemental treatment services or a residential program is not available, may be retained in treatment at a lesser level of service designated as Phase I-A in accordance with the following:

- The program can document a multidisciplinary team case conference that determines a substantial identifiable benefit exists to the client and/or the general public that supports retaining the client in treatment despite the client's continued lack of progress in treatment;
- The program's decision to retain a client in Phase I-A shall be based on a benefit to the client and/or general public which is documented in the client record and supported in writing by the counselor, director of substance abuse counseling, director of nursing services and medical director; and
- Written documentation of alternative treatment (i.e., IOP, residential, hospitalization, etc.) options explored by the program shall be included, along with reasons why these options are inappropriate (i.e., not available in area, etc).
- Clients designated as Phase I-A shall receive at least two (2) counseling sessions per month, including one (1) individual counseling session, and shall receive at least one monthly drug screening; and
- The multidisciplinary team shall review and document the status of clients designated in Phase I-A on a quarterly basis.

Phase I-A Client who refuses treatment services:

- All Phase I clients shall be maintained on a therapeutic dose of methadone for a minimum of one year.
 - All clinical interventions to engage client into treatment shall be documented in the clients file.
 - If, after a minimum of one year on a therapeutic dose of methadone, the client does not make any progress in treatment, despite repeated attempts to engage the client into treatment, the multidisciplinary team may recommend that the client be detoxed from methadone.
 - The contractee shall notify the DAS Project Director at Jude.lheoma@dhs.state.nj.us or at (609) 292- 3326 at least 3 days prior to initiating detoxification off of methadone.
8. The contractee shall ensure that all client Phases be clearly documented in progress notes.
 9. The contractee is required to document in a consistent manner, and by client signature, all client contact and counseling sessions.
 10. The contractee shall provide and/or refer for the clients for:
 - Educational services
 - Vocational counseling and training
 - Job placement for clients
 - Legal services
 11. The contractee must conduct and document client education (developed by medical personnel- i.e. physician, nurse practitioner, physician assistant, registered nurse) specific to methadone pharmacology and to include, but not be limited to:
 - Drug interaction
 - Physical effects
 - Withdrawal effects
 - Long term treatment options
 - Disease management
 - Other medication options
 12. The contractee shall ensure that each client has an up-to-date individual treatment plan that includes goals and objectives of treatment with time frames.
 13. The contractee shall ensure that each client's treatment plan is reviewed every 90 days by a multidisciplinary treatment team.
 14. The contractee shall ensure that each client has a discharge plan and/or continuum of care plan that begins on the onset of treatment.

C. Co-occurring Disorder Requirements

1. The contractee shall have a policy regarding the assessment, treatment and/or referral of clients with co-occurring disorders (classified in Quadrants I , II, III and IV by the National Association of State Mental Health Program Directors and The National Association of State Alcohol and Drug Abuse Directors (NASMHPD/NASADAD)
2. The contractee shall admit and medicate all clients (classified in Quadrants I thru IV, NASMHPD/NASADAD) with co-occurring mental health and substance abuse/dependence disorders.

Level of Care Quadrants

<u>Quadrant III</u>	<u>Quadrant IV</u>
High Substance Abuse Disorder Low Severity Psychiatric Disorder	High Substance Abuse Disorder High Severity Psychiatric Disorder
<u>Quadrant I</u>	<u>Quadrant II</u>
Low Substance Abuse Disorder Low Severity Psychiatric Disorder	Low Substance Abuse Disorder High Severity Psychiatric Disorder

- 1) The contractee shall admit and provide counseling services for methadone clients classified in Quadrants I and III, with co-occurring mental health and substance abuse/dependence disorders, and/or who meet the agency's admissions criteria.
 - The contractee shall ensure that the referral of a client for psychiatric assessment, differential diagnosis, and/or assessment/prescription for, and monitoring of medication, shall be clearly documented in the client's treatment plan.
- 2) The contractee shall ensure that all methadone clients classified in Quadrants II and IV, with co-occurring mental health and substance abuse/dependence disorders are referred to and receive at a minimum the following services:
 - Clients shall be referred to an appropriate mental health agency for counseling services and medication monitoring other then suboxone.
 - The contractee shall work collectively with the mental health facility to ensure participation in the client's treatment plan.

D. Urine Drug Screens

1. The contractee shall ensure that all clients continuing in treatment receive a minimum of 12 random urine drug screens within the first year and at least 8 random urine drug screens in each subsequent year. Any client receiving 6 or more take home bottles shall have random monthly urine drug screenings.
2. The contractee shall ensure that for clients with positive urine drug screens in any Stage of treatment, additional individual, group, and family counseling sessions must be provided, with a focus on addressing the circumstances behind the positive urine drug screens. The client's treatment plan must be reviewed by the multidisciplinary team with the treatment plan revised as appropriate. The review, recommendation and subsequent actions must be appropriately documented in the client chart.

- A client with a positive urine drug screen, the first time after admission, shall return to a minimum of one counseling session per week until symptoms cease and shall remain in the present phase of treatment.
- A client with a second or subsequent positive urine drug screens any time after admission may be returned to a lower stage of treatment.

E. Policies and Procedures:

1. The contractee shall establish and adhere to take-home medication policies which are consistent with State and the Drug and Enforcement Administration (DEA) regulations.
2. The contractee providing methadone treatment or other opiate substitution treatment shall maintain on-site, and make available upon request, an electronic daily log which permits the identification of clients by Phase, length of time in Phase, form of medication and dosing, and urine drug screen results.
3. The contractee shall have written policies and procedures to ensure that when the mobile unit is at full capacity all IVDU clients who are in need of treatment are admitted to an appropriate program. The contractee shall ensure that all clients in need of Medical detoxification are appropriately placed.
 - The Division of Addiction Services Program Director shall be notified immediately if the contractee is unable find treatment for the client.
 - Clients shall be provided and/or referred to interim services immediately.
4. The contractee shall have policies and procedures in place to ensure the provision of treatment for priority populations.

MATI Mobile Unit Annex A

In addition to the General Requirements stated in Annex A-Sections I and II, the contractee shall comply with the following requirements and all services provided/referred shall be documented and/or maintained on file.

***DAS reserves the right to amend this document as necessary during the contract period.**

A. Contract Specific Requirements

1. The contractee shall adhere to the standards for licensure of ambulatory care facilities.
2. The contractee shall appoint an administrator of the mobile unit [satellite] who shall be accountable to the governing authority. The administrator of the satellite may be the same person as the administrator of the licensed facility with which the satellite is affiliated. The administrator of the satellite, or a designated alternate, shall be available on the mobile unit during its hours of operation.
3. The contractee shall accurately complete the New Jersey Substance Abuse Monitoring System (NJ-SAMS) on a computer located in the mobile unit. The NJ-SAMS admission and discharge screen forms shall be completed for all clients to ensure participation in the National Outcome Measures (NOMS).
4. The contractee shall ensure that all clients requesting treatment at the mobile unit (regardless of their choice of drugs) are to be assessed using the Addiction Severity Index (ASI) and entered into the NJSAMS. If it is found that the client is not a candidate for the mobile unit (not using heroin), the client is then to be referred to an appropriate substance abuse treatment facility. The mobile unit shall keep documentation of such referrals.
5. The contractee shall provide all assessments and all necessary medical services on the mobile unit.
6. The contractee shall ensure that all necessary release forms are signed by the client and witnessed. The signed release forms shall be maintained in the client file.
7. The contractee shall provide suboxone induction on the mobile unit in accordance with Federal and state accepted guidelines and regulations.
8. The contractee shall ensure that the physician has face-to-face interaction with every client being prescribed Suboxone. The physician is responsible for:
 - Completing a physical exam for the client
 - Generating a clinical diagnosis
 - Beginning the Suboxone Induction phase
 - Medication orders
 - Supervision of nurse
9. The contractee shall provide methadone maintenance on the mobile unit in accordance with the Drug and Enforcement Administration (DEA) regulations and state accepted guidelines.
10. The contractee shall ensure a minimum of 50 suboxone clients and 150 methadone clients on their census at all times.

11. The contractee shall ensure that the mobile unit will operate at least eight hours a day six days per week. The time shall be divided between two or more consistent sites based on need and final approval from DAS. Induction and maintenance shall be provided on the mobile unit at all locations.
12. The contractee shall ensure that the hours of operation and locations be visibly posted on the mobile unit and the agency. The hours of operation and locations shall be submitted to DAS for approval. All changes in the hours of operation/locations shall be reported to the DAS Program Director immediately.
13. The contractee shall provide transportation as clinically and/or medically needed for clients.
14. The contractee shall ensure clients being referred by the mobile unit for office-based services be accompanied by mobile unit staff ensuring that client's receive the recommended level of treatment.
15. The contractee shall ensure that all mobile unit staff (physician, nurse, case manager, counselor) attend DAS trainings that are scheduled to assist in the development and implementation of the mobile medication unit project.
16. The contractee shall have linkages/affiliation agreements with agencies providing needed services (medical, psychiatric, legal, housing, vocational, etc.). Affiliation agreements shall be maintained on file.

B. Medical Services

1. The contractee's mobile unit shall be able to respond to medical emergencies occurring on the premises during its hours of operation. The agency shall have a written policy and procedure in place and accessible on the mobile unit.
2. The contractee shall ensure that emergency medical services not provided on the mobile unit, or at the fixed site, shall be provided by a hospital or hospitals through written affiliation agreements. The contractee shall have a written plan for emergency transportation of patients.
3. The contractee shall ensure that laboratory services are provided only by facilities that are licensed or approved by the NJ Department of Health and Senior Services.
4. The contractee shall report confirmed and suspected cases of communicable diseases as required by New Jersey state law.

C. Syringe Exchange Program (SEP)

1. The contractee shall collaborate with the local Syringe Exchange Program (SEP) to facilitate access to, and linkage of, IVDU clients interested in treatment services.
2. The contractee shall ensure that the mobile unit's scheduled route(s) and hours of operation correspond with the local SEP site to facilitate access for SEP clients seeking treatment services, to the extent this is practical.

D. Program Reporting Requirements

1. The contractee shall submit a separate budget and quarterly expenditure report identifying expenses incurred by the program to the Division of Addiction Services (DAS) Fiscal Unit.
2. The contractee shall submit signed monthly rosters to DAS for all clients receiving services on the mobile unit. The roster should include at a minimum the following:

- Client I.D.
- Date of Birth
- Date of Admission
- Phase
- Modality of treatment
- Funding source
- Gender
- Household size
- Household income

E. Policies and Procedures

1. The contractee shall have written policies that address the following but not be limited to:
 - Infection control and prevention measures
 - Laboratory services
 - The use and sterilization of patient care items
 - The care and use of sterilizers
 - The handling of regulated medical waste
 - The provision of emergency medical services
 - Patient care services
 - Control of drugs
 - Medical records
 - Treatment planning and updating of treatment plans

2. The contractee shall have a facility-wide policy which prohibits discrimination against clients of substance abuse prevention, treatment and recovery support services who are assisted with legitimate prescribed medication/s, without limits to frequency and duration. The contract ensures that all agencies with which the contractee has linkages/affiliations agreements also have such a policy.

3. The contractee shall have a policy available for DAS review and approval for providing interim services. The policy shall include a list of available services, the frequency of service availability and any associated client fee schedule. At minimum, interim services shall include:
 - Counseling
 - Education about HIV, tuberculosis and Hepatitis C
 - The risks of needle-sharing
 - The risks of HIV and Hepatitis C transmission to sexual partners and infants
 - Steps that can be taken to ensure that HIV and Hepatitis C transmission does not occur
 - Referral/testing for HIV, tuberculosis and Hepatitis C treatment services

4. The contractee shall ensure that written policies for disaster planning, contingency planning and response shall address all hazards and be communicated to staff in annual trainings with updates as needed.

5. The contractee shall conduct full criminal background checks supported by fingerprints for all staff, volunteers, interns and any other personnel routinely scheduled to work in the mobile unit and agency in accordance with their policies and procedures. Documentation of this shall be maintained in the staff's personnel file. The contractee may use DAS funds for this effort. The contractee shall submit a listing of these costs with the final expenditure report for this contract.

F. Staffing

1. The contractee shall ensure that Suboxone is prescribed by a certified physician in Addiction Medicine who has satisfied qualifications set-forth by the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000) and the Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA). The contractee shall ensure that the physician has face-to-face interaction with every client being prescribed Suboxone and ASAM certified or is monitored by an ASAM-level physician. The physician shall be responsible for:
 - Completing a physical exam for the client;
 - Generating a clinical diagnosis;
 - Beginning the Suboxone induction phase;
 - Writing medication orders; and
 - Supervision of nurse.
2. The contractee shall ensure compliance with Title 45, Chapter 6, Clinical Supervision in the New Jersey Office of the Attorney General, Division of Consumer Affairs, State Board of Marriage and Family Therapy Examiners Alcohol and Drug Counselor Committee, Statutes and Regulations and DAS Licensure Regulations.
 - A supervision schedule shall be maintained and submitted to DAS on a quarterly basis.
 - All clinical supervision shall be documented, include date, type, name of supervisor and supervisee, and cases/topics reviewed and discussed.
3. The contractee shall have at a minimum one master level Certified Drug and Alcohol Counselor (CADC) or Licensed Clinical Alcohol and Drug Counselor (LCADC) to provide the following services but not limited to:
 - Supervise the case manger and other support staff
 - Provide clinical supervision
 - Conduct cognitive/behavioral/motivational counseling services
4. The contractee shall ensure that each substance abuse counselor's caseload does not exceed fifty (50) clients. No counselor's caseload of up to 50 clients shall include more than 35 clients in Phase I-III.
5. The contractee shall ensure that the Case Manager have a Bachelor's degree in the human services field.
6. The contractee shall utilize a case management model or combination of models as described in the Center for Substance Abuse Treatment (CSAT) TIP #27, "Comprehensive Case Management for Substance Abuse Treatment." The contractee shall focus on models such as, but not limited to the ones utilized for "Strengths Perspective", "Assertive Community Treatment" or "Clinical Rehabilitation". The model shall require at minimum that case management efforts include the following:
 - Performing eligibility screening for available resources for treatment
 - Ensuring that MATI Eligibility Criteria is met prior to clinical assessment
 - Conducting assessments for recovery support needs
 - Providing client's a single point of contact for multiple health and social services systems
 - Focusing on practical problems of daily living
 - Motivational interviewing techniques/methods
 - Ensuring timely access to various levels of care through DAS fee for service voucher program
 - Monitoring of client's progress through the continuum of care
 - Assertive advocacy methods on behalf of the client

G. Voucher Network

1. The contractee shall ensure that if a client requires another level of care or support services not provided via the mobile unit or office-based program, the contractee should request a MATI voucher through DAS.
2. If issued a DAS-approved voucher, the contractee shall ensure that the client be referred to a DAS MATI Network approved provider for the appropriate services, as clinically indicated.

MATI Office-Based Site Annex A

In addition to the General Requirements stated in Annex A-Sections I and II, the contractee shall comply with the following requirements and all services provided/referred shall be documented and/or maintained on file.

***DAS reserves the right to amend this document as necessary during the contract period.**

A. Contract Specific Requirements

1. The contractee shall adhere to the standards for licensure of ambulatory care facilities.
2. The contractee shall accurately complete the New Jersey Substance Abuse Monitoring System (NJ-SAMS). The NJ-SAMS admission and discharge screen forms shall be completed for all clients to ensure participation in the National Outcome Measures (NOMS).
3. The contractee shall ensure that all clients requesting treatment be assessed using the Addiction Severity Index (ASI) and entered into the NJSAMS. If it is found that the client is not a candidate for the office-based site (not using heroin), the client is then to be referred to an appropriate substance abuse treatment facility. The office-based site shall keep documentation of such referrals.
4. The contractee shall provide all assessments and all necessary medical services at the office-based site.
5. The contractee shall ensure that all necessary release forms are signed by the client and witnessed. The signed release forms shall be maintained in the client file.
6. The contractee shall provide suboxone induction in accordance with Federal and state accepted guidelines and regulations.
7. The contractee shall ensure that the physician has face-to-face interaction with every client being prescribed Suboxone. The physician is responsible for:
 - Completing a physical exam for the client
 - Generating a clinical diagnosis
 - Beginning the Suboxone Induction phase
 - Medication orders
 - Supervision of nurse
8. The contractee shall provide methadone maintenance in accordance with the Drug and Enforcement Administration (DEA) regulations and state accepted guidelines.
9. The contractee shall ensure a minimum of 50 suboxone clients and 150 methadone clients on their census at all times.
10. The contractee shall provide transportation as clinically and/or medically needed for clients.
11. The contractee shall ensure that all office-based staff (physician, nurse, case manager, counselor) attend DAS trainings that are scheduled to assist in the development and implementation of the MATI project.

12. The contractee shall have linkages/affiliation agreements with agencies providing needed services (medical, psychiatric, legal, housing, vocational, etc.). Affiliation agreements shall be maintained on file.

B. Medical Services

1. The contractee shall be able to respond to medical emergencies occurring on the premises during its hours of operation. The agency shall have a written policy and procedure in place and accessible at the office-based site.
2. The contractee shall ensure that emergency medical services not provided at the office-based site be provided by a hospital or hospitals through written affiliation agreements. The contractee shall have a written plan for emergency transportation of patients.
3. The contractee shall ensure that laboratory services are provided only by facilities that are licensed or approved by the NJ Department of Health and Senior Services.
4. The contractee shall report confirmed and suspected cases of communicable diseases as required by New Jersey state law.

C. Syringe Exchange Program (SEP)

1. The contractee shall collaborate with the local Syringe Exchange Program (SEP) to facilitate access to, and linkage of, IVDU clients interested in treatment services.
2. The contractee shall ensure that the office-based site schedule correspond with the local SEP site to facilitate access for SEP clients seeking treatment services, to the extent this is practical.

D. Program Reporting Requirements

1. The contractee shall submit a separate budget and quarterly expenditure report identifying expenses incurred by the program to the Division of Addiction Services (DAS) Fiscal Unit.
2. The contractee shall submit signed monthly rosters to DAS for all clients receiving services at the office-based site. The roster shall include at a minimum the following:
 - Client I.D.
 - Date of Birth
 - Date of Admission
 - Phase
 - Modality of treatment
 - Funding source
 - Gender
 - Household size
 - Household income

E. Policies and Procedures

1. The contractee shall have written policies that address the following but not be limited to:
 - Infection control and prevention measures
 - Laboratory services
 - The use and sterilization of patient care items
 - The care and use of sterilizers
 - The handling of regulated medical waste

- The provision of emergency medical services
 - Patient care services
 - Control of drugs
 - Medical records
 - Treatment planning and updating of treatment plans
2. The contractee shall have a facility-wide policy which prohibits discrimination against clients of substance abuse prevention, treatment and recovery support services who are assisted with legitimate prescribed medication/s, without limits to frequency and duration. The contract ensures that all agencies with which the contractee has linkages/affiliations agreements also have such a policy.
 3. The contractee shall have a policy available for DAS review and approval for providing interim services. The policy shall include a list of available services, the frequency of service availability and any associated client fee schedule. At minimum, interim services shall include:
 - Counseling
 - Education about HIV, tuberculosis and Hepatitis C
 - The risks of needle-sharing
 - The risks of HIV and Hepatitis C transmission to sexual partners and infants
 - Steps that can be taken to ensure that HIV and Hepatitis C transmission does not occur
 - Referral/testing for HIV, tuberculosis and Hepatitis C treatment services
 4. The contractee shall ensure that written policies for disaster planning, contingency planning and response shall address all hazards and be communicated to staff in annual trainings with updates as needed.
 5. The contractee shall conduct full criminal background checks supported by fingerprints for all staff, volunteers, interns and any other personnel routinely scheduled to work in the mobile unit and agency in accordance with their policies and procedures. Documentation of this shall be maintained in the staff's personnel file. The contractee may use DAS funds for this effort. The contractee shall submit a listing of these costs with the final expenditure report for this contract.

F. Staffing

1. The contractee shall ensure that Suboxone is prescribed by a certified physician in Addiction Medicine who has satisfied qualifications set-forth by the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000) and the Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA). The contractee shall ensure that the physician has face-to-face interaction with every client being prescribed Suboxone and ASAM certified or is monitored by an ASAM-level physician. The physician shall be responsible for:
 - Completing a physical exam for the client;
 - Generating a clinical diagnosis;
 - Beginning the Suboxone induction phase;
 - Writing medication orders; and
 - Supervision of nurse.
2. The contractee shall ensure compliance with Title 45, Chapter 6, Clinical Supervision in the New Jersey Office of the Attorney General, Division of Consumer Affairs, State Board of Marriage and Family Therapy Examiners Alcohol and Drug Counselor Committee, Statutes and Regulations and DAS Licensure Regulations.

- A supervision schedule shall be maintained and submitted to DAS on a quarterly basis.
 - All clinical supervision shall be documented, include date, type, name of supervisor and supervisee, and cases/topics reviewed and discussed.
3. The contractee shall have at a minimum one master level Certified Drug and Alcohol Counselor (CADC) or Licensed Clinical Alcohol and Drug Counselor (LCADC) to provide the following services but not limited to:
 - Supervise the case manager and other support staff
 - Provide clinical supervision
 - Conduct cognitive/behavioral/motivational counseling services
 4. The contractee shall ensure that each substance abuse counselor's caseload does not exceed fifty (50) clients. No counselor's caseload of up to 50 clients shall include more than 35 clients in Phase I-III.
 5. The contractee shall ensure that the Case Manager have a Bachelor's degree in the human services field.
 6. The contractee shall utilize a case management model or combination of models as described in the Center for Substance Abuse Treatment (CSAT) TIP #27, "Comprehensive Case Management for Substance Abuse Treatment." The contractee shall focus on models such as, but not limited to the ones utilized for "Strengths Perspective", "Assertive Community Treatment" or "Clinical Rehabilitation". The model shall require at minimum that case management efforts include the following:
 - Performing eligibility screening for available resources for treatment
 - Ensuring that MATI Eligibility Criteria is met prior to clinical assessment
 - Conducting assessments for recovery support needs
 - Providing client's a single point of contact for multiple health and social services systems
 - Focusing on practical problems of daily living
 - Motivational interviewing techniques/methods
 - Ensuring timely access to various levels of care through DAS fee for service voucher program
 - Monitoring of client's progress through the continuum of care
 - Assertive advocacy methods on behalf of the client

G. Voucher Network

1. The contractee shall ensure that if a client requires another level of care or support services not provided via the office-based program, the contractee should request a MATI voucher through DAS.
2. If issued a DAS-approved voucher, the contractee shall ensure that the client be referred to a DAS MATI Network approved provider for the appropriate services, as clinically indicated.

Suboxone Treatment Annex A

In addition to the General Requirements stated in Annex A-Sections I and II, the contractee shall comply with the following requirements and all services provided/referred shall be documented and/or maintained on file.

***DAS reserves the right to amend this document as necessary during the contract period.**

A. Contract Specific Requirements

1. The contractee shall accurately complete the New Jersey Substance Abuse Monitoring System (NJ-SAMS). The NJ-SAMS admission and discharge screen forms shall be completed for all clients to ensure participation in the National Outcome Measures (NOMS).
2. The contractee shall ensure that Suboxone is prescribed by a certified physician in Addiction Medicine who has satisfied qualifications set-forth by the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000) and the Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) (www.buprenorphine.samhsa.gov)
3. The contractee shall ensure Suboxone treatment for New Jersey residents 18 years or older with at least a one-year documented history of Opioid addiction and prior treatment attempts. Exemptions, such as treatment for individuals fewer than 18 years of age, shall be made in accordance with Federal guidelines.
4. The use of Buprenorphine by the contractee shall be approved for the treatment of opioid dependence in the formation of either Suboxone or Subutex. Injectable buprenorphine is not approved for the treatment of opioid dependence.
5. Contractees providing Suboxone treatment or other opiate substitution treatment must maintain on-site (both the mobile van unit and the office-based services site) and make available upon request, an electronic daily log or other record-keeping system, which permits the identification of clients, form of medication and dosing, and urine drug screen results by case.
6. The contractee shall ensure a minimum of fifty (50) suboxone clients at all times.
7. The contractee shall ensure clients being referred by the mobile unit for office-based services be accompanied by mobile unit staff ensuring that client's receive the recommended level of treatment.
8. The contractee shall provide priority treatment to the following in this order: Pregnant injecting drug users, pregnant drug users, injecting drug users, and all other drug users.
9. The contractee shall ensure that all pertinent and required documents be visibly posted, including priority treatment for pregnant women and IV drug users, DAS license, DAS complaint hotline, and request for sign language interpreter.

B. Medical Services

1. The contractee shall ensure that ancillary treatment services be in conformance with the guidelines set forward through the Center for Substance Abuse Treatment (CSAT), Office of Pharmacological and Alternative Therapies, and CSAT TIP #40, Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, as well as the DAS guidelines on the use of buprenorphine.

2. The contractee shall ensure that all clients are instructed to abstain from use of any opiates twelve (12) hours prior to the induction phase of Suboxone treatment.
3. The contractee shall ensure that during the induction and stabilization phase of buprenorphine therapy, medical care and consultation is available on a 24-hour on-call basis. This care shall be supervised by the certified physician performing the induction.
4. The contractee shall ensure that opiate dependent pregnant clients receive proper education about Subutex (the formulation of choice for pregnant opiate dependent clients) treatment. The risks of Buprenorphine (a Category C drug) must be explained in detail to the client by the physician. Once thoroughly discussed with the client, a client can consent to treatment.
 - The discussion shall be clearly documented in the client's file
 - A signed and witnessed informed consent shall be maintained in the client's file.
5. The contractee shall ensure that all necessary physical and psycho-social services, in addition to the induction and use of Suboxone induction treatment, be provided:
 - Directly by the contractee; or
 - Via contractual arrangements with DAS Approved Licensed Treatment Programs.

C. Clinical Services

1. The contractee shall ensure that appropriate assessments are completed on each client including a completed New Jersey Substance Abuse Monitoring System (NJSAMS), Addiction Severity Index (ASI), Diagnostic Statistical Manual (DSM) IV Diagnoses (all 5 Axes), American Society of Addiction Medicine (ASAM) Level of Care Index and Medical evaluation and clearance.
2. The contractee shall ensure that each substance abuse counselor's caseload does not exceed fifty (50) clients.
3. The contractee shall ensure that group therapy includes no more than 12 clients per session.
4. The contractee shall ensure that all individual, group, and didactic sessions shall be a minimum of 45 minutes in duration regardless of the modality of treatment.
5. The contractee shall ensure that all necessary release forms are signed by the client and witnessed. The signed release forms shall be maintained in the client file.
6. The contractee shall utilize Suboxone therapy in conjunction with stabilization (detoxification or maintenance), rehabilitation (counseling and education) and follow-up (aftercare counseling and support groups).
7. The contractee shall ensure that all clients accepted into Suboxone therapy receive substance abuse counseling at a state licensed substance abuse treatment facility.
8. The contractee shall ensure that all counseling services are provided by either a Master's level Certified Alcohol and Drug Counselor (CADC) or a Master's level Licensed Certified Alcohol and Drug Counselor (LCADC) counselor.
9. The contractee shall ensure counselors collaborate with physicians to treat opioid-addicted clients, ensuring both the physician and counselors have access to each other for any client concern.

10. The contractee shall conduct and document client education specific to buprenorphine pharmacology and developed by medical personnel (either a Medical Director, Nurse Practitioner, Physician Assistant, Registered Nurse) to include, but not limited to:
 - Drug interaction
 - Physical effects
 - Withdrawal effects
 - Long-term treatment options
 - Disease management
 - Other medication options available
11. The counselor shall reinforce precautions regarding sedative drug use previously provided by the physician and relate any new pertinent information to the physician.
12. The counselor shall encourage the client to ask questions and discuss concerns with physician throughout the course of treatment.
13. The contractee shall develop a Cognitive/Behavioral/Motivational counseling curriculum and shall have prior approval by DAS.
 - The curriculum shall focus on:
 - Maintaining client involvement in the Suboxone treatment;
 - Assessing for and providing access to support/wraparound services; and
 - Assessing and motivating clients to continue in any and all necessary treatment.
14. The contractee shall immediately refer all clients post-induction to a mandatory stabilization program at an office-based site. This program shall include client participation in a twelve (12) week Cognitive/Behavioral/Motivational counseling curriculum.
15. The contractee shall ensure that clients who require an extended length of stay beyond the initial 12 weeks be approved for an extended length of stay seven days prior to the culmination of the 12 week period. In such cases the contractee should conform to the extension request policy by contacting the Program Coordinator, Adam Bucon (adam.bucon@dhs.state.nj.us) at DAS. The extension request form can be downloaded from <http://www.state.nj.us/humanservices/das/index.htm>.
16. The contractee shall complete an ASAM (American Society of Addiction Medicine) multidimensional level of care review using the LOCI (Level of Care Indicator) tool in NJSAMs (New Jersey Substance Abuse Monitoring System) for each extension request. The LOCI should be completed prior to contacting DAS to request an extension.
17. The contractee shall ensure that clients receiving Suboxone receive counseling services in accordance with 42 CFR requirements for Opioid Treatment Programs.
18. The contractee shall provide and/or refer for the clients for:
 - Educational services
 - Vocational counseling and training
 - Job placement for clients
 - Legal services
19. The contractee shall ensure that each client has an up-to-date individual treatment plan that includes goals and objectives of treatment with time frames.

20. The contractee shall ensure that each client's treatment plan is reviewed every 90 days by a multidisciplinary treatment team, which shall include at minimum the client's physician, nurse, and counselor.
21. The contractee shall ensure that each client has a discharge plan and/or continuum of care plan that begins at the onset of treatment and is updated on an as needed basis.

D. Co-occurring Disorder Requirements

1. The contractee shall have a policy regarding the assessment, treatment and/or referral of clients with co-occurring disorders (classified in Quadrants I , II, III and IV by the National Association of State Mental Health Program Directors and The National Association of State Alcohol and Drug Abuse Directors (NASMHPD/NASADAD)).
2. The contractee shall admit and medicate all clients (classified in Quadrants I thru IV, NASMHPD/NASADAD) with co-occurring mental health and substance abuse/dependence disorders.

Level of Care Quadrants

<p style="text-align: center;"><u>Quadrant III</u></p> <p>High Substance Abuse Disorder Low Severity Psychiatric Disorder</p>	<p style="text-align: center;"><u>Quadrant IV</u></p> <p>High Substance Abuse Disorder High Severity Psychiatric Disorder</p>
<p style="text-align: center;"><u>Quadrant I</u></p> <p>Low Substance Abuse Disorder Low Severity Psychiatric Disorder</p>	<p style="text-align: center;"><u>Quadrant II</u></p> <p>Low Substance Abuse Disorder High Severity Psychiatric Disorder</p>

- 1) The contractee shall admit and provide counseling services for Suboxone clients classified in Quadrants I and III, with co-occurring mental health and substance abuse/dependence disorders, and/or who meet the agency's admissions criteria.
 - The contractee shall ensure that the referral of a client for psychiatric assessment, differential diagnosis, and/or assessment/prescription for, and monitoring of medication shall be clearly documented in the client's treatment plan.
- 2) The contractee shall ensure that all Suboxone clients classified in Quadrants II and IV, with co-occurring mental health and substance abuse/dependence disorders are referred to and receive at a minimum the following services:
 - Clients shall be referred to an appropriate mental health agency for counseling services and medication monitoring other than suboxone.
 - The contractee shall work collectively with the mental health facility to ensure participation in the client's treatment plan.

E. Urine Drug Screening Requirements

1. The contractee shall ensure that clients with any positive urine drug screen(s) after the induction phase of treatment have their treatment plan reviewed by the interdisciplinary team with the treatment plan revised as appropriate. The review, recommendation and subsequent actions must be appropriately documented in the client chart.

2. The contractee shall ensure, following the induction phase, clients with more than one positive urine drug screen within a 30-day period be assessed and/or referred for an increased level of care, to include ancillary services, such as co-occurring assessment, social services, etc. This must be clearly documented in the client chart.

F. Education Requirements

1. The contractee shall ensure that all counselors working with Suboxone clients have taken the three (3) hour online course entitled, Buprenorphine Treatment of Opioid Addiction: A Counselor's Guide (www.danyalearningcenter.org/courseprofile.asp?cid=7)
Documentation of successful completion shall be maintained in the staff's personnel file.
2. The contractee shall ensure registration in the Physician Clinical Support System (PCSS) <http://www.pcssbuprenorphine.org/pcss/index.php>. for all physicians providing services under this contract. Documentation of successful registration shall be maintained in the physician's personnel file.

G. Policies and Procedure Requirements

1. The contractee shall have written policies and procedures to ensure that when the mobile unit is at full capacity all IVDU clients who are in need of treatment are admitted to an appropriate program. The contractee shall ensure that all clients in need of Medical detoxification are appropriately placed.
 - The Division of Addiction Services Program Director or Coordinator shall be notified immediately if the contractee is unable to find treatment for the client.
 - Clients shall be provided and/or referred to interim services immediately.
2. The contractee shall have policies and procedures in place to ensure the provision of treatment for priority populations.

NON-DISCRIMINATION LANGUAGE FOR RFPs

All providers of drug treatment services under these contracts must have in place established, facility-wide policies which prohibit discrimination against clients of substance abuse prevention, treatment and recovery support services who are assisted in their prevention, treatment and/or recovery from substance addiction with legitimately prescribed medication(s). These policies must be in writing in a visible, legible and clear posting at a common location which is accessible to all who enter the facility.

Moreover, no client who is admitted into a treatment facility, or a recipient of or participant in any prevention, treatment or recovery support services, shall be denied full access to, participation in and enjoyment of that program, service or activity available, or offered to others, due to the use of legitimately prescribed medications.

Capacity to accommodate clients who present or are referred with legitimately prescribed medications can be accomplished either through direct provision of services associated with the provision or dispensing of medications and or via development of viable networks/referrals/consultancies/sub-contracting with those who are licensed and otherwise qualified to provide medications.

DAS QUARTERLY MEDICAL DIRECTORS MEETINGS

This serves as a knowledge transfer mechanism through:

- Utilizing a case presentation format for each meeting.
- Advising physicians and medical directors on latest changes in the arena of medication assisted treatment (MAT).
- Providing a collegial framework for the physicians to ask one another and the DAS medical directors questions regarding MAT and treatment.
- Providing a framework for physicians and medical directors to understand how MAT fits into practice and the Division's vision.

APPENDIX C

BRIEF EXAMPLES OF STATE MAT IMPLEMENTATION

- A. Delaware established a State pharmacy that uses State general funds to pay for mental health and substance abuse medications. Clients who require medications for mental health conditions have previously been eligible to receive them through the State pharmacy, but medications for SUDs were recently added. Clients pay a small co-payment and there are no caps on the availability of medications. The program is too new to know if this expansion in medication availability will explode State costs or change the populations that seek treatment.
- B. Maryland had multiple regions without access to MAT. To address these service gaps, the State established mobile treatment units. The vans were initially deployed in urban Baltimore City due to the growing number of opioid overdoses and the City's zoning ordinances. Recently, a mobile medication unit was established in a rural portion of the State to improve access to care in an area with scarce health care resources. The mobile units are also linked to other psychosocial service programs and have added buprenorphine to their treatment capability.
- C. North Carolina has set out to establish a new comprehensive provider model—Critical Access Behavior Health Agencies (CABHAs)—to support its migration to a recovery oriented system of care and the enhanced use of evidence-based practices. The CABHAs are required to have a medical director, clinical director, quality assurance manager, and a training director; provide five services including MAT; and use performance management techniques. The goal is to fund up to 100 providers as CABHAs using Medicaid and State resources.
- D. Thirty mobile crisis teams operate in all counties of North Carolina. Team members are credentialed and trained in substance abuse treatment screening, assessment, and referral to treatment. Teams spend approximately 40 percent of their time in emergency departments to relieve overburdened medical staff. Efforts are underway to encourage law enforcement professionals to bring individuals with SUDs to the mobile crisis teams instead of directly to emergency departments to further relieve the health care system.
- E. Connecticut has implemented an initiative to reduce chronic recidivism among opioid treatment clients. Individuals who have four presentations in six months are encouraged to accept methadone while in the detoxification phase. Most individuals accepted this invitation, completed induction, were assigned a Case Manager for intensive follow-up, and referred to a maintenance program. The initiative has reduced the chronic recidivism rate among opioid treatment clients in the State.
- F. Heroin and other opiates are the primary drugs of choice in New Jersey and MAT is an essential treatment modality. Since 2007, using \$10 million in new treatment funds, the State launched five mobile treatment units and one fixed site providing suboxone and methadone treatment. Maryland and Connecticut provided valuable technical assistance to help implement the units. Two hundred clients are being served at each site, counseling services are mandated as part of treatment, and a continuum of tailored services is available for MAT clients through its MATI network.
- G. New York prepares single-sheet program provider report cards with scores on retention, access, and follow-up measures (includes MAT). During year 1, each program provider receives its own scores and data on statewide averages for comparison purposes. During year 2, all program provider report cards are being shared with the entire provider community. During year 3, all program provider report cards are being shared with the general public. The report card concept and implementation approach were developed by the State in collaboration with the treatment provider community and, as a result, the initiative has received little opposition. Report card data will be used by the State as an incentive to lengthen the period of provider certification if scores are high.
- H. New York was among the first States in the Nation to institute a smoke-free initiative and 80 percent of its treatment programs are now entirely smoke-free.

- I. Arizona's Governor's Initiative on Alcohol and Drug Abuse includes representatives of many State government agencies, private and nonprofit organizations, court systems, and tribal entities. The group is chaired by the Governor's Chief of Staff and is a key vehicle for creating and coordinating substance abuse prevention and treatment plans, priorities, and initiatives that impact the State. With the support of the State's chief executive, the Governor's Initiative is a strategic and visible force for change.

MODEL POLICY ON DATA 2000 AND TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE

Adopted as policy by the House of Delegates of the Federation of State Medical Boards

April 2013

INTRODUCTION

The profile of opioid addiction in the United States is changing, in that nonmedical use of prescription opioids has become a problem as significant as the use of heroin. Recent data indicate that approximately 1.6 million persons in the U.S. misused or were addicted to prescription opioids in 2010 [1], while 323,000 persons misused or were addicted to heroin [2]. Despite the dimensions of the problem, nearly 80% of opioid-addicted persons do not receive treatment for their addiction because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care [3].

To address this need, researchers, federal health agencies, and pharmaceutical manufacturers have focused on developing medications that can be used to treat opioid addiction in medical office settings, rather than being limited to use only in specialized Opioid Treatment Programs (OTPs) [4]. As a result of those efforts, two major products are now available for use in office settings: buprenorphine (alone and in combination with naloxone) and naltrexone (in an oral formulation and an extended-release injectable formulation). These medications have been shown to be effective when used in office-based settings and thus to increase access to treatment for many patients who would not or cannot obtain care in OTPs [5-7].

Regardless of setting, the primary goals of addiction treatment are to reduce or stop opioid use, to improve the patient's overall health and social functioning, and to help the patient avoid some of the more serious consequences of opioid addiction. Treatment also can help the patient see his or her problems from a different perspective, improve self-reliance, and empower the individual to make positive changes in his or her life [8].

Buprenorphine: Buprenorphine is a partial opioid agonist that was approved by the FDA to treat opioid addiction in 2002. It is available in both tablet and film formulations for the treatment of addiction, either as buprenorphine alone (Subutex®) or in a 4:1 combination with naloxone (Suboxone®). The film formulation – which is similar to a dissolvable film strip of mouthwash – is marketed in unit-dose packaging with a serial number on each foil packet. (A transdermal formulation [BuTrans®] has been approved by the FDA, but only for the treatment of chronic pain.)

The addition of naloxone to buprenorphine does not reduce the efficacy of the medication when it is taken sublingually, yet it appears to serve as a deterrent to injection misuse [9]. For this reason, the buprenorphine/naloxone combination is the preferred formulation for most patients, with the exception of pregnant women, for whom current guidelines recommend use of the monoproduct [10]. Whenever the monoproduct is used, extra attention should be given to the risks of misuse and diversion.

Multiple studies have shown that, administered sublingually and at therapeutic doses in appropriately

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selected patients, buprenorphine is safe and effective [11-15]. The blockade of the opioid receptor imposed by buprenorphine limits the effects of subsequently administered opioid agonists or antagonists, reducing the risk of opioid overdose, and the “ceiling effect” appears to confer a higher safety profile and generally milder withdrawal symptoms (compared to full agonists) when the drug is tapered after prolonged administration [16-17].

Nevertheless, overdoses and deaths due to buprenorphine can occur and have been reported [18]. Most overdoses, especially fatal ones, involve concurrent use of another CNS depressant such as benzodiazepines, other opioids, or alcohol [19-22]. Buprenorphine also poses a significant risk to non-tolerant individuals, especially children [23].

Relatively few serious adverse events have been associated with buprenorphine. Where such events have been reported, most have involved abuse of the drug by injection, rather than sublingual administration in a clinical setting [24-28]. A national evaluation of pharmacotherapies for opioid addiction in Australia involving more than 1,200 patients found no significant difference in rates of serious adverse events between methadone, LAAM, and buprenorphine, or between different doses of buprenorphine [29].

Although early reports based on animal studies suggested that buprenorphine would have a low potential for misuse to achieve euphoria, researchers have documented a measurable level of misuse and diversion of buprenorphine [30-31]. Varying levels of misuse and diversion were predicted by early investigators [32] because buprenorphine is prescribed to high-risk individuals who are addicted to opioids. Subsequent research confirms that misuse and diversion have been reported worldwide wherever buprenorphine has been used for the treatment of addiction [33-36].

The tablet form of buprenorphine has proved more vulnerable to diversion and nonmedical use than the sublingual film, so the pharmaceutical company that held the original patent stopped manufacturing the tablet form and petitioned the Food and Drug Administration (FDA) to require that all buprenorphine products be formulated as unit-dose sublingual filmstrips, thereby eliminating tablet formulations from the market. (As of January 2013, the FDA had not acted on the petition.)

Role of Federal Legislation: The use of buprenorphine for the treatment of opioid addiction is governed by the federal Drug Addiction Treatment Act of 2000, commonly referred to as “DATA 2000” (Public Law 106-310, Title XXXV, Sections 3501 and 3502). This legislation is of particular interest to state medical boards because, for the first time in almost a century, it allows physicians to treat opioid addiction with FDA-approved controlled drugs in office-based settings. Specifically, DATA 2000 allows physicians to use buprenorphine and other controlled substances in CSA Schedules III, IV, and V, which have been approved by the FDA for the treatment of opioid dependence, to treat patients in office-based settings, provided certain conditions are met.

DATA 2000 thus has enlarged treatment capacity by lifting the requirement that patients who need opioid agonist treatment can receive such treatment only in specially licensed opioid treatment programs (OTPs), often referred to as “methadone clinics.”

Implementation of DATA 2000 required changes in the oversight systems within the Department of Health and Human Services (HHS) and the Drug Enforcement Administration (DEA). The Secretary of HHS delegated authority in this area to the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA).

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Role of State Medical Boards: The use of opioid agonist medications to treat opioid-addicted patients in the offices of individual physicians significantly increases the role of state medical boards in overseeing such treatment. For this reason, the Federation of State Medical Boards entered into an agreement with SAMHSA to develop model guidelines for use by state medical boards in regulating office-based treatment of addiction. This resulted in the Model Policy adopted by the Federation in 2002 [37].

The updated Model Policy presented here reflects the large body of research and experience accrued in the decade since buprenorphine was approved in 2002 for the treatment of opioid addiction. The Model Policy is designed to encourage state medical boards to adopt consistent standards, to promote the public health by making appropriate treatment available to opioid- addicted patients, and to educate the regulatory and physician communities about the potential of new treatment modalities for opioid addiction.

The Federation acknowledges with gratitude the efforts of the state Board members and directors who worked to update the Model Policy, as well as the contributions of the independent experts and medical organizations that advised the drafting committee and reviewed its work. The Federation also thanks SAMHSA for its support of this important project.

MODEL POLICY ON DATA 2000 AND TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE

SECTION I: PREAMBLE

The (*name of Board*) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the principles of high-quality medical practice dictate that the people of (name of state) have access to appropriate, safe and effective medical care, including the treatment of addiction. The application of up-to-date knowledge and evidence-based treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from addiction.

In this context, the Board recognizes the body of evidence for the effectiveness of buprenorphine in the office-based treatment of opioid addiction [38], when such treatment is delivered in accordance with current standards of care and the requirements of the Drug Addiction and Treatment Act of 2000 (DATA 2000) and state medical licensing boards.

Federal Requirements to Prescribe Buprenorphine for Addiction: Physicians who wish to treat opioid addiction with buprenorphine in their medical offices must demonstrate that they have met the requirements of the DATA 2000 legislation and obtained a waiver from SAMHSA.ⁱ To qualify for such a waiver, physicians must hold a current controlled substance registration with the Drug Enforcement Administration and a current license in the state in which they practice. They also must meet one or more of the following qualifications [39]:

- Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties;
- Subspecialty board certification in addiction medicine from the American Osteopathic Association;
- Addiction certification from the American Board of Addiction Medicine;
- Completion of not less than eight hours of training related to the treatment and management of opioid addiction provided by the American Academy of Addiction Psychiatry, the American Society of Addiction Medicine, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or other approved organizations; or¹
- Participation as an investigator in one or more clinical trials leading to the approval of an opioid drug in Schedule III, IV, or V or a combination of such drugs for treatment of opioid- addicted patients.

To obtain a waiver, a physician must notify SAMHSA in writing of his or her intent to prescribe an approved opioid medication to treat addiction, certifying the physician's qualifications and listing his/her DEA registration number. SAMHSA will then notify DEA whether a waiver has been granted. If SAMHSA grants a waiver, DEA will issue an identification number no later than 45 days after receipt of the physician's written notification. (If SAMHSA does not act on the physician's request for a waiver within the 45-day period, DEA will automatically assign the physician an identification number.) This process is explained, and can be accessed at the following website: <http://buprenorphine.samhsa.gov/howto.html>.

¹ i The "waiver" allows an exception to the Harrison Narcotics Act of 1914, which made it illegal for a physician to prescribe an opioid to any patient with opioid addiction for the purpose of managing that addiction or acute withdrawal. Prior to DATA 2000, the only exception to the Harrison Act was federal legislation that allowed the establishment of methadone maintenance treatment (MMT) clinics, now referred to as Opioid Treatment Programs (OTPs). That exception only allowed the use of methadone to treat addiction or withdrawal within specially licensed and regulated facilities, but not in office-based medical practice.

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

If a physician wishes to prescribe or dispense an appropriately available and approved opioid medication for maintenance treatment or detoxification (so as to fulfill the requirements of DATA 2000) on an emergency basis before the 45-day waiting period has elapsed, the physician must notify SAMHSA and the DEA of his or her intent to provide such emergency treatment.

In addition to a waiver, a physician who wishes to prescribe buprenorphine or another approved opioid for the treatment of addiction in an office setting must have a valid DEA registration number and a DEA identification number that specifically authorizes him or her to engage in office-based opioid treatment.

Prescription Requirements: Prescriptions for buprenorphine and buprenorphine/naloxone must include full identifying information for the patient, including his or her name and address; the drug name, strength, dosage form, and quantity; and directions for use. Prescriptions for buprenorphine and/or buprenorphine/naloxone must be dated as of, and signed on, the day they are issued (21 CFR 1306.05[a]). Both the physician's regular DEA registration number and the physicians' DATA 2000 identification number (which begins with the prefix X) must be included on the prescription (21 CFR 1301.28 [d][3]). [39]

For detailed guidance, physicians are referred to the Buprenorphine Clinical Practice Guidelines published by CSAT/SAMHSA, which can be accessed at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

State Medical Board Requirements: The (state medical board) will determine the appropriateness of a particular physician's prescribing practices on the basis of that physician's overall treatment of patients and the available documentation of treatment plans and outcomes. The goal is to provide appropriate treatment of the patient's opioid addiction (either directly or through referral), while adequately addressing other aspects of the patient's functioning, including co-occurring medical and psychiatric conditions and pressing psychosocial issues.

SECTION II: GUIDELINES

Multiple studies have shown that opioid addiction treatment with buprenorphine can be successfully integrated into office practice by physicians who are not addiction specialists. In such studies, patient outcomes are comparable to or better than outcomes of patients treated in specialized clinics [40-48]. However, as in the treatment of any medical disorder, physicians who choose to offer addiction treatment need to understand the nature of the underlying disorder, the specific actions of each of the available medications (as well as any associated contraindications or cautions), and the importance of careful patient selection and monitoring [40].

The Board has adopted the following guidelines for the treatment of opioid addiction in office-based settings. The guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of accepted professional practice.

Physician Qualifications: The diagnosis and medical management of opioid addiction should be based on current knowledge and research, and should encompass the use of both pharmacologic and nonpharmacologic treatment modalities. Thus, before beginning to treat patients for opioid addiction, the physician should become knowledgeable about opioid addiction and its treatment, including the use of approved pharmacologic therapies and evidence-based nonpharmacologic therapies [49-50].

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As described in the Preamble, physicians who wish to prescribe or dispense buprenorphine for the treatment of opioid addiction must meet the requirements of DATA 2000 [51], which are that the physician must be licensed in the state, have a valid DEA controlled substances registration and identification number, comply with federal and state regulations applicable to controlled substances, and hold a current waiver [39].

In addition to these requirements, DATA limits the number of patients that a physician is permitted to treat at any one time to 30 in the first year after obtaining a waiver, and to 100 patients thereafter. The physician who wishes to treat more than 30 patients after the first year must file an application with the DEA to extend his or her waived capacity to do so [39,51].

DATA 2000 also requires that a physician who wishes to treat opioid addiction with buprenorphine in an office setting must demonstrate a capacity to offer (or refer patients for) appropriate counseling and other ancillary services, and to recognize when those services are needed [51].

Physicians are not permitted to delegate the prescribing of buprenorphine to non-physicians. Even physicians who hold DEA registrations to prescribe controlled substances for other conditions are not allowed to prescribe buprenorphine for the treatment of addiction unless they meet the DATA requirements and hold a waiver. However, non-physician professionals can play an active role in evaluating and monitoring patients and providing other elements of care, in accordance with state regulations and rules governing physician supervision [52].

Physicians should consult the DEA regulations (Title 21 US Code of Controlled Substances Act 1301.28 and 21 USC 823 9GO(2)(G) [51] and the resources available on the DEA's website (at www.deadiversion.usdoj.gov), as well as (*any relevant documents issued by the state medical board*) for specific rules governing the issuance of prescriptions for controlled substances.

Patient Assessment: The objectives of the patient assessment are to determine a given patient's eligibility for treatment, to provide the basis for a treatment plan, and to establish a baseline measure for use in evaluating a patient's response to treatment. Accordingly, the assessment should be designed to achieve the following [49,53]:

- Establish the diagnosis of opiate addiction, including the duration, pattern and severity of opioid misuse; the patient's level of tolerance; results of previous attempts to discontinue opioid use; past experience with agonist therapies; the nature and severity of previous episodes of withdrawal; and the time of last opioid use and current withdrawal status.
- Document the patient's use of other substances, including alcohol and other drugs of abuse.
- Identify comorbid medical and psychiatric conditions and disorders and to determine how, when and where they will be addressed.
- Screen for communicable diseases and address them as needed. Evaluate the patient's level of physical, psychological and social functioning or impairment;
- Assess the patient's access to social supports, family, friends, employment, housing, finances and legal problems.
- Determine the patient's readiness to participate in treatment.

Assessment usually begins at the time of the patient's first office visit and continues throughout treatment. While the evidence is not conclusive, consensus opinion is that an initial patient assessment is of higher quality when it includes a medical and psychiatric history, a substance abuse history, and an evaluation of family and psychosocial supports, as well as a pregnancy test for all women of childbearing age. The physical examination,

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if performed during the initial assessment, can be focused on evaluating neurocognitive function, identifying sequelae of opioid addiction, and looking for evidence of severe hepatic dysfunction [10,53].

As a general rule, a urine drug screen or other toxicologic screen should be part of the initial evaluation to confirm recent opioid use and to screen for unreported use of other drugs. Ideally, this drug screen should include all opioids commonly prescribed and/or misused in the local community, as well as illicit drugs that are available locally [54]. It also is advisable to access the patient's prescription drug use history through the state's prescription drug monitoring program (PDMP), where available, both to confirm compliance in taking prescribed medications and to detect any unreported use of other prescription medications.

Information from family members and significant others can provide useful additional perspectives on the patient's status, as can contact with or records from clinicians who have treated the patient in the past [46].

Treatment Planning: There is an emerging consensus among addiction experts that treatment medications such as buprenorphine should be considered as an option for every opioid-addicted patient [38]. However, the failure to offer medication-assisted treatment does not in itself constitute substandard care. No single treatment is appropriate for all persons at all times. Therefore, an individualized treatment plan is critical to the patient's ultimate success in returning to productive functioning [5,54].

The treating physician should balance the risks and benefits of medication-assisted treatment in general – and treatment with buprenorphine in particular – against the risks associated with no treatment or treatment without medication [4,55]. The various options include:

- Simple detoxification and no other treatment;
- Detoxification followed by antagonist therapy;
- Counseling and/or peer support without medication-assisted therapy;
- Referral to short- or long-term residential treatment;
- Referral to an OTP for methadone maintenance; or
- Treatment with buprenorphine or buprenorphine/naloxone in an office-based setting.

Patients may be suitable candidates for treatment with buprenorphine even if past treatment episodes were not successful [50].

If a decision is made to offer the patient treatment with buprenorphine, the risks associated with possible misuse and diversion are such that the combination buprenorphine/naloxone product is preferable for most patients [38,40,43]. The monoproduct should be used only rarely except in pregnant women, for whom it is the preferred formulation [53].

Psychosocial and other nonpharmacologic interventions often are useful components of treatment [48,50,55]. Such interventions typically work best in conjunction with medication-assisted therapies; in fact, there is some evidence that the combination of pharmacologic and non-pharmacologic interventions may be more effective than either approach used alone [56]. As noted earlier, the ability to offer patients psychosocial supports, either on-site or through referral, is a requirement of the DATA 2000 legislation.

Educating the Patient: Every patient to whom buprenorphine is prescribed should be cautioned to follow the directions exactly, particularly during the induction stage. Critical issues involve when to begin dosing, the frequency of subsequent doses, and the importance of avoiding the use of any other illicit or prescription opioid.

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Concurrent use of non-opioid sedating medications or over-the-counter products also should be discussed, and patients should be advised to avoid the use of alcohol [7].

Patients should be cautioned about potential sedation or impairment of psychomotor function during the titration phase of induction with buprenorphine [57].

Finally, because opioids can contribute to fatal overdoses in individuals who have lost their tolerance to opioids or in those who are opioid-naïve (such as a child or other family member), proper and secure storage of the medication must be discussed. Particularly where there are young people in the patient's home, the subject of safe storage and use should be revisited periodically throughout the course of treatment, with the discussions documented in the patient record [57].

Informed Consent: Although agonist medications such as buprenorphine clearly are effective for the treatment of opioid dependence, they do entail a substitute dependence on the prescribed medication to replace the prior dependence on the misused opioid [46]. This issue should be thoroughly discussed with the patient in terms of potential risks and benefits as part of the informed consent process. Patients and family members often are ambivalent about agonist treatment for this reason and their concerns may influence subsequent treatment choices. Possible topics of discussion include the difference between addiction and physical dependence (including an explanation of why agonist therapy is not simply “switching one addiction for another”), the likelihood of relapse with and without medication-assisted treatment, the projected duration of treatment, the potential for successfully tapering from agonist therapy at some point in the future, and the role and importance of adjunctive therapies such as counseling and peer support. With the patient's consent, this conversation could include family members, significant other(s), or a guardian [7].

A written *informed consent* document, discussed with and signed by the patient, can be helpful in reinforcing this information and establishing a set of “ground rules.” The practitioner should document the informed consent in the patient's medical record [58].

Treatment Agreement: The terms of treatment agreements vary widely, but typical provisions include an acknowledgement of the potential benefits and risks of therapy and the goals of treatment; identification of one provider and one pharmacy from whom the patient will obtain prescriptions; authorization to communicate with all providers of care (and sometimes significant others) and to consult the state's Prescription Drug Monitoring Program (PDMP), if one is available; other treatments or consultations in which the patient is expected to participate, including recovery activities; avoidance of illicit substances; permission for drug screens (of blood, urine, saliva or hair/nails) and pill counts as appropriate; mechanisms for prescription renewals, including exclusion of early renewals; expected intervals between office visits; and specification of the conditions under which therapy will be continued or discontinued [59].

The agreement also should include a statement instructing the patient to stop taking all other opioid medications unless explicitly told to continue. Such a statement reinforces the need to adhere to a single treatment regimen. Inclusion in the agreement of a pharmacy address and telephone number reinforces to the patient the importance of using one pharmacy to fill prescriptions.

Finally, the treatment agreement should set forth the objectives that will be used to evaluate treatment success, such as freedom from intoxication, improved physical and psychosocial function, and adherence to the treatment regimen [59].

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Copies of the treatment agreement and informed consent should be provided to the patient and all other care providers, and file in the patient's medical record. The agreement should be reviewed regularly and adjusted as needed [58].

Induction, Stabilization, and Follow-up: The goal of induction and stabilization is to find the lowest dose of buprenorphine at which the patient discontinues or markedly reduces the use of other opioids without experiencing withdrawal symptoms, significant side effects, or uncontrollable craving for the drug of abuse [60].

The initial induction process requires a higher degree of attention and monitoring than the later maintenance phase [59]. Particular attention should be given to the timing of the initial doses so as to minimize untoward outcomes. Withdrawal symptoms can occur if either too much or too little buprenorphine is administered (i.e., spontaneous withdrawal if too little buprenorphine is given, precipitated withdrawal if buprenorphine is administered while the opioid receptors are substantially occupied by an opioid agonist). Undermedication or overmedication can be avoided through a flexible approach to dosing, which sometimes requires higher doses of treatment medication than expected, and by taking into account patient-reported symptoms [61].

The stabilization phase is focused on finding the right dose for an individual patient. A patient is stabilized when the dose allows him or her to conduct activities of daily living and to be aware of his or her surroundings without intoxication and without suffering withdrawal or distressing drug craving [61-62]. Although there is no precise way to determine in advance what the optimal dose for a particular patient will be [63], most patients are likely to stabilize on eight to 24 mg of buprenorphine per day, although some may need doses of up to 32 mg per day [64].

Buprenorphine blood concentrations stabilize after approximately seven days of consistent dosing [17]. If withdrawal symptoms subsequently emerge during any 24-hour dosing interval, the dose is too low and should be increased [64]. Medical factors that may cause a patient's dose requirements to change include (but are not limited to) starting, stopping, or changing the dose of other prescription medications; onset and progression of pregnancy; onset of menopause; progression of liver disease; and significant increase or decrease in weight [61].

Dose adjustments generally can be made in increments of 2 mg/day. Because buprenorphine has a long plasma half-life and an even longer duration of action at the mu opioid receptor, five days should be allowed between dose adjustments [53].

Patient adherence to medication regimens and session appointments is associated with better treatment outcomes, and regular monitoring can help patients plan for possible obstacles and teach them ways to handle any problems that occur [65]. Regular assessment of the patient's level of engagement in treatment and the strength of the therapeutic alliance allows for modification of the treatment plan and level of care in response to the patient's progress or lack thereof [56].

Early in treatment, medications should be prescribed and follow-up visits scheduled commensurate with the patient's demonstrated stability. Until patients have shown the ability to be compliant with the treatment plan and responsible with their medication supplies, and have discontinued high-risk behaviors and associated diversion risks, they should be seen more frequently and given supplies of medication only as needed until the next visit. As patients demonstrate stability and the risk declines, they can be seen less often (typically once a month) and prescribed larger supplies of medication [46,59].

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Patient monitoring during follow-up visits should address the following points [46,54,59,66]:

- Whether the patient continues to use alcohol or illicit drugs, or to engage in non-medical use of prescription drugs;
- The degree of compliance with the treatment regimen, including the use of prescribed medications as directed;
- Changes (positive or negative) in social functioning and relationships;
- Avoidance of high-risk individuals, situations, and diversion risk;
- Review of whether and to what degree the patient is involved in counseling and other psychosocial therapies, as well as in self-help activities through participation in mutual support meetings of groups such as Narcotics Anonymous;
- The presence or absence of medication side effects; and
- The presence or absence of medical sequelae of substance use and its remission.

The patient's compliance with regard to use of prescribed buprenorphine and avoidance of other opioids should be monitored through patient report, regular toxicologic analyses [54], reports from significant others, and regular checks of the state's Prescription Drug Monitoring Program, where available [46].

Individuals being treated with medication-assisted therapy often demonstrate dramatic improvement in addiction-related behaviors and psychosocial functioning. Such positive changes should be acknowledged and reinforced by the prescribing physician whenever possible. Reducing the frequency of monitoring visits, with their associated costs, and increasing the patient's responsibility for medications are examples of how positive, responsible behaviors can be reinforced [46,67].

Adjusting the Treatment Plan: Treatment outcomes typically are positive for patients who remain in treatment with medication-assisted therapies such as buprenorphine [46,68]. However, some patients struggle to discontinue their misuse of opioids or other drugs, are inconsistent in their compliance with treatment agreements, or succeed in achieving some therapeutic goals while not doing well with others [69].

Behaviors that are not consistent with the treatment agreement should be taken seriously and used as an opportunity to further assess the patient and adapt the treatment plan as needed. In some cases, where the patient's behavior raises concerns about safety or diversion of controlled medications, there may be a need to refer the patient for treatment in a more structured environment (such as an OTP) [69]. However, behavior that violates the treatment agreement or a relapse to nonmedical drug use do not constitute grounds for automatic termination of treatment. Rather, they should be taken as a signal to reassess the patient's status, to implement changes in the treatment plan (as by intensifying the treatment structure or intensity of services), and to document such changes in the patient's medical record [46].

Whenever the best clinical course is not clear, consultation with another practitioner may be helpful. The results of the consultation should be discussed with the patient and any written consultation reports added to the patient's record [59].

Patients with more serious or persistent problems may benefit from referral to a specialist for additional evaluation and treatment. For example, the treatment of addiction in a patient with a comorbid psychiatric disorder may be best managed through consultation with or referral to a specialist in psychiatry or addiction

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psychiatry [10]. In other instances, aberrant or dysfunctional behaviors may indicate the need for more vigorous engagement in peer support, counseling, or psychotherapies, or possibly referral to a more structured treatment setting [56].

Preventing and Managing Relapse: Relapse always should be ruled out as a reason for loss of stability [56]. Relapse to drug use has been described as “an unfolding process in which the resumption of substance abuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli” [70]. It rarely is caused by any single factor; rather, it is a dynamic process in which the patient’s readiness to change interacts with other external and internal factors [59, 71]. Patients in relapse vary in the quantity and frequency of their substance use, as well as the accompanying medical and psychosocial sequelae.

Clinical strategies to prevent and address relapse generally encompass the following steps [10,61,71]:

- Identify environmental cues and stressors that act as relapse triggers.
- Help patients develop skills to cope with or manage negative emotional states;
- Help the patient work toward a more balanced lifestyle.
- Understand and manage craving.
- Identify and interrupt lapses and relapses. Patients should have an emergency plan to address a lapse so that a full-blown relapse can be avoided. If relapse does occur, be prepared to intervene.
- Develop a recovery support system. Families are more likely to provide such support if they are engaged in the treatment process and have an opportunity to ask questions, share their concerns and experiences, and learn practical coping strategies and behaviors to avoid.

It should be noted that lack of adherence to pharmacologic regimens occurs in a substantial portion of patients being treated for addiction, with some studies reporting that a majority of patients fail to follow the treatment plan at some point in their care. Retention in treatment also is a problem [72]. This is no different from the challenges encountered in managing any chronic disease, such as diabetes, hypertension, epilepsy, and other potentially life-threatening disorders [46], and is not an indicate to terminate treatment.

Patients who continue to misuse opioids after sufficient exposure to buprenorphine and ancillary psychosocial services or who experience continued symptoms of withdrawal or craving at 32 mg of buprenorphine should be considered for therapy with methadone [5,7,52,73].

Duration of Treatment: Available evidence does not support routinely discontinuing medication-assisted treatment once it has been initiated and the patient stabilized. However, this possibility frequently is raised by patients or family members. When it is, the physician and patient should carefully weigh the potential benefits and risks of continuing medication-assisted treatment and determine whether buprenorphine therapy can be safely discontinued [74].

Studies indicate that opioid-dependent patients are at high risk for relapse when medication-assisted therapy is discontinued, even after long periods of stable maintenance [7,74]. Research also shows that longer duration of treatment is associated with better treatment outcomes [75]. Such long-term treatment, which is common to many medical conditions, should not be seen as treatment failure, but rather as a cost-effective way of prolonging life and improving the quality of life by supporting the natural and long-term process of change and recovery. Therefore, the decision to discontinue treatment should be made only after serious consideration of the potential consequences [3,7-8].

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As with other disease processes, the continuation of medication-assisted treatment should be linked directly to the patient's response (for example, his or her attainment of treatment goals). Relapse risk is highest in the first six to 12 months after initiating abstinence, then diminishes gradually over a period of years. Therefore, it is reasonable to continue treatment for at least a year if the patient responds well [3,7,10].

If buprenorphine is discontinued, the patient should be tapered off the medication through use of a safely structured regimen, and followed closely [46]. It may be necessary to reinstate pharmacotherapy with buprenorphine or a different medication or other treatment services if relapse appears imminent or actually occurs [59]. Such relapse poses a significant risk of overdose, which should be carefully explained to the patient [74]. Patients also should be assured that relapse need not occur for them to be reinstated to medication-assisted therapy [46].

Medical Records: Accurate and up-to-date medical records protect both the physician and the patient. In the event of a legal challenge, detailed medical records that document what was done and why are essential elements of the practitioner's defense [75-76].

A written informed consent and a treatment agreement articulating measurable treatment goals are key documents. The treatment agreement should be updated as new information becomes available. Both the informed consent and treatment agreement should be carefully explained to the patient and signed by both the patient (or guardian) and the treating physician [76]. The medical record should clearly reflect the decision-making process that resulted in any given treatment regimen.

The first page of the patient's chart should contain a summary of the information needed to understand the treatment plan, even without a thorough knowledge of the patient. This includes some demographic data, the names of other practitioners caring for the patient, all diagnoses, therapies employed, and a list of all medications prescribed. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [10,76].

Other documents that should be part of the medical record, where available, include [10,74,76]:

- Diagnostic assessments, including the patient history, physical examination, and any laboratory tests ordered, with their results;
- Actual copies of, or references to, medical records of past hospitalizations or treatments by other providers;
- The treatment plan, treatment agreement, and informed consent;
- Authorization for release of information to other treatment providers;
- Documentation of discussions with and consultation reports from other health care providers; and
- Medications prescribed and the patient's response to them, including any adverse events.

The medical record also must include all prescription orders, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [75].

Monitoring visits should be carefully documented in the medical record, along with any subsequent changes to the treatment plan [10,76]. The patient's record also should contain documentation of steps taken to prevent the diversion of treatment medications, including any communications with other treating physicians and, where

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available, use of the state's prescription drug monitoring program to verify that all prescribed medicines have been obtained and that no other prescriptions for controlled drugs have been dispensed without the physician's knowledge [77-78].

Records (including drug logs, if buprenorphine is dispensed in the office) should be up-to-date and maintained in an accessible manner, readily available for review [75]. Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [10,74,76].

Physicians who treat patients for addiction must observe the special confidentiality requirements of federal law 42 CFR, Part 2, which addresses the confidentiality of patients being treated for alcohol or drug addiction. 42 CFR includes a prohibition against release of records or other information without the patient's consent or a valid court order, or in cases of a bona fide medical emergency, or in the course of mandatory reporting of child abuse [7].

SECTION III: DEFINITIONS

Accurate use of terminology is essential to understanding office-based treatment of opioid addiction [70]. However, terminology in this area is changing. For many years, the most commonly used terms have been "drug abuse" and "drug dependence," with the latter indicating a severe condition considered synonymous with the term "addiction" (the chronic brain disease). The terms "abuse" and "dependence," in use since the third edition of the *Diagnostic and Statistical Manual of Mental Disorders* [79] will be replaced in the forthcoming fifth edition [80] by the term "substance use disorder." Other new terms include "opioid use" for the activity of using opioids benignly or pathologically, and "opioid use disorder" for the disease associated with compulsive, out-of-control use of opioids.

For the purposes of this Model Policy, the following terms are defined as shown.

Abuse: The definition of "abuse" varies widely, depending on the context in which it is used and who is supplying the definition. For example, in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* [81], the American Psychiatric Association defines drug abuse as "a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by one or more behaviors." The *DSM V*, to be published in 2013, replaces the term "abuse" with "misuse" [80].

Addiction: Addiction is widely defined as a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm [56]. (As discussed below, physical dependence and tolerance are normal physiological consequences of extended opioid therapy and are not the same as addiction.)

A recent definition of addiction, adopted by the American Society of Addiction Medicine in 2011, reads as follows: "Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal

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relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death” [82].

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act [75], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs [83]. Civil and criminal sanctions for serious violations of the statute are part of the government’s drug control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA [75], confers responsibility for scheduling controlled substances on the FDA and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other, but that both are necessary to ensure the public welfare. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

Most opioids are classified as Schedule II or III drugs under the CSA, indicating that they have a high potential for abuse and a currently accepted medical use in treatment in the U.S., and that abuse of the drug may lead to psychological or physical dependence [75]. (Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled substances have some potential for abuse.)

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [76]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition* (ICD- 10) of the World Health Organization (WHO) [84] and the *Diagnostic and Statistical Manual* (DSM) of the American Psychiatric Association [80,81]. In the DSM-IV-TR, a diagnosis of “substance dependence” meant addiction. In the upcoming DSM V, the term dependence is reestablished in its original meaning of physiological dependence; when symptoms are sufficient to meet criteria for substance misuse or addiction, the term “substance use disorder” is used, accompanied by severity ratings [80].

It may be important to clarify this distinction during the informed consent process, so that the patient understands that physical dependence and tolerance are likely to occur if opioids are taken regularly for a period of time, but the risk of addiction is relatively low unless the patient has additional risk factors. According to the World Health Organization, “The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid” [8].

Detoxification: Detoxification (also termed “medically supervised withdrawal”) refers to a gradual reduction, or tapering, of a medication dose over time, under the supervision of a physician, to achieve the elimination of tolerance and physical dependence [85].

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“Detoxification” is a legal and regulatory term that has fallen into disfavor with some in the medical community; indeed, some experts view “detoxification” as a misnomer because many abusable drugs are not toxic when administered in proper doses in a medical environment [86].

Diversion: The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [75].

Pharmaceuticals that make their way outside this closed system are said to have been “diverted” from the system, and the individuals responsible for the diversion (including patients) are in violation of the law. The degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [30,87].

Maintenance Treatment: Maintenance treatment involves the dispensing or administration of an opioid medication (such as methadone or buprenorphine) at a stable dose and over a period of 21 days or more, for the treatment of opioid addiction. When maintenance treatment involves the use of methadone, such treatment must be delivered in an Opioid Treatment Program (OTP). However, maintenance treatment with buprenorphine may be delivered in either an OTP or a medical office by a properly credentialed physician [7].

Medication-Assisted Treatment (MAT): MAT is any treatment for opioid addiction that includes a medication (such as methadone, buprenorphine, or naltrexone) that is approved by the FDA for opioid detoxification or maintenance treatment. MAT may be provided in a specialized OTP or, for buprenorphine or naltrexone, in a physician’s office or other health care setting [7,55].

Misuse: The term misuse (also termed non-medical use) incorporates all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [56].

Opioid: An opioid is any compound that binds to an opioid receptor. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [7,51,83]. Most physicians use the terms “opiate” and “opioid” interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. “Opioid” is the broader, more appropriate term because it includes the entire class of agents that act at opioid receptors in the nervous system, whereas “opiates” refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are “positive for opiates” have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM); drug tests that are “negative for opiates” have found no detectable levels of opiates in the sample, even though other opioids that were not tested for, including the most common currently used and misused prescription opioids, may well be present in the sample that was analyzed.

Opioid agonists are compounds that bind to the mu opioid receptors in the brain, producing a response that is similar in effect to the natural ligand that would activate it. With full mu opioid agonists, increasing the dose produces an more intense opioid effect. Most opioids that are misused, such as morphine and heroin, are full mu opioid agonists, as is methadone.

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Opioid partial agonists occupy and activate the opioid receptors, but the activation they produce reaches a plateau, beyond which additional opioid doses do not produce a greater effect. It should be noted that the plateau (or “ceiling effect”) may limit a partial agonist’s therapeutic activity as well as its toxicity. Buprenorphine is a partial mu opioid agonist.

Opioid antagonists bind to and block the opioid receptors and prevent them from being activated by an opioid agonist or partial agonist. Naltrexone and naloxone both are opioid antagonists, and both can block the effect of opioid drugs.

Opioid Treatment Program (OTP) (sometimes referred to as a “methadone clinic” or “narcotic treatment program”): An OTP is any treatment program certified by SAMHSA in conformance with 42 Code of Federal Regulations (CFR), Part 8, to provide supervised assessment and medication- assisted treatment of patients who are addicted to opioids. An OTP can exist in a number of settings, including intensive outpatient, residential, and hospital facilities. Treatments offered by OTPs include medication-assisted therapy with methadone, buprenorphine or naltrexone, as well as medically supervised withdrawal or detoxification, accompanied by varying levels of medical and psychosocial services and other types of care. Some OTPs also can provide treatment for co-occurring mental disorders [58].

Recovery: A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential [88]. As used in the ASAM Patient Placement Criteria, “recovery” refers to the overall goal of helping a patient achieve overall health and well-being [56]. SAMHSA’s 10 guiding principles recognize that recovery [89]:

1. Emerges from hope;
2. Is person-driven;
3. Occurs via many pathways;
4. Is holistic;
5. Is supported by peers and allies;
6. Is supported through relationship and social networks
7. Is culturally-based and influenced;
8. Is supported by addressing trauma;
9. Involves individual, family and community strengths and responsibility;
10. Is based on respect.

Relapse: Relapse has been variously defined as “a breakdown or setback in a person’s attempt to change or modify any target behavior” and as “an unfolding process in which the resumption of substance misuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli” [70]. Relapse rarely is caused by any single factor and often is the result of an interaction of physiologic and environmental factors [59].

The term *lapse* (sometimes referred to as a *slip*) refers to a brief episode of drug use after a period of abstinence. A lapse usually is unexpected, of short duration, with relatively minor consequences, and marked by the patient’s desire to return to abstinence. However, a lapse also can progress to a full-blown relapse, marked by sustained loss of control [56].

Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug’s effects over time [76]. Tolerance may occur both to an opioid’s

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analgesic effects and to its unwanted side effects, such as respiratory depression, sedation, or nausea. Most investigators agree that absolute tolerance to the analgesic effects of opioids does not occur. In general, tolerance to the side effects of opioids develops more rapidly than does tolerance to the drug's analgesic effects.

Tolerance may or may not be evident during treatment with opioids and is not the same as addiction [70].

Trial Period: A period of time, which can last weeks or even months, during which the efficacy of a medication or other therapy for the treatment of addiction is tested to determine whether the treatment goals can be met. If the goals are not met, the trial should be discontinued and an alternative approach (i.e., a different medication or non-pharmacologic therapy) adopted [76].

Waiver: A documented authorization from the Secretary of Health and Human Services, issued by SAMHSA under the DATA 2000 regulations, that exempts a qualified physician from the rules applied to OTPs and allows him or her to use buprenorphine for the treatment of addiction in office-based practice [51].

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Using Science to Battle Stigma in Addressing the Opioid Epidemic: Opioid Agonist Therapy Saves Lives

In 1965, Dole and Nyswander¹ published the first study of methadone maintenance treatment for opioid use disorder. On the basis of research conducted at The Rockefeller Institute for Medical Research with Kreek, they described the treatment of 22 individuals with methadone for chronic heroin addiction. In this landmark study, they reported the notable findings of craving relief, blockade of the euphoria of subsequent heroin use, and a Lazarus-like effect on psychosocial functioning, with treated subjects resuming schooling, work, and relationships. Over the past 50 years, the evidence base for opioid agonist therapy, first with methadone and now with buprenorphine, has grown exponentially. The lifesaving impact of these medications is so dramatic that the World Health Organization added both to its list of essential medications. Across the globe, opioid agonist therapy has been embraced by countries as diverse as Israel, Iran, and China.

Despite the evidence supporting the use of opioid agonist therapy, only 8% of injecting drug users currently receive treatment, with tremendous variability across the globe ranging from 90% treated in the United Kingdom, compared with 3% in India, and none in Russia.² In the United States, even if every treatment slot for methadone and buprenorphine were filled, there would still be an excess of 914,000 individuals with opioid use disorder unable to access treatment.³ These disparities in treatment access reflect the continued philosophical debate about opioid agonist therapy that has existed since methadone was first discovered.

Mutual help organizations and psychosocial programs sometimes are opposed to medication treatment. In many Narcotics Anonymous groups, individuals receiving pharmacotherapy are restricted from certain types of participation. Disparaging comments by members can be found in online forums, such as “Methadone is a drug, treating

addiction with it is like lightly hosing a fire with gasoline” or we “demand that we draw the line on using drugs and calling it recovery.”⁴ Some recovery programs, for example, halfway houses, may not allow participants to be on agonist therapy. Even the language clinicians use, including terms such as “medication-assisted treatment” or “opioid substitution,” implicitly suggest that pharmacotherapy is a corollary to treatment or simply represents replacing one drug with another.⁵ In the lay press, this stigma has been further enhanced by articles such as a recent National Public Radio piece entitled “When Drug Treatment for Narcotic Addiction Never Ends,” which provides a description of physicians who provide opioid agonist therapy as “legit drug dealers.”⁶

Contrary to what this rhetoric would suggest, scientifically there is no debate about the efficacy and safety of maintenance treatment with opioid agonist therapy. Treatment outcomes for behavioral interventions alone for opioid use disorder are dismal, with more than 80% of patients returning to drug use.⁷ In contrast, treatment with opioid agonists when adequately dosed results in retention rates of 60% to 80%, with only 15% of those treated continuing to use illicit opioids.^{7,8} A recent statewide study comparing those who received agonist therapy with those who received behavioral treatments found a 50% reduction in relapse among those treated with pharmacotherapy.⁹ Opioid agonist therapy also has been shown to reduce new human immunodeficiency virus and hepatitis C virus infection and overdose death.¹⁰⁻¹²

A growing body of evidence has answered the clinical questions of appropriate dosing, expected treatment duration, and timing of treatment initiation. Numerous studies have confirmed that flexible as opposed to fixed dosing strategies and higher dosages for both buprenorphine and methadone maintenance are more effective.^{8,13,14} Adequate treatment duration is a key to success, with tapering strategies of various lengths showing high rates of relapse. Long-term studies of methadone maintenance have demonstrated outcomes that improve with treatment duration. Among those treated for less than 6 months, 67% continue to use heroin compared with only 8% of those treated for more than 4.5 years.¹⁵ A recent study of

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buprenorphine treatment outcomes at 42 months found that 62% of treated individuals were abstinent from opioids, with 30% continuing on opioid agonist therapy.¹⁶ Last, several recent studies have shown that proactive and rapid initiation of opioid agonist therapy, particularly in medically complex patients, can be effective, whereas long wait times for treatment markedly increase the risk of death.¹⁷⁻¹⁹

Methadone and buprenorphine are not just clinically efficacious, but also cost-effective. Total healthcare costs for patients on methadone maintenance are 50% to 62% lower.²⁰ Adherence to buprenorphine is associated with lower outpatient, inpatient, emergency department, and total healthcare costs, and buprenorphine treatment reduces annual total healthcare costs by approximately \$20,000.^{21,22} A recent cost-effectiveness analysis found that every additional dollar spent on opioid agonist therapy would save \$1.80 and that treating 10% of untreated individuals in New England would generate more than \$550 million in regional societal savings.²³

Decades of research support opioid agonist therapy as a cornerstone of effective treatment that is crucial in the fight to end the opioid epidemic. Clinicians, medical systems, public health officials, and patients can be assured that opioid agonist therapy's benefits are robust and far outweigh the risks of treatment. Early treatment initiation and adequately dosed long-term maintenance strategies can be fully endorsed, recognizing the benefits for promoting abstinence, reducing overdose, and preventing new human immunodeficiency virus and hepatitis C virus infections. Opioid agonist therapy can be supported as a cost-effective treatment tool that reduces total healthcare spending. Our main barrier in battling this epidemic is the lack of dissemination, understanding, and adoption of this science-based treatment strategy. As we have done in other epidemics, most recently with human immunodeficiency virus/acquired immune deficiency syndrome, the medical community can and must take a leadership role in ensuring our approach is driven by science and not stigma.

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STATELINE

Nurses Step In to Boost Treatment for Opioid Addiction

August 31, 2016

By Christine Vestal



Colleen LaBelle (center), a registered nurse, talks to members of the opioid addiction team at the Boston Medical Center. States are eyeing the center's nurse-managed approach to buprenorphine therapy as a way to treat more people.

BOSTON — As the opioid epidemic advances, public health officials nationwide are calling on doctors to help stanch overdose deaths and salvage shattered lives by prescribing medications that have proven highly effective at keeping people away from drugs.

So far, though, not enough doctors are signing up, and less than half of the 2.2 million people who need treatment for opioid addiction are receiving it, according to the U.S. Department of Health and Human Services (HHS).

A program developed at Boston Medical Center could change that.

Instead of doctors taking the lead, registered nurses have been managing the medical center's opioid treatment programs, which have been using buprenorphine — a medication that eliminates withdrawal symptoms and reduces drug cravings — since 2003, when the federally approved addiction medication became available.

By taking over the labor-intensive office visits, behavioral health assessments, drug screenings and paperwork that go along with buprenorphine treatment, registered nurses make it easier for physicians to accept more patients and write prescriptions for the medication they want and need.

The Boston program was developed in collaboration with the Massachusetts Department of Public Health. And from its origins here in the city's historic South End, it has been replicated in 30 other health centers across the state.

The U.S. Substance Abuse and Mental Health Services Administration recommends other states replicate Boston Medical's model, and many are considering it.

Washington state recently adopted a similar nurse manager approach at two medical facilities in Seattle. And California, Connecticut, New York and Wisconsin are working with Colleen LaBelle, the founder of the Boston program, to create their own versions.

Once Boston Medical's clinic was up and running, the state Bureau of Substance Abuse Services helped fund its expansion and worked with the state Medicaid program to develop reimbursement rates that would make the program pay for itself.

In the three years after Massachusetts began funding an expansion of the program, in 2007, the number of doctors in the state who signed up for federal permits to prescribe buprenorphine nearly quadrupled, according to a recent study.

With a support staff, busy primary care physicians were more willing to devote part of their time to treating people with addictions, LaBelle said.

Research shows that Medicaid-funded addiction treatment programs that use buprenorphine reduce overdose fatalities by half compared to treatment with no medications.

The buprenorphine programs also cost less per person than comparable regimens using methadone, the only other federally approved opioid replacement medication, the study found.

Another advantage of Massachusetts' program and ones like it is patients can receive treatment for their addictions in doctors' offices and health clinics where their other health needs can also be met, said Michael Botticelli, director of the Office of National Drug Control Policy.

"We must make sure that every American with an opioid-use disorder who wants treatment can get the help they need when they need it, and that includes integrating treatment into primary care settings," he said.

Botticelli, who was appointed drug czar in 2015, directed Massachusetts' substance abuse agency in 2003 when LaBelle first sought funding for the program and was instrumental in expanding it throughout the state.

Strong Federal Support

In July, President Barack Obama signed the Comprehensive Addiction and Recovery Act, which dedicates federal funding for medication-assisted treatment of opioid addiction.

Separately, an HHS ruling loosened a long-standing restriction on the number of patients a physician can treat with the opioid-based medication, increasing the limit from 100 patients to 275.

Earlier in the year, the administration awarded \$94 million to community health centers and proposed \$1.1 billion in the 2017 budget for medication-assisted opioid treatment.

But federal money and looser prescribing rules won't shrink nationwide waiting lists for medication-assisted treatment by themselves, said Dr. Kelly Pfeifer, who leads California Health Care Foundation's work in the opioid epidemic.

What's needed is more physicians and other health care providers who are willing to step up to prescribe the medications, she said.

More than 900,000 U.S. physicians can write prescriptions for painkillers such as OxyContin, Percocet and Vicodin. But only about 34,000 doctors are authorized to prescribe buprenorphine to people who become addicted to those and other opioids. Most only treat a handful of patients.

The biggest reason doctors give for not treating more patients is lack of support staff to assist with the numerous office visits and after-hours calls that typically go along with medication-assisted addiction treatment, said Dr. Kelly Clark, president-elect of

the American Society of Addiction Medicine.

Doctors also complain they don't have time to keep up with the extra paperwork, including insurance claims and pre-authorization requirements, referrals to mental and behavioral health services, and compliance with U.S. Drug Enforcement Administration rules, Clark said.

LaBelle's nurse manager model removes those barriers and makes it possible for individual doctors to treat more patients. It also reduces the overall cost of treatment by minimizing the time spent by doctors, the highest-paid members on any medical team.

Medication-Assisted Treatment

Research shows that addiction medications are at least twice as effective as abstinence and 12-step programs at keeping people in recovery and avoiding relapse for at least a year. Medications also lower the risk of a fatal overdose.

But until 2003, methadone was the only approved medication and it could only be taken under supervision at sparsely scattered clinics across the country.

When the National Institute on Drug Abuse funded the research that led to buprenorphine's development, the hope was that office-based prescribing of buprenorphine would mean greater access to addiction medication nationwide.

Unlike methadone, patients taking buprenorphine don't have to show up at a specialized clinic every morning to receive their daily dose. They can get a prescription from their family doctor, pick up a month's supply at a local pharmacy, and take the medicine in the privacy of their homes.

Taken daily by mouth, buprenorphine is considered more effective at keeping people in recovery from drug addiction than treatment without medication.

But in spite of its positive results, buprenorphine remains underused, in part because of stigma against so-called maintenance medications, including methadone, which was approved for opioid dependence in 1964.

Buprenorphine and methadone are themselves opioids, and critics say their use amounts to trading one addiction for another. Although regulated differently, both medications are considered controlled substances by the federal government because of their potential for diversion into illegal markets.

How it Works

As a registered nurse, LaBelle can't prescribe buprenorphine. But she and other nurses manage nearly every other aspect of its use.

When patients come to a clinic seeking help for their addictions, a nurse on the team checks their urine for opioids and other drugs, talks to them about their drug use, health and mental health history, and makes sure their insurance is up to date and covers the treatment.

A nurse explains how buprenorphine works and makes sure the patient isn't taking benzodiazepines such as Valium or Xanax, which are dangerous when combined with buprenorphine. Nurses also set patients up with behavioral health counseling and group classes and refer them to mental health professionals when needed.

Doctors only enter the picture to prescribe the medication and approve the patient's treatment plan. Over the course of each patient's treatment, which typically includes monthly office visits and can last for years, doctors see patients only occasionally. Nurses are their main point of contact.

Nurses traditionally have done most of the work in treating other chronic diseases like diabetes, kidney disease and AIDS. LaBelle says getting people with opioid addictions started on buprenorphine, maintaining their treatment and coordinating their counseling is no different.

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PRESCRIBING OPIOIDS FOR CHRONIC PAIN

ADAPTED FROM CDC GUIDELINE

Opioids can provide short-term benefits for moderate to severe pain. Scientific evidence is lacking for the benefits to treat chronic pain.

IN GENERAL, DO NOT PRESCRIBE OPIOIDS AS THE FIRST-LINE TREATMENT FOR CHRONIC PAIN (for adults 18+ with chronic pain > 3 months excluding active cancer, palliative, or end-of-life care).

BEFORE PRESCRIBING

1 ASSESS PAIN & FUNCTION

Use a validated pain scale. Example: PEG scale where the score = average 3 individual question scores (30% improvement from baseline is clinically meaningful).

- Q1: What number from 0 – 10 best describes your PAIN in the past week? (0 = “no pain”, 10 = “worst you can imagine”)
- Q2: What number from 0 – 10 describes how, during the past week, pain has interfered with your ENJOYMENT OF LIFE? (0 = “not at all”, 10 = “complete interference”)
- Q3: What number from 0 – 10 describes how, during the past week, pain has interfered with your GENERAL ACTIVITY? (0 = “not at all”, 10 = “complete interference”)

2 CONSIDER IF NON-OPIOID THERAPIES ARE APPROPRIATE

Such as: NSAIDs, TCAs, SNRIs, anti-convulsants, exercise or physical therapy, cognitive behavioral therapy.

3 TALK TO PATIENTS ABOUT TREATMENT PLAN

- Set realistic goals for pain and function based on diagnosis.
- Discuss benefits, side effects, and risks (e.g., addiction, overdose).
- Set criteria for stopping or continuing opioid. Set criteria for regular progress assessment.
- Check patient understanding about treatment plan.

4 EVALUATE RISK OF HARM OR MISUSE. CHECK:

- Known risk factors: illegal drug use; prescription drug use for nonmedical reasons; history of substance use disorder or overdose; mental health conditions; sleep-disordered breathing.
- Prescription drug monitoring program data (if available) for opioids or benzodiazepines from other sources.
- Urine drug screen to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.
- Medication interactions. **AVOID CONCURRENT OPIOID AND BENZODIAZEPINE USE WHENEVER POSSIBLE.**

WHEN YOU PRESCRIBE

START LOW AND GO SLOW. IN GENERAL:

- Start with immediate-release (IR) opioids at the lowest dose for the shortest therapeutic duration. IR opioids are recommended over ER/LA products when starting opioids.
- Avoid ≥ 90 MME/day; consider specialist to support management of higher doses.
- If prescribing ≥ 50 MME/day, increase follow-up frequency; consider offering naloxone for overdose risk.
- For acute pain: prescribe < 3 day supply; more than 7 days will rarely be required.
- Counsel patients about safe storage and disposal of unused opioids.

See below for MME comparisons. For MME conversion factors and calculator, go to TurnTheTideRx.org/treatment.

50 MORPHINE MILLIGRAM EQUIVALENTS (MME)/DAY:

- 50 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300)
- 33 mg of oxycodone (~2 tablets of oxycodone sustained-release 15mg)

90 MORPHINE MILLIGRAM EQUIVALENTS (MME)/DAY:

- 90 mg of hydrocodone (18 tablets of hydrocodone/acetaminophen 5/300)
- 60 mg of oxycodone (4 tablets of oxycodone sustained-release 15mg)

AFTER INITIATION OF OPIOID THERAPY

ASSESS, TAILOR & TAPER

- Reassess benefits/risks within 1-4 weeks after initial assessment.
- Assess pain and function and compare results to baseline. Schedule reassessment at regular intervals (≤ 3 months).
- Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.
- If over-sedation or overdose risk, then taper. Example taper plan: 10% decrease in original dose per week or month. Consider psychosocial support.
- Tailor taper rates individually to patients and monitor for withdrawal symptoms.

TREATING OVERDOSE & ADDICTION

- Screen for opioid use disorder (e.g., difficulty controlling use; see DSM-5 criteria). If yes, treat with medication-assisted treatment (MAT). MAT combines behavioral therapy with medications like methadone, buprenorphine, and naltrexone. Refer to findtreatment.samhsa.gov. Additional resources at TurnTheTideRx.org/treatment and www.hhs.gov/opioids.
- Learn about medication-assisted treatment (MAT) and apply to be a MAT provider at www.samhsa.gov/medication-assisted-treatment.
- Consider offering naloxone if high risk for overdose: history of overdose or substance use disorder, higher opioid dosage (≥ 50 MME/day), concurrent benzodiazepine use.

ADDITIONAL RESOURCES

CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN:
www.cdc.gov/drugoverdose/prescribing/guideline.html

SAMHSA POCKET GUIDE FOR MEDICATION-ASSISTED TREATMENT (MAT):
store.samhsa.gov/MATguide

NIDAMED: www.drugabuse.gov/nidamed-medical-health-professionals

ENROLL IN MEDICARE: go.cms.gov/pecos

Most prescribers will be required to enroll or validly opt out of Medicare for their prescriptions for Medicare patients to be covered. Delay may prevent patient access to medications.

JOIN THE MOVEMENT

and commit to ending the opioid crisis at TurnTheTideRx.org.



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Prescription Drug Abuse Reduction

In the last 20 years, the consumption of prescription stimulants increased from 5 million to 45 million.

Prescription drug abuse is the nation's fastest growing drug problem. More people in the U.S. died last year of drug overdoses than from car accidents, making prescription drug abuse the third leading cause of accidental death. In the U.S., one person dies every 19 minutes from a drug overdose, and overdoses involving prescription painkillers now kill more Americans than those involving heroin and cocaine combined. This epidemic has been particularly widespread on college campuses. Between 1993 and

2005, the proportion of college students using prescription drugs went up dramatically: use of opioids such as Vicodin, Oxycontin, and Percocet increased by 343 percent, and use of stimulants like Ritalin or Adderall increased by 93 percent.

EXPANDING ACCESS TO NALOXONE

Learn about the Adapt Pharma/Clinton Health Matters Initiative One-time Experience Donation of NARCAN® Nasal Spray.

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85 million



people in the U.S. will be reached through strategic partnerships developed across industry sectors at both the local and national level

MORE ABOUT PRESCRIPTION DRUG ABUSE REDUCTION

CHMI seeks to cut prescription drug abuse deaths in half over the next five years – saving approximately 10,000 lives – through strategic partnerships that raise consumer and public awareness, advance business practice change, and mobilize communities.

Naloxone Purchasing Agreements

CHMI has formed national partnerships with two privately held pharmaceutical companies, kaléo and Adapt Pharma, to provide a predictably affordable supply of naloxone to community groups, public safety organizations, and schools and universities, creating a window of opportunity for the naloxone distribution field to scale over the next five years. These partnerships help place this potentially life-saving medicine in the hands of those who can intervene quickly during an opioid overdose emergency. The injectable form of naloxone HCl was first approved by FDA in 1971 and has been the standard of care for the treatment of opioid overdose in the hospital and by emergency medical services for over 40 years.

Johns Hopkins Working Group

In 2014, CHMI engaged Johns Hopkins University as a key research and content partner and, together, the Clinton Foundation and the Johns Hopkins Bloomberg School of Public Health hosted a working meeting and public forum with the goal of taking a public health approach to the prescription drug misuse and abuse epidemic and using evidence to inform policy and practical action.

Northeast Florida: Model Community of Practice

CHMI is partnering with Drug Free Duval to create a replicable and scalable model of intervention at the community level. Together, CHMI and Drug Free Duval will harness the collective resources of local organizations impacted by the epidemic to create an actionable blueprint on how to provide

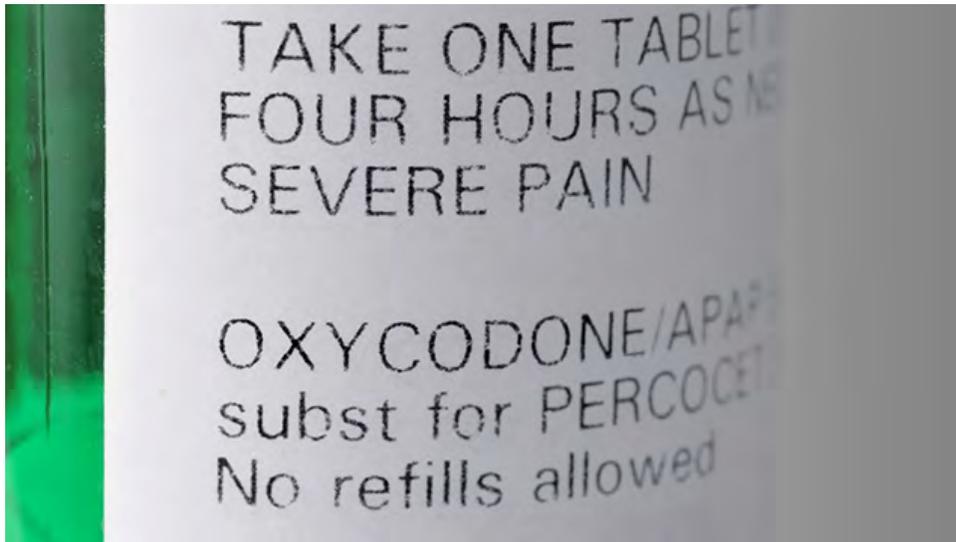
comprehensive and multi-sectoral prevention, treatment, and recovery services for the residents of the Jacksonville, Florida, metropolitan area.

In addition to the immediate and crucial impact of reducing deaths, CHMI aims to integrate naloxone access and implementation into a comprehensive prevention, intervention, treatment, and recovery model that is scalable and replicable across a diverse range of communities and populations. Currently, CHMI is working with partners and stakeholders from the opioid misuse and abuse prevention space to identify a new generation of communities primed not only for increased naloxone access, but a community-based model which incorporates a broad range of prevention and treatment goals.

Pain Care As A Catalyst For Primary Care Transformation

Joan Randell and Raquel Mazon Jeffers

September 8, 2016



As part of our mission to improve New Jersey's health care delivery systems and reduce the costs of care for its underserved populations, The Nicholson Foundation has been working to strengthen primary care in the state's safety-net system. Central to this effort is support for the integration of behavioral health care (substance use and mental health treatment) into primary care settings.

With the explosion of the prescription opioid crisis in the past several years, and the concomitant awareness of the role of primary care providers in inadvertently contributing to it, this integration work has become urgent and essential.

Pain is a common symptom reported by primary care patients—40 percent report pain as their chief complaint. However, despite sparse evidence that opioid pain relievers confer long-term benefits and evidence that they pose a significant risk of addiction or even death from unintentional overdose, they are often used to treat chronic noncancer pain. As many as one in four people who receive long-term opioid treatment from their primary care provider become addicted. A Henry J. Kaiser Family Foundation analysis of Centers for Disease Control and Prevention (CDC) data showed that in 2014, opioids caused 28,647 overdose deaths nationally and 728 in New Jersey.

For those who become dependent on opioids, the substance use problem is often compounded by co-occurring mental health conditions. In New Jersey, as in many other states, limited behavioral health treatment capacity makes it difficult for those dependent on opioids to access adequate and timely care.

As a result of the alarming toll of the prescription opioid crisis in New Jersey, The Nicholson Foundation felt compelled to act. However, we wanted to act in a strategic way that dovetailed with and reinforced our broader efforts to improve New Jersey's safety-net primary care system. Consequently, we looked to support a care model that would:

- offer primary care providers (PCPs) evidence-based pain management strategies so they could reduce inappropriate prescribing of prescription pain medications,
- improve PCPs' understanding of the role of behavioral health in both pain management and the treatment of physical health conditions so they could take a more active role in managing behavioral health conditions,

- train and support PCPs in using medication-assisted treatment for their opioid-dependent patients, and
- provide coaching to clinical and administrative staff to facilitate the adoption of practice-wide improvement strategies to support PCPs in providing state-of-the-art pain care.

In the years leading up to 2014, we became acquainted with a care model that fulfilled these criteria. Project ECHO, which was pioneered at the University of New Mexico, uses telecommunications technology to connect PCPs with an interdisciplinary team of nationally recognized medical specialists in specific disease areas. These specialists remotely mentor and collaborate with PCPs to enhance their knowledge and clinical skills in these specific areas. Since its inception, Project ECHO's model has been applied around the world to address many health conditions.

In 2014 we supported a pilot of a two-pronged application of Project ECHO to test this model's feasibility in New Jersey. First, the model was used to enable PCPs to make greater use of multimodal nonopioid approaches—including behavioral health interventions—to treat chronic pain. The aim was to reduce the number of patients who might become opioid dependent in the first place.

Second, the model was applied to help PCPs improve their skills in prescribing buprenorphine, a Food and Drug Administration-approved medication for the treatment of opioid addiction. The aim was to increase the ease of access to, and efficacy of, substance use treatment for those who were already opioid dependent.

The eighteen-month project was conducted by the Connecticut-based Weitzman Institute in three New Jersey safety-net, primary care practices. We learned from its findings that the Project ECHO approach to improve pain management was feasible. PCPs were eager to participate and receive the support of a team of experts.

We also learned that buprenorphine treatment could be successfully integrated into primary care practices in New Jersey and that it reduced opiate misuse by already-dependent patients.

Based on these and other findings, we deemed the pilot a success.

Consequently, as of July 2016, we have funded the Weitzman Institute to operate the New Jersey Pain Care Collaborative, which expanded the model to twenty-nine PCPs in twenty safety-net practices across the state. The majority of the participating practices are located in areas with the highest opioid-overdose death rates.

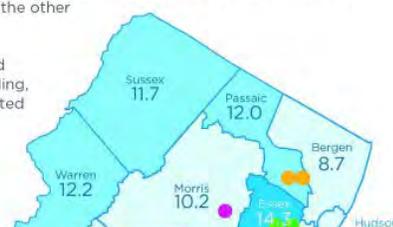


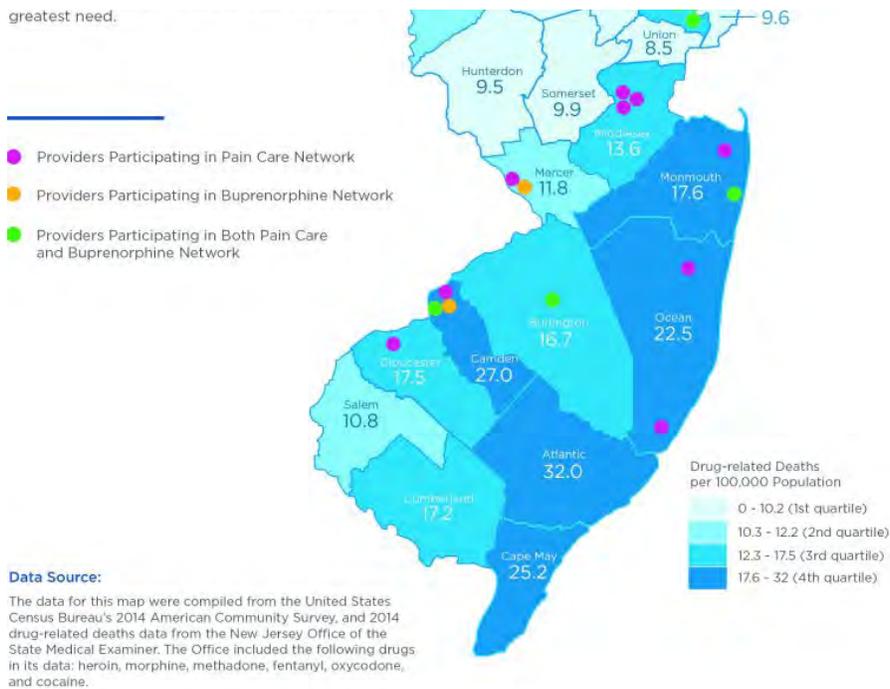
The New Jersey Pain Care Collaborative

Sponsored by a grant from The Nicholson Foundation and administered by the Weitzman Institute, the New Jersey Pain Care Collaborative addresses the prescription opioid crisis in New Jersey. The Collaborative utilizes the Project ECHO model of hub-and-spoke knowledge-sharing networks, led by expert teams who use multi-point videoconferencing to conduct virtual mentoring with community providers. One network is focused on pain care and the other on buprenorphine treatment.

This infographic presents each county's drug-related deaths per 100,000 population. The darker the shading, the higher the population-adjusted rate of drug-related deaths.

The primary care practices participating in the Collaborative are also indicated on the map. The Collaborative sites are spread throughout New Jersey, and many are targeted at the "hotspots" of





The overuse of prescription pain medications to treat chronic pain is clearly an urgent concern, both nationally and in New Jersey. Although it can be addressed in a variety of ways, it is essential that efforts focus on primary care practices and providers.

Around the country, states are implementing practice-level approaches that educate PCPs about the potential dangers of over-prescribing opioids, urge or require use of prescription drug monitoring programs, and encourage PCPs whose opioid prescriptions exceed accepted levels to change their prescribing practices, if appropriate. These approaches improve current prescribing patterns. However, they do not fundamentally alter the fragmented care provided to the millions of patients whose chronic pain involves aspects of both behavioral and physical health.

We believe a more comprehensive approach to pain care represents a key opportunity to have a long-term impact on the primary care system. This approach entails helping PCPs understand pain as a critical nexus where behavioral and physical health issues intersect. Treating this nexus holistically, as a component of whole-person care, can lead to overall changes in practice patterns if PCPs also apply this treatment approach to the way they address other medical conditions that involve aspects of both behavioral and physical health. These include such conditions as cardiovascular disease and diabetes, which are among the largest cost drivers of our health care system. We suggest that groups that are interested in fostering systemic change within the primary care setting, including foundations, government agencies, and health plans, could benefit from what we are learning through our work on the New Jersey Pain Care Collaborative: Models that work collaboratively with PCPs to comprehensively address a specific health issue can also be catalysts for broader primary care transformation.

Related reading on Health Affairs Blog:

Benjamin Miller, "Creating A Culture Of Whole Health: A Realistic Framework For Advancing Behavioral Health And Primary Care Together," GrantWatch section, April 14, 2016.

Joan Randell and John Jacobi, "State Licensing And Reimbursement Barriers To Behavioral Health And Primary Care Integration: Lessons From New Jersey," GrantWatch section, April 7, 2016.

Becky Hayes Boober and Rick Ybarra, "Advancing Integrated Behavioral Health Care In Texas And Maine: Lessons From The Field," GrantWatch section, August 11, 2015.

David Barash, "Project ECHO: Force Multiplier For Community Health Centers," GrantWatch section, July 20, 2015.

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The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013

Curtis S. Florence, PhD, Chao Zhou, PhD, Feijun Luo, PhD, and Likang Xu, MD

Importance: It is important to understand the magnitude and distribution of the economic burden of prescription opioid overdose, abuse, and dependence to inform clinical practice, research, and other decision makers. Decision makers choosing approaches to address this epidemic need cost information to evaluate the cost effectiveness of their choices.

Objective: To estimate the economic burden of prescription opioid overdose, abuse, and dependence from a societal perspective.

Design, Setting, and Participants: Incidence of fatal prescription opioid overdose from the National Vital Statistics System, prevalence of abuse and dependence from the National Survey of Drug Use and Health. Fatal data are for the US population, nonfatal data are a nationally representative sample of the US civilian noninstitutionalized population ages 12 and older. Cost data are from various sources including health care claims data from the Truven Health MarketScan Research Databases, and cost of fatal cases from the WISQARS (Web-based Injury Statistics Query and Reporting System) cost module. Criminal justice costs were derived from the Justice Expenditure and Employment Extracts published by the Department of Justice. Estimates of lost productivity were based on a previously published study.

Exposure: Calendar year 2013.

Main Outcomes and Measures: Monetized burden of fatal overdose and abuse and dependence of prescription opioids.

Results: The total economic burden is estimated to be \$78.5 billion. Over one third of this amount is due to increased health care and substance abuse treatment costs (\$28.9 billion). Approximately one quarter of the cost is borne by the public sector in health care, substance abuse treatment, and criminal justice costs.

Conclusions and Relevance: These estimates can assist decision makers in understanding the magnitude of adverse health outcomes

associated with prescription opioid use such as overdose, abuse, and dependence.

Key Words: prescription opioid, overdose, abuse and dependence, economic burden

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The adverse health effects of the misuse of prescription opioids, including abuse, dependence, and overdose are a well-documented public health problem.¹ Fatal prescription drug overdoses have been described as an epidemic by the US Centers for Disease Control and Prevention.² Prescription opioids account for approximately 70% of fatal prescription drug overdoses.^{3,4}

Decision makers at both the federal and state levels have responded to the epidemic with several strategies aimed at reducing the burden of the epidemic. For example, in 2011 the US Office of National Drug Control Policy issued a set of recommendations that, in part, call for all states to have functional prescription drug monitoring programs (PDMPs), and encourages federal agencies such as the Veterans Administration to share data with state PDMPs when legally permitted to do so.⁵ Policies such as these face a difficult task in addressing the overdose epidemic while balancing the care of patients who need treatment for pain. Also, decision makers in government and the health care sector face financial constraints that require strategies that are cost efficient as well as effective, while also considering the resource use for addressing other social and health problems.

An essential component in identifying prevention strategies that are cost-effective is understanding the economic burden produced by the adverse health outcomes. Previous researchers have estimated the overall societal impact of prescription opioid misuse.^{6,7} Other studies have examined specific components of the overall issue of opioid misuse, such as the cost of poisonings, nonmedical use,⁸ and abuse and workplace absenteeism.⁹ Most recently, Birnbaum et al¹⁰ estimated the overall societal impact of prescription opioid abuse, dependence, and misuse in the United States to be \$55.7 billion in 2007. Since that year, however, the epidemic has continued to progress. From 2007 to 2013, the annual number of prescription opioid overdose deaths has increased by over 1800 cases,³ and the annual number of persons who abuse or are dependent on prescription opioids has increased by over 200,000 persons.¹¹

In this study, we present updated estimates of the economic burden of prescription opioid overdose, abuse, and

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

The authors declare no conflict of interest.

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dependence for 2013 using the most recently available data. We also incorporate more comprehensive health care spending data than previous studies, and we use recently updated methods for valuing the loss of productivity (both through employment and household activities) for fatal and nonfatal cases.

METHODS

Overview

In this study, we calculated cost estimates of prescription opioid overdose, abuse, and dependence based on the incidence of overdose deaths and the prevalence of prescription opioid abuse and dependence for calendar year 2013. We considered a societal perspective, which means we considered both the cost for persons experiencing overdose or abuse/dependence, and costs incurred by society in general, such as criminal justice–related costs. The cost components that considered were health care and substance abuse treatment cost, criminal justice cost, and lost productivity. Costs calculated for abuse and dependence are annual costs, while costs for fatal cases are lifetime costs discounted to 2013 present value at a rate of 3%. We used the most recently available year of data for all cost components. When the most recent year of data available was earlier than 2013, costs were inflation-adjusted to 2013 dollars.

Our measure of incidence of prescription opioid overdose deaths in 2013 came from the CDC WONDER database, which records all deaths reported in the United States National Vital Statistics System.³ Cases were identified using the multiple cause of death ICD-10 codes (T40.2–T40.4), which identify deaths across all intents (unintentional, intentional, and undetermined). Prevalence of prescription opioid abuse and dependence was measured using the 2013 National Survey on Drug Use and Health (NSDUH). The NSDUH is a nationally representative sample of the US civilian noninstitutionalized population ages 12 and older. The survey collects detailed information on substance use, including a questionnaire that can identify abuse and dependence based on the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV)¹² definition for a variety of substances, including prescription opioids. The survey also collects detailed data on health insurance coverage during the year, and basic demographic information such as sex and age. This information was used in assigning health care costs and lost productivity costs to abuse/dependence cases, as described in more detail below. Survey weights were included in the data that allow for estimation of nationally representative population totals for cases of substance abuse and dependence. Details of all calculations presented below may be found in the electronic appendix (Supplemental Digital Content 1, <http://links.lww.com/MLR/B261>) that accompanies this study.

Health Care Costs

A matched case-control design was used to estimate the impact of prescription opioid abuse diagnoses on health care spending. This design was implemented using the identified Truven Health MarketScan Research Databases for

commercial, Medicaid, and Medicare health plan enrollees. The MarketScan data capture person-specific utilization, expenditures, and enrollment across inpatient, outpatient, and prescription drug claims. The commercial database includes private-sector health data from approximately 100 different insurance companies. The Medicare database contains claims for Medicare-eligible retirees with employer-sponsored Medicare Supplemental plans, and include expenditures buy both Medicare and supplemental coverage. The MarketScan Medicaid Database contains the pooled health care experience of approximately 7 million Medicaid enrollees from 11 geographically dispersed states. The Medicaid data does not identify the states included to preserve confidentiality. As the estimation strategy requires the comparison of expenditures at an individual level, the analysis excludes those in capitated payment plans.

Prescription opioid abuse and dependence cases were identified using previously described methodology.¹³ Diagnosed commercial, Medicare, and Medicaid cases were identified as patients with ≥ 1 diagnosis for opioid abuse or dependence during the third quarter of 2011 through the fourth quarter of 2012, defined using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes for opioid abuse, dependence or overdose [304.0X (opioid type dependence), 304.7X (combinations of opioid type dependence with any other drug dependence), 305.5X (nondependent opioid abuse), 965.00 (poisoning by opium (alkaloids) unspecified), 965.02 (poisoning by methadone), and 965.09 (poisoning by other opiates and related narcotics)]. It is not possible to distinguish prescription opioid dependence from heroin dependence with the ICD-9 codes. The implications of this limitation of the data for our results will be discussed below.

All patients were continuously eligible with non-capitated plan coverage during the 18-month study period. The 18-month study period consisted of a 12-month observation period with first diagnosis as the index date, and a 6-month baseline period preceding the observation period that was used for propensity score matching. For example, if patient A's first abuse diagnosis date was February 1, 2012 then this date was considered the index date for this patient. Then the 18-month study period included the 6-month baseline period (August 1, 2011–January 31, 2012) before the index date and the 12-month period (February 1, 2012–January 31, 2013) after the index date. For the comparison patients, the index date was assigned as the date of a random medical claim, and the data were then organized around this date by the same method.

To account for baseline differences in demographics, comorbidities, and health care resource use, abusers were matched 1:1 to comparison patients based on propensity scores estimated using a logistic regression model for all study patients. For commercial and Medicare analyses, the regression model included age, sex (male/female), baseline health care costs, Charlson comorbidity index, region of patient residence (Northeast, North Central, South, West), and plan type (eg, Exclusive Provider Organization, Health Maintenance Organization, Non-Capitated Point-of-Service, etc.) as independent variables. Because Medicaid has slightly different variables, the logistic regression used following variables: age, sex (male/

female), race (white, black, Hispanic, and other), baseline health care costs, Charlson comorbidity index, Medicare eligibility, basis of eligibility (eg, low income child), and plan type (eg, basic/major medical, comprehensive, Exclusive Provider Organization, Health Maintenance Organization, Preferred Provider Organization, etc.). The cost was total health care cost including inpatient and outpatient care and all prescription drugs. Health care costs in the 12-month observation period were compared between abuse or dependence cases and matched comparison patients to determine the excess annual per patient health care costs. Nonlinear regression models were estimated to account for the skewed nature of the health care expenditure data (gamma family with log link), with expenditures as the dependent variable and an indicator for diagnosed or control group as the independent variable.¹⁴

Excess medical and drug per-patient costs were then multiplied by the relevant number of opioid abuse patients derived from the NSDUH for each insurance coverage category reported in the survey data (Private, Medicare, Medicaid, CHAMPUS/VA, other, and uninsured). CHAMPUS/VA and other categories were assigned costs for private coverage. The uninsured were assigned 50% of the cost of private insurance, based on reports that show this to be the typical ratio of spending for the uninsured population.¹⁵

While the estimation described above will account for the cost of health services reimbursed by insurance plans for those diagnosed with opioid use disorder, there are other sources of payment for substance abuse treatment that are important to measure. Substance abuse treatment costs that were not paid by health insurance (such as public programs like SAMSHA block grants and private foundation funding) were calculated by identifying non-insurance-based federal, state, local, and private expenditures on substance abuse treatment.¹¹ These costs were multiplied by the share of drug abuse and dependence cases associated with prescription opioids in the 2013 NSDUH.

Criminal Justice Costs

We followed an apportionment approach previously described¹⁰ to update criminal justice costs to 2013.¹⁶ This method consists of using reported criminal justice spending for drug crimes and multiplying that number by the share of drug abuse and dependence cases represented by prescription opioids from NSDUH. The criminal justice costs consisted of 4 components: (1) police protection, (2) legal and adjudication, (3) correctional facilities, and (4) property lost due to crimes. We obtained spending data on police protection, legal and adjudication activities, and correctional facilities from the Justice Expenditure and Employment Extracts, 2012—Preliminary¹⁷ and data on property lost due to crimes from the Crime in the United States 2012.¹⁸ We replicated the calculation procedures by Birnbaum and colleagues to estimate the proportions of these 3 components attributable to prescription opioid abuse or dependence: the ratio of arrests for the components of police protection and legal and adjudication,^{18–21} the ratio of incarcerations for the correctional facilities component,²² and the ratio for the component of property lost due to crimes.

Lost Productivity Costs

We considered lost productivity costs from: (1) premature death from prescription opioid abuse or dependence, (2) reduced productive hours for abuse/dependence, and (3) incarceration. We estimated the cost of fatal opioid abuse or dependence by entering the number of prescription opioid overdose deaths in 2013 into the Cost of Injury Reports application under CDC's WISQARS (Web-based Injury Statistics Query and Reporting System) cost module.²³ The WISQARS cost module estimates the lost productivity of a fatal injury based on the sex and age of the decedent and the mechanism of injury. Cost are assigned based on the earnings expected for a person of the decedent's sex and age over the remaining expected lifespan. We used the cost estimate for those that died from poisonings, for all intents.

In calculating lost productivity for abuse and dependence, we used an approach that values the loss of "productive hours." Productive hours are any time that is spent in paid employment or household productivity. The measure of production value used estimated the average time spent in employment and household production and estimated the value (including fringe benefits) of this time by age and sex category. This value then was multiplied by the percentage reduction in productivity attributable to drug abuse/dependence (17% for males and 18% for females²⁴), and finally summed over values across all sex and age groups. The prevalence of prescription opioid abuse/dependence cases for each sex and age group were tabulated from the 2013 NSDUH, then multiplied that by the corresponding per person annual production value of US population,²⁵ which was inflated to 2013 dollars.

To calculate lost productivity due to incarceration, we first used the numbers of inmates incarcerated for crimes attributed to prescription opioid abuse/dependence at federal, state, and local levels in 2013. After estimating the numbers of federal, state, and local inmates incarcerated for crimes attributed to prescription opioid abuse or dependence, we then multiplied those numbers by the per person annual production value of the US population inflated to 2013 dollars.

Finally, a sensitivity analysis for all major cost categories was conducted. This was done by calculating the cost numbers at the endpoints of the 95% confidence interval of both the prevalence of prescription opioid abuse and dependence and the number of prescription opioid deaths.

RESULTS

Table 1 reports the prevalence of prescription opioid abuse and dependence, and the number of fatal overdoses from prescription opioids in 2013. Almost 2 million people are estimated to meet the DSM-IV criteria for abuse and dependence, and over 16,000 died from prescription opioid overdoses. Both of these numbers represent a substantial increase from the most recently published comprehensive cost estimates from 2007, with the number of fatal cases over 1800 higher, and the prevalence of abuse and dependence increased by approximately 200,000 persons.

TABLE 1. Prevalence of Prescription Opioid Abuse and Dependence, and Fatal Overdose, United States 2013

Outcome	Cases in 2013* (95% Confidence Interval)
Prescription opioid abuse and dependence (Millions)	1.935 (1.586, 2.284)
Fatal overdose (no. deaths) [†]	16,235 (15,985, 16,485)

*National Survey of Drug Use and Health, 2013.

[†]CDC WONDER database, ICD-10 Multiple Cause of Death Codes.

Table 2 reports the estimates of annual health care cost differences for patients diagnosed with opioid abuse or dependence and their matched comparisons. The cost differences for all 3 types of insurance are large and statistically significant. Medicare has the largest cost difference at over \$17,000. Private insurance has a cost increase of \$15,500, and Medicaid is over \$13,700. Full regressions results for the propensity score matching and health care expenditure regressions are available in the electronic appendix (Supplemental Digital Content 2, <http://links.lww.com/MLR/B262>).

The aggregate costs associated with fatal overdose and abuse/dependence cases, and the range of estimates based on the variation in estimated abuse, dependence, and overdose outcomes, are reported in Table 3. The aggregate cost for these prescription opioid-related overdose, abuse, and dependence was over \$78.5 (\$70.1–\$87.3) billion. Almost two thirds of these costs were related to health care, substance abuse treatment, and lost productivity for nonfatal cases (Fig. 1). Total spending for health care and substance abuse treatment accounted for over \$28 billion [\$26.1 (\$21.4–30.8) billion from insurance and \$2.8 (\$2.6–\$3.2) billion from other sources]. Fatal cases account for a little more than one quarter of the costs [\$21.5 (\$21.2–\$21.8) billion].

The aggregate costs demonstrate the substantial amount of the economic burden that is borne by federal, state, and local government. Over 14% of the cost is funded by public health insurance programs (Medicare, Medicaid, and Champus/VA), and 3.2% is from additional government sources for substance abuse treatment. Almost all of the criminal justice-related costs (96%, or \$7.3 of \$7.7 billion) goes to activities directly funded by state and local government. Taken together, this means that almost 25% of the aggregate economic burden is funded by public sources. In addition, some portion of the lost earnings will be borne by the public sector in the form of forgone tax revenue.

TABLE 2. Estimated Annual Health Insurance Cost Increase After Diagnosis With Prescription Opioid Misuse Disorder—MarketScan Commercial, Medicare, and Medicaid Databases, United States (2013 Dollars)

	Estimated Incremental Effect (95% Confidence Interval)
Private health insurance (N = 116,225)	\$15,500 (\$14,922, \$16,078)
Medicare (N = 6917)	\$17,052 (\$13,472, \$20,632)
Medicaid (N = 30,454)	\$13,743 (\$12,341, \$15,145)

TABLE 3. Aggregate Societal Costs of Prescription Opioid Abuse, Dependence, and Fatal Overdose, United States (Millions of 2013 Dollars)

Nonfatal Costs	Aggregate Costs (Range Based on 95% CI of Prevalence)	Percentage of Aggregate Costs
Health care		
Private insurance	\$14,041	17.9
Medicare	\$2593*	3.3
Medicaid	\$5490*	7.0
Champus/VA	\$428*	0.5
Other	\$1003	1.3
Uninsured	\$2519	3.2
Total	\$26,075 (\$21,372–\$30,778)	33.2
Substance abuse treatment		
Federal	\$721*	0.9
State and local	\$1823*	2.3
Private	\$276	0.4
Total	\$2820 (\$2567–\$3245)	3.6
Criminal justice		
Police protection	\$2812*	3.6
Legal and adjudication	\$1288*	1.6
Correctional facilities	\$3218*	4.1
Property lost due to crime	\$335	0.4
Total criminal justice costs	\$7654 (*)	9.7
Lost productivity		
Reduced productive time/increased disability	\$16,262 (\$13,329–\$19,195)	20.7
Production lost for incarcerated individuals	\$4180 (\$3957–\$4556)	5.3
Total	\$20,441 (\$17,286–\$23,751)	26.0
Total nonfatal costs	\$56,990 (\$48,879–\$65,428)	72.6
Fatal costs		
Lost productivity	\$21,429	27.3
Health care	\$84	0.1
Total fatal costs	\$21,513 (\$21,182–\$21,844)	27.4
Total of nonfatal and fatal	\$78,503 (\$70,061–\$87,272)	100.0

*Public sector costs.

CI indicates confidence interval.

DISCUSSION

The analysis presented here is subject to several limitations. In some cases, these limitations can help identify areas for further research that will improve our understanding of the impact of the prescription opioid overdose epidemic. For example, our estimates of nonfatal costs are based on the prevalence of abuse and dependence. Ideally, the economic burden of an adverse health outcome would be estimated by calculating the lifetime cost of the condition—that is, observing the condition from its onset until it ends. Then, the total value of preventing the condition from occurring would be known. At the present time though, information in the research literature about the natural history of opioid misuse does not allow for such a calculation, and surveillance systems are not in place to adequately measure the incidence of the condition in the population.

DISTRIBUTION OF THE ECONOMIC BURDEN OF PRESCRIPTION OPIOID OVERDOSE, ABUSE AND DEPENDENCE

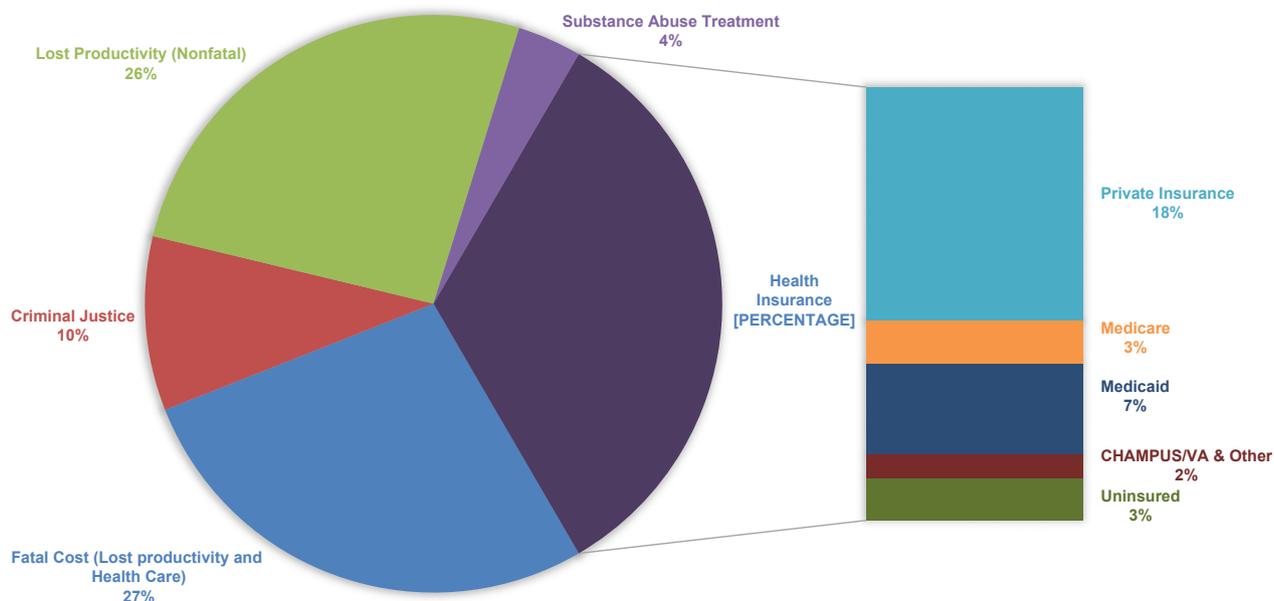


FIGURE 1. Distribution of the economic burden of prescription opioid overdose, abuse, and dependence.

Our health care cost estimates used the definition of opioid abuse and dependence identified by ICD-9 diagnosis codes. This definition does not differentiate between prescription opioids and heroin. Because we are interested in the difference in health care spending between those with abuse or dependence and those without, this will bias our results if prescription opioid abuse or dependence and heroin abuse or dependence have different effects on health care spending. On the basis of responses to the NSDUH, prescription opioid abuse and dependence is far more common than for heroin. In 2013, an estimated 1.9 million people reported prescription opioid abuse or dependence, whereas 517,000 reported heroin abuse or dependence (with some reporting both). If diagnosed opioid abuse/dependence follows a pattern similar to NSDUH responses and heroin and prescription opioid users are equally likely to be treated, the effect on our estimates should be mitigated.

Finally, we did not attempt to attribute costs to specific drugs if multiple types of drug abuse were reported. This could bias our results if the health care cost impact of abuse and dependence is different between prescription opioids and heroin, or if abuse of prescription opioids alone has a different effect from abuse of multiple drugs. We are also unable to account for the impact of diversion of drugs for nonmedical use. Future research could analyze whether this is the case using data that allows for these different sources of abuse and dependence to be identified.

We also estimated the per case health care cost impact using a convenience sample of persons enrolled in commercial insurance plans, Medicare plans with an employer-sponsored supplemental plan, and subset of state Medicaid

plans. The populations covered by these plans are not representative of the US population, and also may not be representative of the populations most at risk for opioid overdose, abuse, or dependence. For example, many people receiving Social Security disability payments are covered by both Medicare and Medicaid. In our analysis, health care spending was only measured for 1 health insurance plan for each dependent person. In the case of these “dual eligible” patients, our health care cost estimates will be too low. We also depended on medical diagnosis of abuse and dependence, which could underreport the true rate.

Finally, it is extremely difficult to measure all costs to society from an epidemic. In this case, there are many costs we were unable to measure, such as the reduction in quality of life of those who are dependent. These impacts are substantial, with a previous study finding a quality-adjusted life year reduction of approximately 50%.²⁶ We also cannot account for the pain and suffering of family members who have lost loved ones due to fatal overdoses. The costs that we can identify, however, do help increase our understanding of the impact of the epidemic.

The economic burden estimates presented here help to quantify some of the adverse health impacts associated with prescription opioids. In the ideal case, decision makers could use these estimates when weighing the benefits and risks of using opioids to treat pain, and evaluating prevention measures to reduce harmful use. However, at the present time a full accounting of both the benefits and costs of prescription opioid use is not available.

The results presented here are also helpful in understanding the distribution of the economic burden. A large share of the cost

is borne by the public sector, both through direct services from government agencies, but also through tax revenue that will be lost from reduced earnings. Also, the health care sector bears approximately one third of the costs we have estimated here.

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[Who's Calling the Shots in State Politics?](#)

Politics of pain: Drugmakers fought state opioid limits amid crisis

Makers of prescription painkillers tried to kill state measures aimed at stemming the tide of opioid drugs

By [Liz Essley Whyte](#)   email [Geoff Mulvihill](#)   email [Ben Wieder](#)   email 12:01 am, September 18, 2016 Updated: 21 hours, 39 minutes ago



Jennifer Weiss-Burke, executive director of a youth recovery center in Albuquerque, N.M., stands by one of the rooms at the recovery center named after her son, Cameron Weiss. He died of a heroin overdose in 2011. Weiss-Burke said her teenage son's descent into drug addiction started with an opioid prescription a doctor wrote for him for a wrestling injury. AP Photo/Mary Hudetz

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Editor's note: This is the first installment of a two-day series. Day two explores how a loose coalition of drugmakers and industry-backed nonprofits shaped the **federal response to the opioid crisis**.

The makers of prescription painkillers have adopted a 50-state strategy that includes hundreds of lobbyists and millions in campaign contributions to help kill or weaken measures aimed at stemming the tide of prescription opioids, the drugs at the heart of a crisis that has cost 165,000 Americans their lives and pushed countless more to crippling addiction.

The drugmakers vow they're combating the addiction epidemic, but [The Associated Press](#) and the [Center for Public Integrity](#) found that they often employ a statehouse playbook of delay and defend that includes funding advocacy groups that use the veneer of independence to fight limits on the drugs, such as OxyContin, Vicodin and fentanyl, the narcotic linked to Prince's death.

The mother of Cameron Weiss was no match for the industry's high-powered lobbyists when she plunged into the corridors of New Mexico's Legislature, crusading for a measure she fervently believed would have saved her son's life.

It was a heroin overdose that eventually killed Cameron, not long before he would have turned 19. But his slippery descent to death started a few years earlier, when a hospital sent him home with a bottle of Percocet after he broke his collarbone in wrestling practice.

Jennifer Weiss-Burke pushed for a bill limiting initial prescriptions of opioid painkillers for acute pain to seven days. The bill exempted people with chronic pain, but opponents still fought back, with lobbyists for the pharmaceutical industry quietly mobilizing in increased numbers to quash the measure.

They didn't speak up in legislative hearings. "They were going individually talking to senators and representatives one-on-one," Weiss-Burke said.

Unknowingly, she had taken on a political powerhouse that [spent more than \\$880 million nationwide](#) on lobbying and campaign contributions from 2006 through 2015 — more than 200 times what those advocating for stricter policies spent and more than eight times what the formidable gun lobby recorded for similar activities during that same period.

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The pharmaceutical companies and allied groups have a number of legislative interests in addition to opioids that account for a portion of their political activity, but their steady presence in state capitals

About this project

This two-part investigation by the [Center for Public Integrity](#) and [The Associated Press](#) examines the politics

means they're poised to jump in quickly on any debate that affects them.

Collectively, the AP and the Center for Public Integrity found, the drugmakers and allied advocacy groups employed an annual average of 1,350 lobbyists in legislative hubs from 2006 through 2015, when opioids' addictive nature came under increasing scrutiny.

"The opioid lobby has been doing everything it can to preserve the status quo of aggressive prescribing," said Dr. Andrew Kolodny, founder of [Physicians for Responsible Opioid Prescribing](#) and an outspoken advocate for opioid reform. "They are reaping enormous profits from aggressive prescribing."

The drug companies say they are committed to solving the problems linked to their painkillers. Major opioid-makers have launched initiatives to, among other things, encourage more cautious prescribing, allow states to share databases of prescriptions and help stop drug dealers from obtaining pills.

And the industry and its allies have not been alone in fighting restrictions on opioids. Powerful doctors' groups are part of the fight in several states, arguing that lawmakers should not tell them how to practice medicine.

While drug regulation is usually handled at the federal level — where the makers of painkillers also have pushed back against attempts to impose restrictions — ordinary citizens struggling with the opioid crisis in their neighborhoods have looked to their state capitals for solutions.

Hundreds of opioid-related bills have been introduced at the state level just in the last several years. The few groups pleading for tighter prescription restrictions are mostly fledgling mom-and-pop organizations formed by families of young people killed by opioids. Together, they spent about \$4 million nationwide at the state and federal level on political contributions and lobbying from 2006 through 2015 and employed an average of eight state lobbyists each year.

Prescription opioids are the synthetic cousins of heroin and morphine, prescribed to relieve pain. Sales of the drugs have boomed — quadrupling from 1999 to 2010 — and overdose deaths rose just as fast, totaling 165,000 this millennium. Last year, 227 million opioid prescriptions were doled out in

behind the nation's opioid addiction epidemic.

AP reporters [Geoff Mulvihill](#) and [Matthew Perrone](#) and Center for Public Integrity reporters [Liz Essley Whyte](#) and [Ben Wieder](#) collaborated on the project for seven months.

Wieder collected and analyzed campaign finance and lobbying data covering 2006 through 2015 from the [National Institute on Money in State Politics](#), [Center for Responsive Politics](#), Federal Election Commission, the U.S. House of Representatives Office of the Clerk and the IRS.

Mulvihill, Perrone and Whyte reviewed hundreds of documents and interviewed more than 150 officials, experts, advocates and others to gain insights into how the political process influenced the response to the opioid epidemic.

Taken together, this information provides a [unique national look](#) at how drugmakers and their allies often [sought to delay steps](#) intended to combat opioid abuse while [pushing their own priorities](#) with lawmakers and regulators. The findings were provided in advance to news outlets around the country to help reporters prepare stories for their local audiences and augment their ongoing reporting about the nation's opioid crisis.

the U.S., enough to hand a bottle of pills to nine out of every 10 American adults.

The drugmakers' revenues are robust, too: [Purdue Pharma](#), the maker of OxyContin and one of the largest opioid producers by sales, pulled in an estimated \$2.4 billion from opioids last year alone, according to estimates from health care information company [IMS Health](#).

That's even after executives pleaded guilty to misleading the public about OxyContin's risk of addiction in 2007 and the company agreed to pay more than \$600 million in fines.

Opioids can be dangerous even for people who follow doctors' orders, though they also help millions of people manage pain associated with cancer, injuries, surgeries and end-of-life care.

The industry group [Pharmaceutical Research and Manufacturers of America](#) issued a statement saying, "We and our members stand with patients, providers, law enforcement, policymakers and others in calling for and supporting national policies and action to address opioid abuse."

And Purdue said: "Purdue does not oppose — either directly or indirectly — policies that improve the way opioids are prescribed, including when those policies may result in decreased opioid use."

One of the chief solutions the drugmakers actively promote now are new formulations that make their products harder to crush or dissolve, thwarting abusers who want to snort or inject painkillers. But the new versions also extend the life of their profits with fresh patents, and some experts question their overall effectiveness.

A focus on pain treatment

An analysis of state records collected by the [National Institute on Money in State Politics](#) provides a snapshot of the drugmakers' battles

to limit opioids. For instance, they show that pharmaceutical companies and their allies ramped up their lobbying and campaign contributions in New Mexico in 2012 as lawmakers considered — and ultimately killed — the bill backed by Cameron Weiss’ mother.

But one of the drug companies’ most powerful engines of political might isn’t part of the public record — a largely unknown network of opioid-friendly nonprofits they help fund and meet with monthly known as the Pain Care Forum, formed more than a decade ago.

Combined, its participants contributed more than \$24 million to 7,100 candidates for state-level offices from 2006 through 2015, with the largest amounts going to governors and the lawmakers who control legislative agendas, such as house speakers, senate presidents and health committee chairs.

They’ve gotten involved in nitty-gritty fights even beyond legislatures. After Washington state leaders drafted the nation’s first set of medical guidelines urging doctors not to prescribe high doses of opioids in 2007, the **Pain Care Forum hired a public relations firm** to convince the state medical board that the guidelines would hurt patients with chronic pain.

A sizable slice of the drugmakers’ battles are carried out by pharma-funded advocates spreading opioid-friendly narratives — with their links to drug companies going unmentioned — or by persuading pharma-friendly lawmakers to introduce legislation drafted by the industry.

Two years ago, it was a major patient organization receiving grants from the opioid industry, the **American Cancer Society’s Cancer Action Network**, that led the fight against a measure in Tennessee aimed at reducing the number of babies born addicted to narcotics.

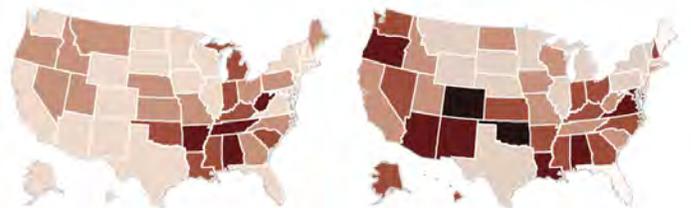
The politics of pain

States nationwide are grappling with a devastating opioid crisis. Yet attempts at regulating pain medications have faced resistance from a powerful pro-drug political machine, the Center for Public Integrity and the AP found.

THE OPIOID PROBLEM

The rate of opioid prescriptions per adult was higher in the southeast. (2014 data)

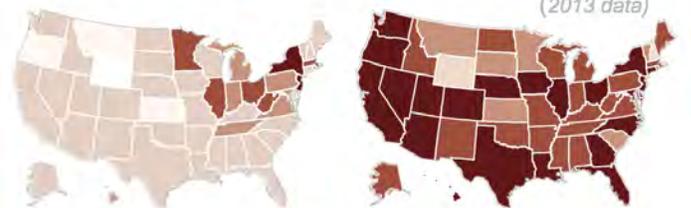
Nonmedical use of pain relievers in 2013 - 2014 among adults. (percentages)



LEGISLATION AND LOBBYING

Number of state bills mentioning opioids. (2013-16)

Number of state legislators for each pro-opioid lobbyist. (2013 data)



POLITICAL SPENDING

Opioid manufacturers and their allies have contributed roughly \$80 million to state and federal candidates and have spent about \$746 million on state and federal lobbying since 2006. How the spending breaks down:

to State	to Federal	for State/Federal candidates	
\$109 mil.	\$716 mil.	45% Dems	54% Reps

SOURCES: Substance Abuse and Mental Health Services Administration; AP IMS Health; National Institute on Money in State Politics; Quorum; Federal Election Commission



Drugmakers fought domino effect of Washington opioid limits

limits

By Geoff Mulvihill and Liz Essley Whyte
September 18, 2016

And in Maine last year, drugmakers persuaded a state representative to successfully push a bill — drafted by the industry — requiring insurers to cover so-called abuse-deterrent painkillers, the new forms of opioids that are harder to abuse.

Legislatures have begun considering limits on the length of first-time opioid prescriptions. But the new laws and proposals in states including Connecticut and Massachusetts carve out a common exception: They do not apply to chronic pain patients. Drugmaker-funded pain groups, which can mobilize patients to appear at legislative hearings, advocate for the exceptions.

Many patients vouch that opioids have given them a better quality of life.

“There’s such a hysteria going on” about those who have died from overdoses, said Barby Ingle, president of the [International Pain Foundation](#), which receives pharmaceutical company funding. “There are millions who are living a better life who are on the medications long term.”

That’s contrary to what researchers are increasingly saying, however. Studies have shown weak or no evidence that opioids are effective ways to treat routine chronic pain. And one 2015 study from a hospital system in Pennsylvania found about 40 percent of chronic non-cancer pain patients receiving opioids had some signs of addiction and 4 percent had serious problems.

“You can create an awful lot of harm with seven days of opioid therapy,” said Dr. [David Juurlink](#), a toxicology expert at the University of Toronto. “You can send people down the pathway to addiction ... when they never would have been sent there otherwise.”

A surprising opponent

Letting advocacy groups do the talking can be an especially effective tactic in state legislatures, where many lawmakers serve only part time and juggle complicated issues.

Lawmakers in Massachusetts, for example, said they didn’t hear directly from pharmaceutical lobbyists when they took up opioid prescribing issues this year. But they did hear from a patient advocate with ongoing back pain who works with and volunteers for groups that receive some of their funding from pharmaceutical companies. She also brought in patients to meet with them.

“A lot of times those legislators, they don’t have the ability to really thoroughly look into who these organizations are and who’s funding them,” said [Edward](#)

Walker of the University of California Los Angeles, who studies grassroots groups.

Nonprofit advocacy groups led the countercharge in Tennessee in 2014 when Republican state Rep. Ryan Williams began work to stanch the flow of prescription painkillers, alarmed by a rapidly rising number of drug-addicted babies, who suffer from withdrawal in their first weeks of life and complications long after they leave the hospital.

More than 900 babies had been born addicted in Tennessee the year before, many of them hooked on the prescription opioids their mothers had taken. That number had climbed steadily since 2001, when there were fewer than 100.

Whitney Moore and her husband adopted two girls born addicted to prescription opioids and other drugs in eastern Tennessee, and she still remembers her older daughter's cries in the hospital, "the most high-pitched scream you've ever heard in your life" — a common symptom in babies in the throes of withdrawal.

Doctors gave Moore's infant daughter morphine to ease her seizures, vomiting and diarrhea, and she stayed in a neonatal intensive care unit more than a month. Now 3 years old, she still suffers from gastrointestinal problems and remains sensitive to loud noises.

When Williams was mulling potential legislation, doctors told him that part of Tennessee's problem was a 2001 law — similar to measures on the books in more than a dozen states — that made it difficult to discipline doctors for dispensing opioids and allowed clinicians to refuse to prescribe powerful narcotics only if they steered patients to an opioid-friendly doctor.

The result, according to the experts Williams worked with, was a rash of prescribing, even for pregnant women. In 2014, Tennessee ranked third in the country for per-capita opioid prescriptions, with roughly 1.3 prescriptions doled out for every person in the state, according to an analysis of prescription data from IMS Health.

Williams' mission to repeal the law failed that year, and he was shocked by the group that came out in opposition — the American Cancer Society Cancer Action Network, the advocacy arm of one of the country's biggest and best-known charities.

Two Cancer Society lobbyists worked against the bill, even though prescribing painkillers for cancer patients is a widely accepted medical practice that would have remained legal.



Republican State Rep. Ryan Williams introduced a bill to put limits on opioid prescriptions in Tennessee, concerned about pregnant mothers getting hooked on opioids and passing the addiction on to their babies. Williams' mission failed that year, but his bill succeeded the next year. AP Photo/Mark Zaleski

“We injected ourselves into the debate because we did not want cancer patients to not be able to have access to their medication,” said Theodore Morrison, a lobbyist working for the network that year.

The society’s annual ranks of about 200 lobbyists around the country have taken similar positions elsewhere, defending rules that some argue encourage extensive prescriptions and opposing opioid measures even if the proposed legislation specifically exempted cancer patients.

The Cancer Action Network listed four major opioid makers that provided funding of at least \$100,000 in 2015, in addition to five that contributed at least \$25,000. Companies that donate such sums get **one-on-one meetings** with the group’s leaders and other chances to discuss policy.

The network said only 6 percent of its funding last year came from drugmakers and that its ties to drug companies do not influence the positions

it takes. “ACS CAN’s only constituents are cancer patients, survivors, and their loved ones nationwide,” spokesman Dave Woodmansee said.

The network said it advocates for certain measures despite exemptions for cancer because some patients continue to experience pain even after their cancer is gone.

ACS CAN teamed up with another group to defend the Tennessee painkiller law — the Academy of Integrative Pain Management, an association of doctors, chiropractors, acupuncturists and others who treat pain, until recently known as the [American Academy of Pain Management](#). The group promotes access to pain drugs as well as non-pharmaceutical treatments such as acupuncture.

Seven of the academy’s nine corporate council members [listed online](#) are opioid makers. The other two are [AstraZeneca](#), which has invested heavily in a drug to treat opioid-induced constipation, and Medtronic, which makes implantable devices that deliver pain medicine.

The academy’s executive director, Bob Twillman, said his organization receives 15 percent of its funding from pharmaceutical companies, not including revenue from advertisements in its publications. Its [state advocacy project](#) is 100 percent funded by drugmakers and their allies, but he said that does not mean it is beholden to pharmaceutical interests.

“We don’t always do the things they want us to do,” he said. “Most of the time we’re saying, ‘Gosh, yes, there should be some limits on opioid prescribing, reasonable limits,’ but I don’t think they would be in favor of that.”

Both the academy and the cancer group have been active across the country, making the case that lawmakers should balance efforts to address the opioid crisis with the needs of chronic pain patients. Between them, they have contacted legislators and other officials about opioid-related measures in at least 18 states.

In Massachusetts this year, they helped persuade lawmakers to soften strict proposals that would have limited first-time opioid prescriptions to three days’ worth. They also have weighed in on how often doctors should be required to check prescription-monitoring databases, which can help crack down on prescription-shopping with multiple doctors.

The academy reported on its website that, since 2013, its state advocacy network had provided “extensive comments” on clinician guidelines in New Mexico, Pennsylvania, Indiana and elsewhere; issued action alerts resulting in

more than 300 emails and phone calls to more than 80 legislators in 2014 alone; and held teleconferences with more than 100 advocates.

Purdue, which gives to both the academy and the cancer network, said it contributes to a range of advocacy groups, including some with differing views on opioid policy. “It is imperative that we have legitimate policy debates without trying to silence those with whom we disagree. That’s the American political system at work,” the company said in a statement.

As for Williams, he tried again last year to repeal Tennessee’s intractable pain law — and won unanimous approval in both houses. The extra year had given Williams and his co-sponsor time to help educate their fellow lawmakers, he said, even though the Cancer Society still opposed the repeal.

Lobbyists ‘were killing it’

The tried-and-true tactics of lobbying and campaign contributions remain a major plank of the pharmaceutical playbook. In 2014 alone, for instance, participants in the Pain Care Forum spent at least \$14 million nationwide on state-level lobbying.

Two years earlier — facing the threat of limits on opioid-prescribing — forum members had upped their number of lobbyists in New Mexico, which is second only to West Virginia in per-capita deaths primarily due to prescription and illegal opioid drugs, according to the most recent federal data available.

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The aim of the bill Jennifer Weiss-Burke backed was to limit initial prescriptions of opioids for acute pain to seven days to make addictions less likely and produce fewer leftover pills that could be peddled illegally.

After her son had left the hospital with his first bottle of Percocet in 2009 at the age of 16, the Albuquerque teen had suffered two more injuries and gotten two more prescriptions. He also took pills he found at his grandparents’ house. Less than a year later, he started smoking heroin, which costs less than black-market prescription drugs.



After Cameron Weiss's death from a heroin overdose in 2011, his mother pushed for a bill in New Mexico limiting initial prescriptions of opioid painkillers for acute pain to seven days. The bill

He repeatedly went into rehab, and just as repeatedly relapsed. In August 2011, his mother found him at home, dead.

Weiss-Burke said she didn't realize how dangerous prescription pills could be until her son already had moved on to heroin, a tortuous progression mirrored by the downward spirals of tens of thousands of other people across the country.

Heeding concerns from the state medical society, the bill's sponsors amended it to allow the boards overseeing doctors and other prescribers to set their own limits. Still, the bill died in the House Judiciary Committee.

"The lobbyists behind the scenes were killing it," said Bernadette Sanchez, the Democratic state senator who sponsored the measure.

Lobbyists for three Pain Care Forum members declined to comment, saying they were not authorized to speak about their clients' work.

Forum participants had 15 lobbyists registered in New Mexico that year, up from nine the previous year. One was reported to be working out of the office of a high-ranking lawmaker; another was a former lawmaker himself.

Pfizer said that its two lobbyists in Santa Fe — up from one — reflected a change in firms, not an addition, and that the company did not lobby on opioid restrictions.

Still, the majority of the judiciary committee received drug industry contributions in 2012. Overall that year, drug companies and their employees contributed nearly \$40,000 to New Mexico campaigns — roughly 70 percent more than in previous years with no governor's race on the ballot.

In New Mexico alone, opioid makers spent \$32,000 lobbying in 2012 — more than double their outlay the year before.

Restrictions like the ones considered in New Mexico did not become law anywhere until this year, after the U.S. Centers for Disease Control and Prevention **called for even tighter restrictions**. In 2016, they have been adopted in Connecticut, Maine, Massachusetts, New York and Rhode Island, all with exceptions for patients with chronic pain.

The next frontier

Now, pharmaceutical companies are directing their lobbying efforts to their new legislative frontier in the states — medicines known as abuse-deterrent

exempted people with chronic pain, but opponents still fought back, with lobbyists for the pharmaceutical industry quietly mobilizing in increased numbers to quash the measure.

Jennifer Weiss-Burke via AP

formulations. These drugs ultimately are more lucrative, since they're protected by patent and do not yet have generic competitors. They cost insurers more than generic opioids without the tamper-resistant technology.

Skeptics warn that they carry the same risks of addiction as other opioid versions, and the U.S. Food and Drug Administration noted that they don't prevent the most common form of abuse — swallowing pills whole.

“This is a way that the pharmaceutical industry can evade responsibility, get new patents and continue to pump pills into the system,” said Dr. [Anna Lembke](#), chief of addiction medicine at the Stanford University School of Medicine and author of a book on the opioid epidemic.

Opioid-makers have especially courted attorneys general, who have helped spread tamper-resistant opioid talking points.

Since 2006, Pain Care Forum participants have given more than \$600,000 in campaign contributions to attorneys general candidates, and another \$1.6 million to the Republican and Democratic attorneys general associations. Purdue, with \$100,000 in 2015 alone, tied with four other entities for top contributor to the [Democratic Attorneys General Association](#); it was among the top 10 donors to the [Republican group](#), giving more than \$200,000.

In 2013, Alabama's Republican attorney general, [Luther Strange](#), helped spearhead a [letter to the FDA](#) recommending the agency not approve new generic versions of opioids without tamper-resistant technology, which effectively would give the market to brand-name drug companies such as Purdue and Pfizer for several years. In all, 48 attorneys general, including Strange, [signed the letter](#).

Strange has received \$50,000 in campaign contributions from Pain Care Forum members, more than any other attorney general from 2006 through 2015, with more than \$20,000 of that coming from Pfizer.

“As Attorney General, I will not apologize for my efforts to protect Alabamians from a drug abuse epidemic that is claiming more lives than automobile accidents in my state,” Strange said.

More than 100 bills related to abuse-deterrent opioids have been introduced in various states thus far, at least 81 of them since January 2015, according to the legislative tracking service [Quorum](#). At least 21 of the recent bills featured nearly identical language, and several of their sponsors said they received the wording from pharmaceutical lobbyists.



Pro-painkiller echo chamber shaped policy amid drug epidemic

By Matthew Perrone and Ben Wieder September 19, 2016



Pharma lobbying held deep influence over opioid policies

In Maine last year, a measure that required insurers to cover abuse-deterrent opioids at more favorable rates was introduced at the request of a lobbyist and sailed through the Legislature, after overdose deaths in the state hit a record peak.

Insurance lobbyists argued in vain against the measure, saying it would allow drug companies to raise prices and push up insurance premiums.

The bill's sponsor, Democratic Rep. [Barry Hobbins](#), has a family member struggling with opioid addiction and said he was asked to introduce the bill by a longtime acquaintance who also lobbies for Pfizer.

"Everyone was trying to figure out a way to do anything they could to address this major health crisis," Hobbins said. "I was asked to sponsor that bill because of my personal family issues."

Pushing for the legislation was a team effort: Pfizer's director of U.S. policy [testified in favor of the bill](#), citing a study that showed it would help curb abuse. But he neglected to say the study was co-authored by employees of Purdue, which also sent a lobbyist to push for the bill.

The drugmakers tried similar tactics in New Mexico earlier this year, with less success.

Randy Marshall, director of the [New Mexico Medical Society](#), which represents doctors, said he turned down a request from a Purdue lobbyist that he introduce a measure calling for tamper-resistant drugs to be covered by insurers. He said he was told that if he testified, the company would lobby behind the scenes.

But the [New Mexico Osteopathic Medical Association](#) did help at the request of a Pfizer lobbyist, said the group's executive director, Ralph McClish.

In response to a question about its role in that legislation, Pfizer issued a statement that it "works with many different stakeholders on areas of mutual interest."

A Purdue statement acknowledged that the abuse-deterrent pills won't stop all misuse, but added, "They are an important part of the comprehensive approach needed to address this public health issue."

The New Mexico measure failed, and McClish said that the perceived self-interest of the drug companies was key to its defeat.

“People were sitting there going, ‘Pharma is going to make a lot of money off of these drugs,’” he said.

Associated Press health reporter Matthew Perrone contributed to this article.

This story was co-published with [The Associated Press](#).

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Bonita Griffin Martin · RN CaseManager at Choctaw Nation of Oklahoma

I would think that the majority of people that are abusing the opioids are not acquiring them legally.

[Like](#) · [Reply](#) · Sep 18, 2016 9:49am



Joffre Essley · University of Virginia

But the start by being prescribed a painkiller legally

[Like](#) · [Reply](#) · [5](#) · Sep 18, 2016 12:53pm



Tom Cuddy · Music Production at Emmerson Biggins Band

Joffre Essley So they should just suffer? I think you have no idea what real pain is like if you think they should just suffer. Look up suicide rates among chronic pain patients.

[Like](#) · [Reply](#) · [3](#) · Sep 18, 2016 3:58pm



Mercedes Nunez · Works at Self-Employed

Tom Cuddy The problem is that dentists and MDs prescribe opioid pain killers even for when they pull a tooth. My goodness! what everybody did when these drugs were not around? We humans can endure pain, we can learn to do it, there are many alternative ways. The problem is that the drug companies make a fortune convincing people that they cannot endure any pain. I had a mastectomy, two hip replacements and Tylenol was just enough. When you accept pain, you can easily endure it.

[Like](#) · [Reply](#) · Sep 20, 2016 12:16pm

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Tom Cuddy · Music Production at Emmerson Biggins Band

Exceptions to these limits are not truly available to true intractable pain patients. The negative atmosphere discourages MD's from even talking to pain patients. My tales of sheer hell and being treated like true scum as the partner of a RSD sufferer should make you sick. An addict can jump thru any hoop. A intractable pain patient usually cannot physically manage the hoops so they just kill themselves. Don't believe me check the stats. I just want someone to tell me why the life of a potential overdose victim is more important than the life of a RSD/CRPS victim.

[Like](#) · [Reply](#) · [4](#) · Sep 18, 2016 3:57pm · Edited



Laura Ferry · Human Resource Manager at Webber Restaurant Group

For the few in this country that suffer from "chronic pain" we should live with an

absolute epidemic of opioid abuse? The thousands, maybe millions of babies being born with drug addiction. The millions of young adults that have died because of drug overdoses. Really now, how about 400 milligrams of ibuprofen or maybe 800 milligrams. I am thinking that too many people don't want to live with any pain at all and that may be the problem. How can you justify the trade off. How do the lobbyists and legislators in Washington get up each morning and look at themselves in the mirror. It's really unfortunate that the people in charge care more about the almighty dollar than the lives of human beings.

Like · Reply ·  2 · Sep 19, 2016 8:35am



Cathy Young · Renton, Washington

How about the seniors that are given this shit when their bodies cannot process it properly. They have my 80 year old mom on 200 opioid pills per month! They turned an elderly woman, who had never used drugs in her life, into a nodding junkie. How did people manage chronic pain before opiates were handed out like candy? Chronic pain is not new, how was it managed prior to this epidemic? All the people she knows take opiates! Are they just trying to kill them off? I remember when kids got hurt in sports and they just gave them tylenol, now they give them prescription heroin. It's sickening. Really, truly sickening to turn so many into junkies, zombies and corpses so they can make money.

Like · Reply ·  4 · Sep 19, 2016 3:40pm



Jeff Laurich · Instructor at FVTC

"Few in this country that suffer from chronic pain"? You might want to look up a few statistics. 1.3 million Americans suffer from Rheumatoid Arthritis alone. Ibuprofen does nothing for that. If you have never experienced arthritis pain yourself, you don't know what you are talking about. It feels like knives stabbing into your joints 24 hours a day. And yes, many people commit suicide rather than deal with that kind of pain.

If your doctor sends your 16 year-old home with percocet for a sports injury, take them away and find a new doctor. But if you have arthritis, sometimes that's the only thing that will help.

Like · Reply ·  2 · Sep 20, 2016 11:46am



Mercedes Nunez · Works at Self-Employed

Jeff Laurich I had osteoarthritis in both my hips and it was bone-to-bone for many months, I know what pain is. I couldn't stand erect. I never took an opioid, just Tylenol. Yoga makes miracles, acupuncture, knowing how to breath and other alternatives. The problem is that these ways require effort and discipline. It is easier to pop a pill.

Like · Reply ·  1 · Sep 20, 2016 12:26pm

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Allison Kaplan · Planner at AECOM

Hi authors, can you please cite a source for this quote: "Studies have shown weak or no evidence that opioids are effective ways to treat routine chronic pain." Thank you!

Like · Reply ·  1 · Sep 20, 2016 9:48am



Tom Cuddy · Music Production at Emmerson Biggins Band

That is a canard that is repeated with minimal evidence. There is a condition specific to morphine in which too much morphine can cause pain but the Mu receptors are different on different medicines (one reason oxycodone is used more than morphine today). People would also say opioids are no good for RSD pain, which in my patients case is not true.

Like · Reply · Sep 20, 2016 10:19pm



The Center for Public Integrity 

Thanks Allison. Here are two studies:

A review study: <http://annals.org/article.aspx?articleid=2089370>

And: http://www.cochrane.org/.../SYMPT_opioids-long-term...

Like · Reply ·  1 · Sep 21, 2016 8:41am



Allison Kaplan · Planner at AECOM

[The Center for Public Integrity](#) Thank you for the response. I think it's important to go back to why people start using opioids in the first place, and how effective opioids are at treating the problem (symptom or underlying issue), and whether there's a more effective solution. Digging into some studies is a first step!

[Like](#) · [Reply](#) · Sep 21, 2016 8:45am



Dan Hartsgrove · Henry Hudson Regional High School

It's very sad what happened to this lady's son. However can anyone be sure that percocet was the reasoning? Who is to say that this young man would not have been doing heroin regardless of a prescription? Legitimate chronic pain suffering patients have no recourse but pain medication. Furthermore any legitimate pain suffering patient that I know has never contributed to this heroin epidemic! They are patients not addicts

[Like](#) · [Reply](#) · 3 · Sep 20, 2016 2:03pm



Tom Cuddy · Music Production at Emmerson Biggins Band

The current definition of addiciton is continued use despite extrmem negative consequences. If taking opioids, even if physically dependant. improve one's qual;ity of life LONG TERM, it is not addiciton even if physical dependance occurs. Look it up, this is the current definitions.

[Like](#) · [Reply](#) · 1 · Sep 20, 2016 10:21pm



Lan Farley · El Dorado At Santa Fe, New Mexico

I've had two total knee replacements and one hip surgery this year. In each case, my orthopods prescribed 80 (that's eighty) oxycodone. That's 240 for non-math majors. I live in New Mexico which has the record for most undesirable statistics (need I list them?) This article describes well the problem we have with lobbyists influencing our legislature to the detriment of our citizens.

When I went in for my 3 month checkup for my knees, I asked my doc why he prescribed so many opioids for me. I told him that I'd taken four and that pretty much did it for me. He (jokingly) said, "Well, you can take them on the street corner and sell them for \$20 a pill."

I can remember 20 years ago when it was extremely difficult to get pain meds, but the pendulum has swung the other way and its time for a correction.

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Naloxone



Revised August 2016

What is naloxone?

Naloxone is a medication designed to rapidly reverse opioid overdose. It is an opioid antagonist—meaning that it binds to opioid receptors and can reverse and block the effects of other opioids. It can very quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of overdosing with heroin or prescription opioid pain medications.

How is naloxone given?

There are three FDA-approved formulations of naloxone:

Injectable (professional training required)

Generic brands of injectable naloxone vials are offered by a variety of companies that are listed in the [FDA Orange Book under "naloxone"](#) (look for "injectable").

Note: There has been widespread use of improvised emergency kits that combine an injectable formulation of naloxone with an atomizer that can deliver naloxone intranasally. Use of this product requires the user to be trained on proper assembly and administration. These improvised intranasal devices may not deliver naloxone levels equivalent to FDA-approved products. An approved, prefilled nasal spray is now available (see below).

Autoinjectable

[EVZIO](#)[®] is a prefilled auto-injection device that makes it easy for families or emergency personnel to inject naloxone quickly into the outer thigh. Once activated, the device provides verbal instruction to the user describing how to deliver the medication, similar to automated defibrillators.

Prepackaged Nasal Spray

[NARCAN](#)[®] Nasal Spray is a prefilled, needle-free device that requires no assembly and is sprayed into one nostril while patients lay on their back.

Note: Both NARCAN[®] Nasal Spray and EVZIO[®] are packaged in a carton containing two doses to allow for repeat dosing if needed. They are relatively easy to use and suitable for home use in emergency situations.

Who can give naloxone to someone who has overdosed?

The liquid for injection is commonly used by paramedics, emergency room doctors, and other specially trained first responders. To facilitate ease of use, NARCAN[®] Nasal Spray is now available, which allows for naloxone to be sprayed into the nose. While improvised atomizers have been used in the past to convert syringes for use as nasal spray, these may not deliver the appropriate dose. Depending on the state you live in, friends, family members, and others in the community may give the auto-injector and nasal spray formulation of naloxone to someone who has overdosed. Some states require a physician to prescribe naloxone; in other states, pharmacies may distribute naloxone in an outpatient setting without bringing in a prescription from a physician. To learn about the laws regarding naloxone in your state, see the [Prescription Drug Abuse Policy System](#) website.

What dose can be provided?

The dose varies depending on the formulation, and sometimes more than one dose is needed to help the person start breathing again. Anyone who may have to use naloxone should carefully read the package insert that comes with the product. You can find copies of the package insert for [EVZIO](#)[®] and [NARCAN](#)[®] Nasal Spray on the FDA website.

What precautions are needed when giving naloxone?

People who are given naloxone should be observed constantly until emergency care arrives and for at least 2 hours by medical personnel after the last dose of naloxone to make sure breathing does not slow or stop.

What are the side effects of naloxone?

Naloxone is an extremely safe medication that only has a noticeable effect in people with opioids in their systems. Naloxone can (but does not always) cause withdrawal symptoms which may be uncomfortable, but are not life-threatening; on the other hand, opioid overdose is extremely life-threatening. Withdrawal symptoms may include headache, changes in blood pressure, rapid heart rate, sweating, nausea, vomiting, and tremors.

How much does naloxone cost?

The cost varies depending on where and how you get it. Patients with insurance should check with their insurance company to see what their co-pay is for EVZIO[®] or NARCAN[®] Nasal Spray. Patients without insurance can check on the retail costs with their local pharmacies. Kaleo, the maker of EVZIO[®], has a [cost assistance program](#) for patients with financial difficulties and no insurance.

Where can I get naloxone?

Naloxone is a prescription drug. You can buy naloxone in many pharmacies, in some cases without bringing in a prescription from a physician. Law enforcement, EMS, and community-based naloxone distribution programs can apply to be a [Qualified Purchaser](#) to order naloxone or work with their [state or local health departments](#). Here are some resources to help you find naloxone in your area:

- [Naloxone finder](#) - This website also offers access to training for first responders and potential bystanders.

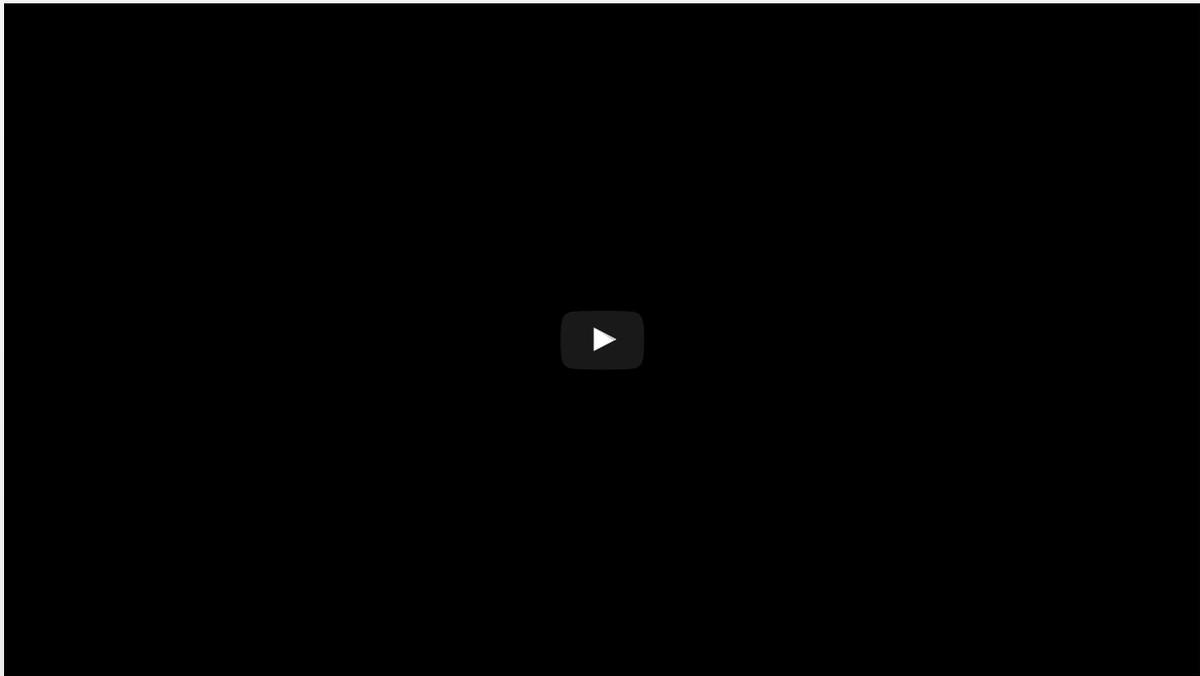
Some states have their own website:

- [Illinois](#)
- [Pennsylvania](#)
- [Washington](#)

Some pharmacies offer naloxone in an outpatient setting (without bringing in a prescription from a physician). Check with your local pharmacy. Here is a sampling:

- [CVS stores](#) - no prescription needed in Ohio, Arkansas, California, Minnesota, Mississippi, Montana, New Jersey, North Dakota, Pennsylvania, South Carolina, Tennessee, Utah, and Wisconsin
- [Walgreens stores](#) - available in many states without a prescription by the end of 2016
- Discount program for EVZIO[®] : [click here](#) for information or email healthmatters@clintonfoundation.org
- NARCAN[®] Nasal Spray: <http://www.narcannasalspray.com/>

Videos



NIDA Related Resources

- [Co-prescribing naloxone in primary care settings may reduce ER visits \(Science Spotlight, 6/28/16\)](#)
- [NIDA creates online resource to raise awareness about naloxone \(Press Announcement, 6/2/16\)](#)
- [Naloxone prescriptions from pharmacies increased ten-fold \(Science Spotlight, 2/18/16\)](#)
- [NARCAN[®] Nasal Spray: Life-Saving Science at NIDA \(Director's Blog, 11/18/15\)](#)

- [FDA approves naloxone nasal spray to reverse opioid overdose \(Press Announcement, 11/18/15\)](#)
- [#CPDD What's Hot: Naloxone Rescue Kits \(Video, 8/11/15\)](#)
- [Naloxone – A Potential Lifesaver \(Director's Blog, 3/4/14\)](#)
- NIDA Naloxone Research in [PubMed](#)
- [Pharmacokinetic Properties and Human Use Characteristics of an FDA Approved Intranasal Naloxone Product for the Treatment of Opioid Overdose \(Journal of Clinical Pharmacology\)](#)

Other Related Resources

- [Harm Reduction Coalition](#)
- Daily Med (U.S. National Library of Medicine); [EVZIO](#)® naloxone hydrochloride injection, solution; [NARCAN](#)® naloxone hydrochloride spray
- Medline Plus (U.S. National Library of Medicine)
 - [Naloxone Nasal Spray](#)
 - [Naloxone Injection](#)
- [Opioid Overdose Prevention Toolkit \(SAMHSA\)](#)
- [The Clinical Use of Naloxone \(FDA\)](#)

This page was last updated August 2016

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Commonly Abused Drugs Charts



Revised August 2016

The previous Commonly Abused Drugs Chart, Prescription Drugs Chart, and Health Effects content have been merged into this section

Most drugs of abuse can alter a person's thinking and judgment, leading to health risks, including addiction, drugged driving and infectious disease. Most drugs could potentially harm an unborn baby; pregnancy-related issues are listed in the chart below for drugs where there is enough scientific evidence to connect the drug use to specific negative effects.

For information about treatment options for drug addiction, see [NIDA's Treatment pages](#). For drug use trends, see our [Trends and Statistics page](#).

Alcohol



Ayahuasca



Cocaine



DMT



GHB



Hallucinogens



Heroin



Inhalants



Ketamine



Khat



Kratom



LSD



Marijuana (Cannabis)



MDMA (Ecstasy/ Molly)



Mescaline (Peyote)



Methamphetamine



Over-the-counter Cough/ Cold Medicines (Dextromethorphan or DXM)



PCP



Prescription Opioids



Prescription Sedatives (Tranquilizers, Depressants)



Prescription Stimulants



Psilocybin



Rohypnol© (Flunitrazepam)



Salvia



Steroids (Anabolic)



Synthetic Cannabinoids



Synthetic Cathinones (Bath Salts)



Tobacco



**The Drug Enforcement Agency (DEA) schedule indicates the drug's acceptable medical use and its potential for abuse or dependence. Information on the most current scheduling decisions can be found on the [DEA website](#).

This page was last updated August 2016



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Treatment



Brief Description

Drug addiction is a chronic disease characterized by compulsive, or uncontrollable, drug seeking and use despite harmful consequences and changes in the brain, which can be long lasting. These changes in the brain can lead to the harmful behaviors seen in people who use drugs. Drug addiction is also a relapsing disease. Relapse is the return to drug use after an attempt to stop. [Learn more](#) ▶

Also more about:

- [Naloxone](#) - a medication designed to rapidly reverse opioid overdose

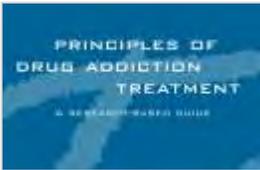
Step-by-Step Guides

- What to do if you have a problem with drugs:
 - [For Teens and Young Adults](#)
 - [For Adults](#)
- What to do if someone you know has a problem with drugs:
 - [Your Teen or Young Adult](#)
 - [Your Adult Friend or Loved One](#)
- What to do if you or a loved one has a problem with drugs: [En español](#)

Related Publications

[Principles of Drug Addiction Treatment: A Research-Based Guide \(Third Edition\)](#)

Published October 1999. Revised December 2012. Presents research-based principles of addiction treatment for a variety of drugs, including nicotine, alcohol, and illicit and prescription drugs, that can inform drug



treatment programs and services. [En Español](#) 



[Therapeutic Communities](#)

Revised July 2015. Describes a type of long-term residential treatment for substance use disorders called therapeutic communities, including how they treat populations with special needs and how they can be incorporated into the criminal justice system.



[Treatment Approaches for Drug Addiction](#)

Revised July 2016. Describes research findings on effective medication and behavioral treatment approaches for drug addiction and discusses special considerations for the criminal justice setting. [En Español](#) 



[Drug-Related Hospital Emergency Room Visits](#)

Revised May 2011. Provides national estimates on drug-related visits to hospital emergency departments and makes comparisons with previous years' data. Discusses illicit drugs, alcohol and other drugs, and prescription drugs. [En Español](#) 



[Treatment Statistics](#)

Revised March 2011. Reports data on the number of people in need of drug abuse treatment and characteristics of admissions to substance abuse treatment facilities. [En Español](#) 

[View all related publications](#) ►

Related NIDA Notes Articles

- [Slow-Release Amphetamine Medication Benefits Patients With Comorbid Cocaine Addiction and ADHD](#) (August 2016)
- [Narrative of Discovery: Can Magnets Treat Cocaine Addiction? Part 2](#) (July 2016)
- [Dual Regimen Aims To Shorten Medication-Assisted Therapy](#) (May 2016)

[View more related NIDA Notes](#) ►

Related News Releases

- [Recruitment begins for landmark study of adolescent brain development](#) (September 2016)
- [Brain region may manage reward expectations and responding](#) (August 2016)

- [Smoking cessation success linked to sex difference](#) (July 2016)

[View more related News Releases](#) ▶

Related Resources

Resources to Help Curb Adolescent Drug Use:

- [If a Teen or Young Adult Has a Drug Abuse Problem](#)
- [Principles of Drug Abuse Treatment for Adolescents: Summary](#)
- [Family Checkup](#)

Therapy Manuals For Cocaine Addiction (Archives):

- [Cognitive-Behavioral Approach: Treating Cocaine Addiction](#) (Manual 1)
- [Community Reinforcement Approach: Treating Cocaine Addiction](#) (Manual 2)
- [Individual Drug Counseling Approach to Treat Cocaine Addiction: The Collaborative Cocaine Treatment Study Model](#) (Manual 3)
- [Drug Counseling for Cocaine Addiction: The Collaborative Cocaine Treatment Study Model](#) (Manual 4)
- [Brief Strategic Family Therapy for Adolescent Drug Abuse](#) (Manual 5)

Other Resources

- [MEDLINEplus Health Information on Drug Abuse](#) - National Library of Medicine, NIH
- www.abovetheinfluence.com - Office of National Drug Control Policy
- healthfinder.gov - U.S. Department of Health and Human Services

Past information on many drugs of abuse is available on our [Archives](#) site.

Clinical Trials

Clinical trials are research studies in human volunteers conducted to answer specific health questions. Learn about the NIH-sponsored clinical trials available to you.

- [NIDA Clinical Trial Locator](#) - answer a few simple questions and get contact information for Clinical Trials near you.

Other Clinical Trials information sources:

- [NIH Clinical Trials and You](#) - NIH site that helps explain about clinical trials and why people participate.
- [NIDA Trials at ClinicalTrials.gov](#) - a resource of federally and privately supported clinical trials.
- [Clinical Research Studies from the National Drug Abuse Treatment Clinical Trials Network \(CTN\)](#) - a NIDA coordinated network of research institutions conducting human trials on drug abuse solutions.
- [Research Studies at NIDA Intramural Research Program](#) - located in Baltimore, Maryland.

This page was last updated June 2014



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*Acid control (pH >4) does not imply symptom relief. The correlation of pH data to clinical outcome has not been directly established.

Pfizer Consumer Healthcare NXM018E02 1/16

American Family Physician

AFP BY TOPIC

Pain: Chronic

 Editors' Choice of Best Available Content

This collection features the best content from AFP, as identified by the AFP editors, on chronic pain and related issues, including end-of-life care, NSAIDs, and opioid therapy. New research may affect the interpretation and application of this material. Clinical judgment is advised. Note that AFP content published within the past 12 months is accessible to AAFP members and paid subscribers only.

Categories

Overview	Improving Practice
Treatment-Specific Therapies	Patient Education, Self-Care
Complications and Special Situations	Other AFP Content
Editorials and Letters	Other Resources from AAFP

Overview

- 03/01/2016 Chronic Pelvic Pain in Women (<http://www.aafp.org/afp/2016/0301/p380.html>) Alg
- 08/15/2010 ICSI Releases Guideline on Chronic Pain Assessment and Management (<http://www.aafp.org/afp/2010/0815/p434.html>) [Practice Guidelines]
- 11/15/2008 Chronic Nonmalignant Pain in Primary Care (<http://www.aafp.org/afp/2008/1115/p1155.html>) Alg PtEd

Treatment-Specific Therapies

- 06/15/2016 CDC Develops Guideline for Opioid Prescribing (<http://www.aafp.org/afp/2016/0615/p1042.html>) [Practice Guidelines]
- 06/15/2016 Weighing the Risks and Benefits of Chronic Opioid Therapy (<http://www.aafp.org/afp/2016/0615/p982.html>)
- 12/01/2015 Gabapentin for Chronic Neuropathic Pain (<http://www.aafp.org/afp/2015/1201/od1.html>) [Medicine by the Numbers]
- 11/15/2015 Effectiveness, Adverse Effects, and Safety of Medical Marijuana (<http://www.aafp.org/afp/2015/1115/p856.html>) [Editorials]
- 07/01/2015 The Role of Levetiracetam in Treating Chronic Neuropathic Pain Symptoms (<http://www.aafp.org/afp/2015/0701/p23.html>) [Cochrane for Clinicians]
- 03/01/2015 Controlled-Release Oxycodone for Neuropathic Pain and Fibromyalgia in Adults (<http://www.aafp.org/afp/2015/0301/p286.html>) [Cochrane for Clinicians]
- 08/15/2014 Cardiovascular Effects of NSAIDs (<http://www.aafp.org/afp/2014/0815/od2.html>) [FPIN's Clinical Inquiries]
- 08/01/2012 Rational Use of Opioids for Management of Chronic Nonterminal Pain (<http://www.aafp.org/afp/2012/0801/p252.html>)

05/01/2012 Tapentadol (Nucynta) for Treatment of Pain (<http://www.aafp.org/afp/2012/0501/p810.html>) [STEPS]

07/01/2010 Opioid

12/01/2009

Guidelines
Guidelines]

actice

Complications and Special Situations

End of Life

07/01/2014 Pharmacologic Management of Pain at the End of Life (<http://www.aafp.org/afp/2014/0701/p26.html>)

Neuropathic Pain

07/15/2010 Treating Diabetic Peripheral Neuropathic Pain (<http://www.aafp.org/afp/2010/0715/p151.html>)

Alg PtEd

04/01/2010 Peripheral Neuropathy: Differential Diagnosis and Management (<http://www.aafp.org/afp/2010/0401/p887.html>)

Alg

Editorials and Letters

06/15/2016 Using the CDC Guideline and Tools for Opioid Prescribing in Patients with Chronic Pain (<http://www.aafp.org/afp/2016/0615/p970.html>) [Editorials]

06/15/2016 The Opioid Epidemic: AMA's response (<http://www.aafp.org/afp/2016/0615/p975.html>) [Editorials]

10/01/2012 Opioid Abuse and Pain Management (<http://www.aafp.org/afp/2012/1001/p600.html>) [Editorials]

12/01/2011 Prolotherapy for Chronic Musculoskeletal Pain (<http://www.aafp.org/afp/2011/1201/p1208.html>) [Editorials]

12/15/2009 NSAIDs and Cardiovascular Risk (<http://www.aafp.org/afp/2009/1215/p1366.html>) [Editorials]

Improving Practice

FROM FAMILY PRACTICE MANAGEMENT AAFP's Journal of Practice Improvement

01/01/2010 A Proactive Approach to Controlled Substance Refills (<http://www.aafp.org/fpm/2010/1100/p22.html>)

11/01/2001 A Tool for Safely Treating Chronic Pain (<http://www.aafp.org/fpm/2001/1100/p47.html>)

11/01/2014 How to Monitor Opioid Use for Your Patients With Chronic Pain (<http://www.aafp.org/fpm/2014/1100/p6.html>)

Patient Education, Self-Care

06/15/2016 Avoiding Problems from Opioid Pain Medicine (<http://www.aafp.org/afp/2016/0615/p982-s1.html>)

PtEd

07/01/2014 Managing Pain at the End of Life (<http://www.aafp.org/afp/2014/0701/p26-s1.html>)

PtEd

11/15/2008 Chronic Pain (<http://www.aafp.org/afp/2008/1115/p1164.html>)

PtEd

FROM FAMILYDOCTOR.ORG AAFP's Patient Education Resource

Chronic Pain (<http://familydoctor.org/familydoctor/en/diseases-conditions/chronic-pain.html>)

Other AFP Content

07/01/2009 When a Patient's Chronic Pain Gets Worse (<http://www.aafp.org/afp/2009/0701/p77.html>) [Curbside Consultation]

05/01/2009 Nonmalignant Chronic Pain: Taking the Time to Treat (<http://www.aafp.org/afp/2009/0501/p743.html>) [Curbside Consultation]

03/01/2004 Cutting Back on High-Dosage Narcotics (<http://www.aafp.org/aafp/2004/0301/p1313.html>) [Curbside Consultation]

Other Resources



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Opioid Prescribing and Pain Management (<http://www.aafp.org/patient-care/nrn/studies/all/opiod.html>)

Pain: Chronic - American Family Physician

<http://www.aafp.org/aafp/topicModules/viewTopicModule.htm?topicModuleId=61>

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Pain Management and Opioid Abuse

Challenges of Pain Management

Chronic pain management is a public health concern with significant increases in the use of opioids for pain relief. There is a corresponding growth in the number of opioids prescribed in the U.S. and the overdose from those drugs.^{1,2,3} Family physicians and other primary care providers play a vital role in balancing patients' pain management needs with the risk of drug misuse and abuse.

The American Academy of Family Physicians (AAFP) is dedicated to finding solutions to the crisis of pain management and opioid abuse. We recognize that long-acting and extended-release opioids are powerful drugs that require oversight, but these drugs can be controlled without unduly limiting their proper use. Creating additional prescribing barriers for primary care physicians would limit patient access when there is a legitimate need for pain relief.

Treating Patients with Chronic Pain

Patients with chronic pain will often initially consult their family physician for treatment. Treatment may include subspecialists, but it is often the family physician's role to coordinate and manage care, including the use of opioid pain relievers. The AAFP views the goal of pain management to be primarily improvement and maintenance of function. We urge family physicians to individualize treatment based on a review of a patient's potential risks, benefits, side effects, and functional assessments, and to monitor ongoing therapy accordingly.

The AAFP will continue to be an active participant in issues concerning pain management and opioid abuse through advocacy, collaboration, and education. Use the resources on this page and on our healthy interventions page to guide your patients through pain management issues.

Healthy Interventions Pain Management & Opioid Abuse Resources

Gain access to valuable information and tools to help your practice and community address pain management and opioid abuse issues.

Access Resources

(<http://www.aafp.org/patient-care/public-health/pain-opioids/toolkit.html>)

Learn More

[AAFP Substance Abuse and Addiction Policy](http://www.aafp.org/about/policies/all/substance-abuse.html)

(<http://www.aafp.org/about/policies/all/substance-abuse.html>)

[Opioid and Pain Management Position Paper](http://www.aafp.org/about/policies/all/pain-management-opioid.html)

(<http://www.aafp.org/about/policies/all/pain-management-opioid.html>)

[AAFP Encourages Widespread Access to Naloxone](http://www.aafp.org/content/dam/AAFP/documents/branding/branding/branding-branded-naloxone.pdf)

(<http://www.aafp.org/content/dam/AAFP/documents/branding/branding/branding-branded-naloxone.pdf>)

[AAFP News](http://www.aafp.org/patient-care/public-health/pain-opioids.htm#AAFP-News) (<http://www.aafp.org/patient-care/public-health/pain-opioids.htm#AAFP-News>)

[Journal Articles](http://www.aafp.org/patient-care/public-health/pain-opioids.htm#Journals)

(<http://www.aafp.org/patient-care/public-health/pain-opioids.htm#Journals>)

[Related Articles](http://www.aafp.org/patient-care/public-health/pain-opioids.htm#Related)

(<http://www.aafp.org/patient-care/public-health/pain-opioids.htm#Related>)

Earn CME

[FP Essentials™ edition on Chronic Pain Management](http://www.aafp.org/content/dam/AAFP/documents/essentials_chronic-pain-management.pdf)

(http://www.aafp.org/content/dam/AAFP/documents/essentials_chronic-pain-management.pdf)

[Take the quiz for CME credit »](https://nf.aafp.org/a/6250)

(<https://nf.aafp.org/a/6250>)

CME Webcasts

■ [Chronic Opioid Therapy](http://www.aafp.org/cme/cme-topic/all/chronic-opioid-therapy.html)

(<http://www.aafp.org/cme/cme-topic/all/chronic-opioid-therapy.html>)

■ [Appropriate and Effective Pain Management - Overcoming the Barriers](http://www.aafp.org/cme/cme-topic/all/pain-management.html)

(<http://www.aafp.org/cme/cme-topic/all/pain-management.html>)

■ [Chronic Pain: Management and Safe Treatment](http://www.aafp.org/cme/cme-topic/all/chronic-pain.html)

(<http://www.aafp.org/cme/cme-topic/all/chronic-pain.html>)

More Pain Management CME >>

(<http://www.aafp.org/cme/browse/topics.tag-pain.html>)

Help Your Patients

[Chronic Pain](http://familydoctor.org/familydoctor/en/diseases-conditions/chronic-pain.html)

(<http://familydoctor.org/familydoctor/en/diseases-conditions/chronic-pain.html>)

[Opioid Addiction](http://familydoctor.org/familydoctor/en/diseases-conditions/opioid-addiction.html)

(<http://familydoctor.org/familydoctor/en/diseases-conditions/opioid-addiction.html>)

[Prescription Drug Abuse in the Elderly](http://familydoctor.org/familydoctor/en/diseases-conditions/opioid-addiction/prescription-drug-abuse-in-the-elderly.html)

(<http://familydoctor.org/familydoctor/en/diseases-conditions/opioid-addiction/prescription-drug-abuse-in-the-elderly.html>)

[Safe Use, Storage, and Disposal of Opioid Drugs](http://familydoctor.org/familydoctor/en/drugs-procedures-devices/prescription-medicines/safeuse.html)

(<http://familydoctor.org/familydoctor/en/drugs-procedures-devices/prescription-medicines/safeuse.html>)

Review Related Articles

- [Stop the Stigma and Expand Access to Comprehensive Treatment](http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/stigma-of-substance-use-disorder.page) (<http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/stigma-of-substance-use-disorder.page>): The AMA Task Force to Reduce Opioid Abuse believes it's up to America's physicians, patients and policymakers to help stop the stigma of substance use disorders.
- [NIH's Draft National Pain Strategy](http://www.aafp.org/news/health-of-the-public/20150522painstrategyltr.html) (<http://www.aafp.org/news/health-of-the-public/20150522painstrategyltr.html>): Academy strongly supports more physician education on pain treatment.

AAFP'S DR. WERGIN ON PAIN MANAGEMENT

Past AAFP president and current board chair, Robert Wergin, MD, FAAFP, was featured in a 2016 New York Times article about the complexities and challenges family physicians face when treating patients with chronic pain.

Read the Article

(http://www.nytimes.com/2016/03/17/pain-pills-opioids-addiction-doctors._r=1)

- **Providers' Clinical Support System for Opioid Therapies (PCSS-O) Modules** (<http://pcss-o.org/modules/>): Free, non-CME opioid training modules, developed in cooperation with the AAFP.
- **National Institute for Drug Abuse (NIDA) Addiction Performance** (<http://www.drugabuse.gov/nidamed-medical-health-professionals/about-addiction-performance-project/addiction-performance-project>): This online tool, developed in cooperation with the AAFP, may help you identify and help drug-abusing patients.
- **Opioid Studies Mark Slowdown in Abuse, but Work Remains** (<http://www.aafp.org/news/health-of-the-public/20150128nihopioidstudy.html>): More research is need to fine-tune prescribing practices to combat abuse.
- **Many Physicians Leery of Using Opioids for Noncancer Pain** (<http://www.aafp.org/news/health-of-the-public/20141222opioidsurvey.html>): Even though opioid abuse rates across the United States are still sky-high, it appears progress is being made on the physician end of the supply chain.

Journal Articles

FROM AMERICAN FAMILY PHYSICIAN (AFP)

(<HTTP://WWW.AAFP.ORG/AFP/2012/0801/P252.HTML?>

AAFPVLOGIN=8125322&AAFPVPW=&URL_SUCCESS=HTTP%3A%2F%2FWWWW.AAFP.ORG%2FAFP%2F2012%2F0801%2FP252.HTML)

- **Weighing the Risks and Benefits of Chronic Opioid Therapy** (<http://www.aafp.org/afp/2016/0615/p982.html>)
- **Avoiding Problems from Opioid Pain Medicine (patient handout)** (<http://www.aafp.org/afp/2016/0615/p982-s1.html>)
- **The Opioid Epidemic: AMA's Response (editorial)** (<http://www.aafp.org/afp/2016/0615/p975.html>)
- **Opioids for Chronic Back Pain: Short-Term Effectiveness, Long-Term Uncertain** (<http://www.aafp.org/afp/2014/0815/od5.html>)
- **Rational Use of Opioids for Management of Chronic Non-terminal Pain** (<http://www.aafp.org/afp/2012/0801/p252.html>)
- **Collection on Chronic Pain** (http://www.aafp.org/afp/topicModules/view_TopicModule.htm?topicModuleId=61)

FROM FAMILY PRACTICE MANAGEMENT (FPM)

- **Chronic Care Management and Other New CPT Codes** (<http://www.aafp.org/fpm/2015/0100/p7.html>)
- **How to Monitor Opioid Use for Your Patients with Chronic Pain** (<http://www.aafp.org/fpm/2014/1100/p6.html>)
- **SPPACES: Medical Apps Review Safe Opioids** (<http://www.aafp.org/fpm/2014/0500/p31.html>)

- [A Proactive Approach to Controlled Substance Refills \(http://www.aafp.org/fpm/2010/1100/p22.html\)](http://www.aafp.org/fpm/2010/1100/p22.html)

FROM ANNALS OF FAMILY MEDICINE

- [Opioids for Chronic Pain: First Do No Harm \(http://www.annfamned.org/content/10/4/300.full\)](http://www.annfamned.org/content/10/4/300.full)
- [Opioids for Chronic Noncancer Pain: As the Pendulum Swings, Who Should Set Prescribing Standards for Primary Care? \(http://www.annfamned.org/content/10/4/302.full\)](http://www.annfamned.org/content/10/4/302.full)
- [Objective Evidence of Severe Disease: Opioid Use in Chronic Pain \(http://www.annfamned.org/content/10/4/366.full\)](http://www.annfamned.org/content/10/4/366.full)

Read the Latest from AAFP News

- [FDA Requires New Warnings on Combined Opioid, Benzodiazepine Use - 9/7/2016 \(http://www.aafp.org/news/health-of-the-public/20160907opioid-benzos.html\)](http://www.aafp.org/news/health-of-the-public/20160907opioid-benzos.html)
- [AAFP Calls for 'All-Hands-on-Deck' Effort to End Opioid Crisis \(http://www.aafp.org/news/health-of-the-public/20160907hhsopioidrfi.html\)](http://www.aafp.org/news/health-of-the-public/20160907hhsopioidrfi.html)
- [Improve Rule to Increase Opioid Abuse Treatment, Academy Urges - 05/27/2016 \(http://www.aafp.org/news/government-medicine/20160527matrule.html\)](http://www.aafp.org/news/government-medicine/20160527matrule.html)
- [AAFP Responds to Senator's Call to Lead on Opioid Issue - 05/25/2016 \(http://www.aafp.org/news/government-medicine/20160525opioidletter.html\)](http://www.aafp.org/news/government-medicine/20160525opioidletter.html)
- [AAFP Advises Lawmakers on Bills Intended to Curb Opioid Abuse - 05/04/2016 \(http://www.aafp.org/news/government-medicine/20160504opioidbills.html\)](http://www.aafp.org/news/government-medicine/20160504opioidbills.html)
- [AAFP Gives CDC's Opioid Guideline 'Affirmation of Value' - 04/27/2016 \(http://www.aafp.org/news/health-of-the-public/20160427opioidguideline.html\)](http://www.aafp.org/news/health-of-the-public/20160427opioidguideline.html)
- [White House, HHS Expand Fight Against Opioid, Heroin Abuse - 04/06/2016 \(http://www.aafp.org/news/health-of-the-public/20160406hhsopioids.html\)](http://www.aafp.org/news/health-of-the-public/20160406hhsopioids.html)
- [HHS Releases Final Version of National Pain Strategy - 03/30/2016 \(http://www.aafp.org/news/government-medicine/20160330painstrategy.html\)](http://www.aafp.org/news/government-medicine/20160330painstrategy.html)
- [CDC Releases Final Guideline for Prescribing Opioids for Chronic Pain - 03/16/2016 \(http://www.aafp.org/news/health-of-the-public/20160316opioidguideline.html\)](http://www.aafp.org/news/health-of-the-public/20160316opioidguideline.html)
- [Senate Bill to Reduce Opioid Abuse Draws Bipartisan Support - 03/09/2016 \(http://www.aafp.org/news/government-medicine/20160309opioidbill.html\)](http://www.aafp.org/news/government-medicine/20160309opioidbill.html)
- [FDA Devises Action Plan to Fight Opioid Abuse - 02/09/2016 \(http://www.aafp.org/news/health-of-the-public/20160209fda-opioids.html\)](http://www.aafp.org/news/health-of-the-public/20160209fda-opioids.html)

- [AAFP Joins White House Conversation on Opioid Abuse - 01/27/2016](http://www.aafp.org/news/health-of-the-public/20160127whitehouseopioids.html) (<http://www.aafp.org/news/health-of-the-public/20160127whitehouseopioids.html>)
- [Family Physicians Can Lead Fight Against Opioid Abuse, Say Speakers - 11/16/2015](http://www.aafp.org/news/practice-professional-issues/20151116stateopioidabuse.html) (<http://www.aafp.org/news/practice-professional-issues/20151116stateopioidabuse.html>)
- [Opioid Abuse Task Force: Increasing Access to Naloxone Saves Lives - 10/21/2015](http://www.aafp.org/news/health-of-the-public/20151021amanaloxone.html) (<http://www.aafp.org/news/health-of-the-public/20151021amanaloxone.html>)
- [HHS Lays Out Multifaceted Plan to Combat Opioid Abuse - 04/08/2015](http://www.aafp.org/news/health-of-the-public/20150408hhsopioids.html) (<http://www.aafp.org/news/health-of-the-public/20150408hhsopioids.html>)

Pain Management and Opioid Abuse

<http://www.aafp.org/patient-care/public-health/pain-opioids.html>

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Healthy Interventions

Pain Management and Opioid Abuse Resources

Chronic pain represents a substantial public health issue with tremendous economic, social, and medical costs. As the percentage of the U.S. population utilizing opioid analgesics for pain control grows, so do the rates of abuse, misuse, and overdose of these drugs. The American Academy of Family Physicians (AAFP) recognizes the seriousness of the prescription drug abuse problem in the United States. As a medical organization, we must address the ongoing public health responsibility to provide adequate pain management.

The AAFP is actively working toward addressing pain management and opioid abuse problems in the U.S. through advocacy, collaboration, and education.



Office-Based Tools

<http://www.aafp.org/patient-care/public-health/pain-opioids/resources.html#office>

Practical tools to support patient care strategies



Community Engagement

<http://www.aafp.org/patient-care/public-health/pain-opioids/resources.html#community>

Data and resources to collaborate with community-based organizations



Advocacy Action

<http://www.aafp.org/patient-care/public-health/pain-opioids/resources.html#advocacy>

[link](#)
Information on local, state, and national advocacy efforts



Science and Education

<http://www.aafp.org/patient-care/public-health/pain-opioids/resources.html#science>

Evidence-based knowledge and education

OFFICE-BASED TOOLS Opioid Abuse Support



- **National Institute for Drug Abuse (NIDA) Addiction Performance**
(<http://www.drugabuse.gov/nidamed-medical-health-professionals/about-addiction-performance-project/addiction-performance-project>) -- This online tool, developed in cooperation with the AAFP, may help you identify and help drug-abusing patients.
- **Providers' Clinical Support System for Opioid Therapies (PCSS-O) Modules**
(<http://pcss-o.org/modules/>)
- **Stop the Stigma of Substance Abuse** (<http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/stigma-of-substance-use-disorder.page>) - Read the AMA's Task Force to Reduce Opioid Abuse education piece about reducing the stigma of opioid abuse.
- **Stakeholders Consensus Document on Prescribing and Dispensing Controlled Substances** (https://www.nabp.net/system/rich/rich_files/rich_files/000/000/209/original/consensus-document.pdf)

American Medical Association's Task Force to Reduce Opioid Abuse

(http://www.aafp.org/dam/AAFP/documents/patient_care/pain_management/co-branded-naloxone.pdf)

Take advantage of this important education piece developed by the task force on prescribing naloxone.

Practice Improvement

- **Basics of Quality Improvement** (<http://www.aafp.org/practice-management/improvement/basics.html>) - Learn more about and implement quality improvement.

Coding & Payment

- **Article: CCM Billing Code** (http://www.aafp.org/news/inside-aafp/20141212fpm-ccmcode.html?utm_content=buffer398c8&utm_medium=social&utm_source=facebook.com&utm_campaign=buffer) - Medicare now offers payment for chronic care management (CCM). Family Practice Management details the information and tools your practice needs to bill for these services.

COMMUNITY ENGAGEMENT

- **AAFP position paper: Opioid and Pain Management**
(<http://www.aafp.org/about/policies/all/pain-management-opioid.html>)
- **National Take-back Initiative** (http://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html)



- **The North American Syringe Exchange Network** (<https://nasen.org/directory/>) - The North American Syringe Exchange Network is provided as a public health information resource. Please inform yourself about local laws and regulations before participating in syringe exchange services.
- **Up and Away Campaign** (<http://upandaway.org/>) - The AAFP is a partner of this CDC campaign aimed at keeping drugs out of the reach of children.

ADVOCACY ACTION



- **AAFP position paper: Opioid and Pain Management** (<http://www.aafp.org/about/policies/all/pain-management-opioid.html>)
(<http://www.aafp.org/about/policies/all/pain-management-opioid.html>)
- **Good Samaritan and Naloxone Access Laws** (<http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/increase-naloxone-access.page>) - Find out the laws in your state.
- **NIH's National Pain Strategy** (https://iprcc.nih.gov/docs/HHSNational_Pain_Strategy.pdf) - Physician education on pain treatment.
- **Risk Evaluation and Mitigation Strategies/Prescription Drug Abuse** (<http://www.aafp.org/advocacy/informed/pubhealth/rxabuse.html>) - The AAFP works with a number of federal agencies to develop policies that reduce the risk of prescription drug misuse, while allowing for the appropriate, medically supervised treatment of debilitating, chronic pain. See recent letters of recommendations to lawmakers.

SCIENCE & EDUCATION



- **Guideline on Prescribing Opioids for Chronic Pain** (<http://www.aafp.org/patient-care/clinical-recommendations/all/opioid-prescribing.html>)
- **Choosing Wisely™ Recommendation for Low Back Pain** (<http://www.aafp.org/patient-care/clinical-recommendations/all/cw-back-pain.html>)
- **Read a recent FP Essentials™ edition on Chronic Pain Management, free for AAFP members (log-in required)** (http://www.aafp.org/content/dam/AAFP/documents/patient_care/restricted/432_fp-essentials_chronic-pain-management.pdf)

[Take the quiz to receive CME credit » \(https://nf.aafp.org/a/6250\)](https://nf.aafp.org/a/6250)

- Watch the following CME webcasts and earn up to 1 Prescribed credit for each webcast. Free for AAFP members (log-in required)

[Chronic Opioid Therapy](http://www.aafp.org/cme/cme-topic/all/chronic-opioid-therapy.html) (<http://www.aafp.org/cme/cme-topic/all/chronic-opioid-therapy.html>)

[Appropriate and Effective Pain Management - Overcoming the Barriers](http://www.aafp.org/cme/cme-topic/all/pain-management.html)

(<http://www.aafp.org/cme/cme-topic/all/pain-management.html>)

[Chronic Pain: Management and Safe Treatment](http://www.aafp.org/cme/cme-topic/all/chronic-pain.html) ([http://www.aafp.org/cme/cme-](http://www.aafp.org/cme/cme-topic/all/chronic-pain.html)

[topic/all/chronic-pain.html](http://www.aafp.org/cme/cme-topic/all/chronic-pain.html))

- [More CME on Pain Management](http://www.aafp.org/cme/browse/topics.tag-pain.html) (<http://www.aafp.org/cme/browse/topics.tag-pain.html>) - Earn CME credit and get the knowledge you need to treat your patients living with chronic pain.

For Your Patients

Educational information to provide to patients and/or their caregivers

FamilyDoctor.org is the AAFP patient education website featuring trusted, reliable health information. Read more about pain management and opioid abuse at familydoctor.org

(<http://www.aafp.org/familydoctor/en.html>)

- **Chronic Pain** (<http://familydoctor.org/familydoctor/en/diseases-conditions/chronic-pain.html>)
- **Opioid Addiction** (<http://familydoctor.org/familydoctor/en/diseases-conditions/opioid-addiction.html>)
- **Prescription Drug Abuse in the Elderly** (<http://familydoctor.org/familydoctor/en/diseases-conditions/opioid-addiction/prescription-drug-abuse-in-the-elderly.html>)
- **Safe Use, Storage, and Disposal of Opioid Drugs**
(<http://familydoctor.org/familydoctor/en/drugs-procedures-devices/prescription-medicines/safeuse.html>)

Pain Management and Opioid Abuse Resources

<http://www.aafp.org/patient-care/public-health/pain-opioids/resources.html>

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Pain Policies & Online Education

Pain Policies & Online Education

Pain Policies and Online Educational Activities

In 2012, the FSMB in collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA) met to begin the process of revising FSMB's responsible opioid prescribing and office-based opioid treatment policies. FSMB's Workgroup on Pain Policy and the Workgroup on Office-Based Opioid Treatment met periodically and after receiving comments from FSMB's member boards and other key stakeholder organizations, the final policy documents of Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain and Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office were adopted in 2013.

In accordance with a contract awarded by SAMHSA, FSMB created learning activities to educate the state medical boards and the physicians and other health care providers they license on the recently revised pain policies. These learning activities serve as a valuable resource to physicians seeking education related to opioid addiction as well as the appropriate use of opioid analgesics in the treatment of pain. These courses are available free of charge to the learner and may be taken for continuing medical education credit.

Continuing Medical Education (CME) Activities

Course	Maximum CME Credit	Expiration Date	Information/Link to Activity
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Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain (/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf)	1.00	February 28, 2016	information (http://www.cecocity.com/cebin/owa/bel?cc=MCK&aid=15904)
Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office (/Media/Default/PDF/FSMB/Advocacy/2013_model_policy_treatment_opioid_addiction.pdf)	1.00	February 28, 2016	information (http://www.cecocity.com/cebin/owa/bel?cc=MCK&aid=15903)

Additional Resources for Pharmacovigilance and Pain Management

In addition to staying current with state and federal regulations governing controlled substance prescribing, it's also important to stay abreast of safe and effective pain management. As with any job, effectively treating patients in chronic pain is easier when you use the right tools. These include assessment instruments, scales for quantifying pain, intake questionnaires, patient education handouts and well-crafted doctor-patient agreements. Many versions of these kinds of tools are available for downloading from the Internet and can be accessed from the following websites:

Federal Government Resources:

- 1) Substance Abuse and Mental Health Services Administration (SAMHSA): www.samhsa.gov (<http://www.samhsa.gov/>)
 - Population Data/National Survey on Drug Use and Health (NSDUH): <http://www.samhsa.gov/data/population-data-nsduh> (<http://www.samhsa.gov/data/population-data-nsduh>)
 - Directory of Drug and Alcohol Abuse Treatment Programs: <http://findtreatment.samhsa.gov> (<http://findtreatment.samhsa.gov/>)
- 2) Drug Enforcement Administration (DEA): www.usdoj.gov/dea/index.htm (<http://www.usdoj.gov/dea/index.htm>)
 - Drug Scheduling: www.usdoj.gov/dea/pubs/scheduling.html (<http://www.usdoj.gov/dea/pubs/scheduling.html>)
 - Drug Information: www.usdoj.gov/dea/concern/concern.htm (<http://www.usdoj.gov/dea/concern/concern.htm>)
 - Diversion Control: www.deadiversion.usdoj.gov/ (<http://www.deadiversion.usdoj.gov/>)
 - DEA Practitioners Manual: www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html (<http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html>)
- 3) U.S. Food and Drug Administration (FDA): www.fda.gov (<http://www.fda.gov/>)
 - The National Institute on Drug Abuse (NIDA): www.drugabuse.gov (<http://www.drugabuse.gov/>)
 - Prescription Drug Abuse Chart: www.drugabuse.gov/DrugPages/PrescripDrugsChart.html (<http://www.drugabuse.gov/DrugPages/PrescripDrugsChart.html>)
- 4) The Office of National Drug Control Policy: www.whitehousedrugpolicy.gov (<http://www.whitehousedrugpolicy.gov/>)
 - The President's National Drug Control Strategy: www.whitehousedrugpolicy.gov (<http://www.whitehousedrugpolicy.gov/>)

State Laws, Regulations and Policies

- University of Wisconsin Pain & Policy Studies Group Database of Laws, Regulations and Other Official Governmental Policies: www.painpolicy.wisc.edu/ (<http://www.painpolicy.wisc.edu/>)
- Federation of State Medical Boards Pain Management Overview by State: <https://www.fsmb.org/policy/advocacy-policy/key-issues#pm> (<https://www.fsmb.org/policy/advocacy-policy/key-issues#pm>)

Medical Specialty Society Sites

- American Academy of Orofacial Pain: www.aaop.org (<http://www.aaop.org/>)
- The American Academy of Pain Medicine: www.painmed.org (<http://www.painmed.org/>)
- American Medical Association: www.ama-assn.org (<http://www.ama-assn.org/>)
- American Pain Society: www.ampainsoc.org (<http://www.ampainsoc.org/>)
- American Psychological Association: www.apa.org (<http://www.apa.org/>)
- American Society of Addiction Medicine: www.asam.org (<http://www.asam.org/>)
- American Society for Pain Management Nursing: www.aspmn.org (<http://www.aspmn.org/>)

Non-profit Pain Organizations and Other Sites of Interest

- American Council for Headache Education: www.achenet.org (<http://www.achenet.org/>)
- Arthritis Foundation: www.arthritis.org (<http://www.arthritis.org/>)
- City of Hope Pain/Palliative Care Resource Center: <http://prc.coh.org/> (<http://prc.coh.org/>)
- The Cochrane Collaboration: www.cochrane.org (<http://www.cochrane.org/>)
- International Association for the Study of Pain: www.iasp-pain.org (<http://www.iasp-pain.org/>)

- National Consensus Project for Quality Palliative Care: www.nationalconsensusproject.org (<http://www.nationalconsensusproject.org/>)
- National Institute of Dental and Craniofacial Research: www.nidcr.nih.gov (<http://www.nidcr.nih.gov/>)
- National Headache Foundation: www.headaches.org (<http://www.headaches.org/>)
- UCLA History of Pain Project: The John C. Liebskind History of Pain Collection: www.library.ucla.edu/libraries/biomed/ (<http://www.library.ucla.edu/libraries/biomed/>)

Treatment Consensus Statements, Guides and Guidelines

- Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain ([/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf](#))
- Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office ([/Media/Default/PDF/FSMB/Advocacy/2013_model_policy_treatment_opioid_addiction.pdf](#))
- The Use of Opioids for the Treatment of Chronic Pain: www.asam.org (<http://www.asam.org/>); www.painmed.org (<http://www.painmed.org/>) (American Pain Society, American Academy of Pain Medicine, American Society of Addiction Medicine)
- JCAHO Pain Management Standards: www.jcrinc.com (<http://www.jcrinc.com/>)
- Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf (http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf) (Substance Abuse and Mental Health Services Administration)
- World Health Organization Cancer Pain Relief: Guide to Opioid Availability: www.who.int/cancer/publications/en/ (<http://www.who.int/cancer/publications/en/>)
- Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain: www.ampainsoc.org (<http://www.ampainsoc.org/>) (American Pain Society)

Pain and Function Assessment Tools

- Initial Pain Assessment Tool: <http://www3.mdanderson.org/depts/prg/bpi.htm> (<http://www3.mdanderson.org/depts/prg/bpi.htm>)
- Brief Pain Inventory: http://prc.coh.org/res_inst.asp (http://prc.coh.org/res_inst.asp)
- McGill Pain Questionnaire: <http://prc.coh.org/pdf/McGill%20Pain%20Questionnaire.pdf> (<http://prc.coh.org/pdf/McGill%20Pain%20Questionnaire.pdf>)
- Emerging Solutions in Pain Management: www.emergingsolutionsinpain.com (<http://www.emergingsolutionsinpain.com/>)
- Pain.com: www.pain.com (<http://www.pain.com/>)
- PainEDU.org: www.painedu.org (<http://www.painedu.org/>)
- Partners Against Pain: www.partnersagainstpain.com (<http://www.partnersagainstpain.com/>)
- Legal Side of Pain: www.legalsideofpain.com (<http://www.legalsideofpain.com/>)

Medical Journals Focusing on Pain

- Headache: The Journal of Head and Face Pain: [http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1526-4610](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1526-4610) ([http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1526-4610](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1526-4610))
- Journal of Pain (American Pain Society): <http://journals.elsevierhealth.com/periodicals/yjpai> (<http://journals.elsevierhealth.com/periodicals/yjpai>)
- Pain (International Association for the Study of Pain): www.sciencedirect.com/pain (<http://www.sciencedirect.com/pain>)
- Pain Medicine (American Academy of Pain Medicine): <http://painmedicine.oxfordjournals.org/content/17/4> (<http://painmedicine.oxfordjournals.org/content/17/4>)

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Opioids

Get the facts on the misuse and abuse of prescription opioids such as hydrocodone, oxycodone, morphine, and codeine, and the illegal opioid, heroin.

Opioids are a class of drugs chemically similar to alkaloids found in opium poppies. Historically they have been used as painkillers, but they also have great potential for misuse. Repeated use of opioids greatly increases the risk of developing an opioid use disorder. The use of illegal opiate drugs such as heroin and the misuse of legally available pain relievers such as oxycodone and hydrocodone can have serious negative health effects. [According to the CDC, 44 people die every day in the United States from overdose of prescription painkillers.](#)

Prescription Opioids

A number of opioids are prescribed by doctors to relieve pain. These include hydrocodone, oxycodone, morphine, and codeine. While many people benefit from using these medications to manage pain, prescription drugs are frequently diverted for improper use. In the 2013 and 2014 National Survey on Drug Use and Health (NSDUH), 50.5% of people who misused prescription painkillers got them from a friend or relative for free, and 22.1% got them from a doctor. As people use opioids repeatedly, their tolerance increases and they may not be able to maintain the source for the drugs. This can cause them to turn to the black market for these drugs and even switch from prescription drugs to cheaper and more risky substitutes like heroin.

According to the [National Survey on Drug Use and Health \(NSDUH\) – 2014 \(PDF | 3.4 MB\)](#):

- 4.3 million Americans engaged in non-medical use of prescription painkillers in the last month.
- Approximately 1.9 million Americans met criteria for prescription painkillers use disorder based on their use of prescription painkillers in the past year.
- 1.4 million people used prescription painkillers non-medically for the first time in the past year.
- The average age for prescription painkiller first-time use was 21.2 in the past year.

Heroin

Heroin is a powerful opiate drug. Heroin looks like a white or brownish powder, or as the black sticky substance known on the streets as “black tar heroin.” It is diluted with other drugs or with sugar, starch, powdered milk, or quinine before injecting, smoking, or snorting. Some of the physical symptoms of heroin are euphoria, drowsiness, respiratory depression, constricted pupils, nausea, and dry mouth.

A heroin overdose causes slow and shallow breathing, blue lips and fingernails, clammy skin, convulsions, coma, and can be fatal.

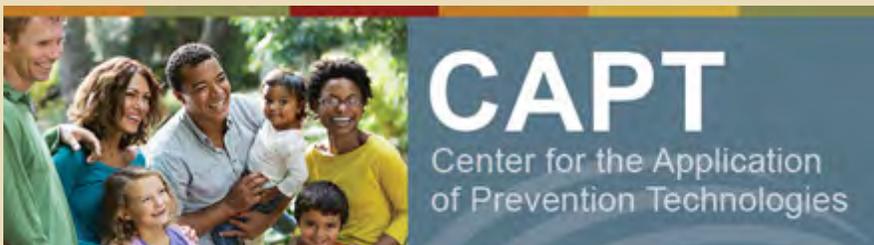
Many young people who inject heroin report misuse of prescription opioids before starting to use heroin. In addition to increasing the risk of overdose, the intravenous use of heroin places individuals at higher risk of diseases like [HIV and hepatitis C](#).

According to SAMHSA’s [2014 NSDUH \(PDF | 3.4 MB\)](#):

- 4.8 million people have used heroin at some point in their lives.
- Among people between the ages of 12 and 49, the average age of first use was 28.
- 212,000 people aged 12 or older used heroin for the first time within the past 12 months.
- Approximately 435,000 people were regular (past-month) users of heroin.

For more information about the treatment of opioid use disorders, visit the topics [Behavioral Health Treatments and Services](#), [Mental and Substance Use Disorders](#), and [Prescription Drug Misuse and Abuse](#).

Last Updated: 02/23/2016



Data and Statistics

- » [Behavioral Health Barometer – 2014 \(PDF | 3.4 MB\)](#)
- » [Drug Abuse Warning Network \(DAWN\)](#)
- » [National Survey on Drug Use and Health \(NSDUH\)](#)
- » [Substance Abuse and Mental Health Data Archive \(SAMHDA\)](#)
- » [Treatment Episode Data Set \(TEDS\)](#)

SAMHSA Quick Links



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Prescription Opioid Overdose Data

Overdose deaths involving prescription opioids have quadrupled since 1999,¹ and so have sales of these prescription drugs.² From 1999 to 2014, more than 165,000 people have died in the U.S. from overdoses related to prescription opioids.¹

Opioid prescribing continues to fuel the epidemic. Today, at least half of all U.S. opioid overdose deaths involve a prescription opioid.¹ In 2014, more than 14,000 people died from overdoses involving prescription opioids.

Most Commonly Overdosed Opioids

The most common drugs involved in prescription opioid overdose deaths include:

- Methadone
- Oxycodone (such as OxyContin®)
- Hydrocodone (such as Vicodin®)³

Overdose Deaths

Among those who died from prescription opioid overdose between 1999 and 2014:

- Overdose rates were highest among people aged 25 to 54 years.
- Overdose rates were higher among non-Hispanic whites and American Indian or Alaskan Natives, compared to non-Hispanic blacks and Hispanics.
- Men were more likely to die from overdose, but the mortality gap between men and women is closing.⁴

Additional Risks

Overdose is not the only risk related to prescription opioids. Misuse, abuse, and opioid use disorder (addiction) are also potential dangers.

- In 2014, almost 2 million Americans abused or were dependent on prescription opioids.⁵
- As many as 1 in 4 people who receive prescription opioids long term for noncancer pain in primary care settings struggles with addiction.⁶
- Every day, over 1,000 people are treated in emergency departments for misusing prescription opioids.⁷

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GUIDELINE FOR PRESCRIBING
OPIOIDS FOR CHRONIC PAIN

Page last reviewed: June 21, 2016

Page last updated: June 21, 2016

Content source: Centers for Disease Control and Prevention (<http://www.cdc.gov/>), National Center for Injury Prevention and Control (<http://www.cdc.gov/injury>), Division of Unintentional Injury Prevention



Addicts For Sale

In the rehab capital of America, addicts are bought, sold, and stolen for their insurance policies, and many women are coerced into sex.



Cat Ferguson
BuzzFeed News Reporter

posted on Mar. 19, 2016, at 8:14 a.m.

DELRAY BEACH, Florida — One early evening last October, a group of young men and women were hanging out at the Starbucks on the main drag here, Atlantic Avenue, smoking cigarettes and bullshitting. They were sitting next to a pile of suitcases, the telltale sign of an addict looking for a place to stay. Some get kicked out of their old

halfway house because they relapse; others because their insurance coverage has been used up.

These kids, like hundreds or even thousands of others like them in Delray, are easy targets: They're often broke and far from home, with limited support from family and friends; they can be mentally and physically unstable; and they're frequently running from parole or pending court cases.

The people targeting them are variously called "marketers," "body brokers," and even "junkie hunters." They know addicts better than anyone (and many used to be addicts themselves). They spot kids dragging suitcases along the road and ask them if they need a place to go. Their phone numbers circulate in South Florida among the untold addicts looking for "clean time" — or those looking for a flop house that will let them get away with using drugs.

In the midst of a national opiate epidemic, politicians are talking a lot about addiction treatment. In February, Obama asked Congress for \$1.1 billion in additional funding to combat opioid and heroin addiction. Hillary Clinton wants to [increase addicts' access](#) to treatment programs. Ted Cruz, whose sister died of an overdose, has [mentioned](#) counseling, Alcoholics Anonymous, and "securing the borders" as solutions to the epidemic. But few if any of these public discussions address what "getting help" actually looks like.

In South Florida's Delray Beach, home to hundreds of rehab facilities and halfway houses, scams abound to profit off of addicts and their insurance policies. The recent uptick in addicts adds energy to the hurricane, but the biggest driving force for the fraud is Obamacare and the [2008 Parity Act](#), which together give everyone access to private insurance that's legally bound to pay for rehab. "Marketers" act like headhunters, picking up addicts when they're down, then bringing them to rehab centers and halfway houses for a fee — usually about \$500 per head.

"There's a lot of cynicism around because there's these headhunters that hang out at Starbucks and coffeehouses," said Harold Jonas, an addiction counselor who has run recovery-oriented businesses in South Florida for 25 years and was one of the first sober-home owners in Delray Beach. "They'll pay people to use because they get a \$500-per-head fee to get them into detox."

Because the best way to milk insurance is to cycle addicts through detox, rehab, and outpatient programs, there's plenty of incentive to keep them relapsing. Five recovering addicts told BuzzFeed News that some marketers give their recruits money for drugs so they test positive on urine tests when checking into treatment.

"He told me, 'You gotta be dirty to go to detox,'" one addict told BuzzFeed News, describing a marketer who gave him cash for drugs.

The FBI partnered with the state in 2014 on a task force investigating fraud in the \$1 billion Florida recovery industry, resulting in at least two closures of addiction treatment businesses, as reported by the [Palm Beach Post](#). But local law enforcement in South Florida isn't eager to take up the cause.

“The patient brokering stuff, most of that is being handled by the federal government,” Jeffrey Goldman, the chief of police of Delray Beach, told BuzzFeed News by phone. When the police do get a call, they hand it off to the feds.



Outside of Starbucks Coffee on the busy street of Atlantic Avenue in Delray Beach, Florida. This coffee shop is a popular hangout spot for the rehab community. Alicia Vera for BuzzFeed News

Byron Ira, a 45-year-old from Indiana who's recovering from drug addiction, shows how easily a brokered patient can become the broker.

After going through rehab in his home state and relapsing, in November 2015 he contacted the [HART Foundation](#), a nonprofit group that connects addicts with rehab centers. He then got a text, he says, from someone in the sales office of a rehab center in South Florida

called C.A.R.E. Addiction Recovery, asking for his insurance information and some questions about his drug use.

“The next call I got was flight information,” he told BuzzFeed News. “The day after Thanksgiving, I got picked up at the Fort Lauderdale airport.”

(Mitchell Wallick, the executive director at C.A.R.E., said the facility only pays for patients’ travel if they sign a promissory note promising to pay it back; Ira denies signing anything before his flight, though he notes it’s possible he signed something during his intake once he was in Florida. He says he has never received a bill of any kind from C.A.R.E.)

Ira had googled the place ahead of his flight and was expecting a 12-step-based holistic center far from home where he could change his life. Instead, he spent most days at “the Center,” an office building where addicts did group and individual therapy, but not based on the 12-step program. Nights were spent mostly back at the residence, a two-bedroom apartment housing four men.

The residence and the Center were understaffed and crowded. During his 23-day stay, Ira estimates he made it to only about five 12-step meetings outside the rehab center, because the staff didn’t have access to enough vans to take the residents anywhere. (Wallick denied these allegations, saying that patients are taken to 12-step meetings every night.)

Shortly before Christmas, Ira’s counselor at C.A.R.E. told him he was ready to rejoin life on the outside. But the doctor in charge of the counselors didn’t want to hear it. Ira was told that if he chose to leave, despite his counselor’s recommendation, it would be against medical advice.

Out of the almost \$22,000 the program charged Ira’s insurance, they were only reimbursed \$1,638.50. So Ira believes that they were trying to keep him another week in order to cover the cost of his flight. Wallick declined to confirm or deny that Ira was a patient, citing privacy laws.

Ira left the facility. A few weeks later, a man who Ira says was a patient at C.A.R.E. during his stay texted Ira with an offer. The former patient said he was making \$1,500 for every insured addict he recruited to C.A.R.E. He invited Ira to join in recruiting patients, but Ira says he declined to participate.

“If this is going on, there will be hell to pay,” Wallick said about the brokering accusations. “I would close that damn program down — pardon my French — before I would allow anything illegal or unethical to go down under my license or my name.”

In Florida, the line between illegal patient brokering and legal marketing is simple, according to Jeffrey Lynne, a Delray Beach–based lawyer who routinely represents businesses in the recovery industry. It’s legal to pay someone a flat rate to market your treatment center by setting up an advertorial website, for example, or by recommending your center after doing an intervention.

But under the [Florida Patient Brokering Act](#), paying a marketer a per-head fee for addicted patients, or offering any kind of financial incentive directly to an addict to entice them to pick your service, is a third-degree felony.

Not that the law means much, given the way it's currently enforced. Law enforcement doesn't have the resources to track down these marketers, and prosecutors don't have the motivation to work hard for little payoff. "If you have a victim who's a co-conspirator with the marketer, how are you going to prove it?" Lynne told BuzzFeed News. "It takes a lot of manpower to prosecute, and for what?"

The victims — the addicts — become implicated in several ways, usually by getting free stuff in exchange for their insurance information.

Halfway houses often set up addicts with in-kind kickbacks — like cell phones, grocery store gift cards, and free rent — if they agree to attend an affiliated outpatient program, a violation of the anti-brokering law. Halfway houses can't charge insurance companies for anything beyond a simple urine test, so they often partner with outpatient rehab centers that can charge hundreds of dollars a day for treatment services. The halfway house operators take an (illegal) cut of the profit in exchange for feeding patients to the outpatient programs, which covers the addict's rent — and more.





Jessica Bostic, a former heroin addict, texts her boyfriend at her halfway house in Lake Park, Florida. Alicia Vera for BuzzFeed News

Sometimes an addict can earn a little extra cash as a “mole,” checking into another detox center or halfway house and recruiting patients away to their employer’s programs.

Steve, who has worked at several treatment centers in South Florida over the years and asked to not use his full name because speaking to the media would affect his employment, has seen this firsthand. While working as a behavioral health technician at a rehab center in Pompano Beach, Florida, a man came in for a short stint, known as a “two-week stabilization.”

Steve noticed that he was very personable, chatting with everyone. A previous experience with a suspected mole had taught Steve to be wary, so one night after curfew he sat the new kid down and pressed him on whether he was being paid to steal patients away.

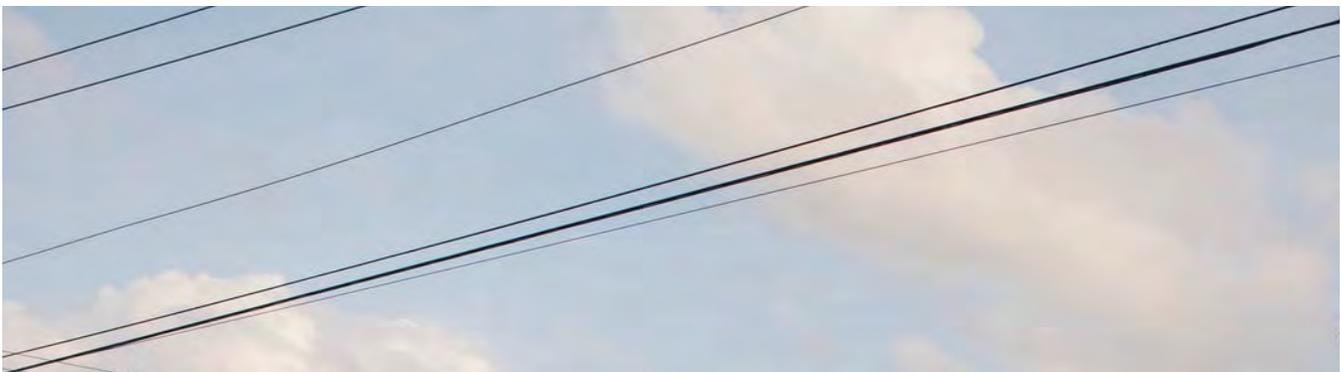
The kid broke and told him the details of the scam: For every person he convinced to leave, he’d get a few hundred dollars. “I said, ‘Do you realize these guys have pimped you out?’” Steve said. “It’s really easy to get people who are vulnerable and in need of money to say yes.”

Goldman, Delray Beach’s chief of police, confirmed to BuzzFeed News that this is a problem. “Moles are going in and they’re trying to tell Johnny that this place is better,” he said.

But not everybody wants to work for somebody else. It’s easy for someone in early recovery to start eyeing the marketers’ and owners’ fancy cars and wads of cash and decide to make big deals of their own.

“People come in, within six days, they’re counting how much money we’re making,” Jonas, the sober-home operator, told BuzzFeed News. “They get out six months later or less, and they’re opening their own [house] — they’re under 30 years old, they don’t have any real recovery time.”

And the cash rolls in. “You sit on Atlantic, you watch the Lamborghinis and the Bugattis go by,” Jonas said.





A motorcycle drives by street art that reads "Love Truth in Delray Beach". Alicia Vera for BuzzFeed News

Some marketers will pay the first few Obamacare insurance premiums for addicts they pick up off the street. According to Chris Harshbarger, who has lived in several sober homes in Palm Beach County, one such marketer is Jamal Boyd, the past owner of Ambitious Venture, a halfway house. (The house's [Facebook](#) page claims it's accredited by the Florida Association of Recovery Residences, which a spokesperson for FARR says is untrue. Boyd told BuzzFeed News he closed the house in February.)

Around August of last year, according to Harshbarger (who is now in jail for an unrelated charge), Boyd offered to pay his insurance premium on a Cigna plan in order to place him in an outpatient program and halfway house that Boyd is affiliated with. He declined Boyd's offer, he says, and had trouble finding halfway houses that would let him live there without attending outpatient programs that would give the houses insurance kickbacks.

Boyd told BuzzFeed News that Harshbarger's claims are the result of a personal beef. He said he offered Harshbarger technical assistance in choosing an insurance plan, but did not offer to pay his premiums. Boyd acknowledged that some "other marketers" do pay insurance premiums for addicts seeking treatment, but said that he refers clients who can't afford insurance to a nonprofit for assistance.

Between 2012 and 2014, while Boyd was living in halfway houses himself, he said, he did take per-head fees from marketers to refer his friends. "They tell the kids, OK, I get X

amount of dollars if you can find people who need to go to detox,” he said. “Through their commission, they would kick me back something like 50 or 100 bucks. The most I was getting paid was \$250 for a 30-day treatment.”

Boyd opened the Ambitious Venture house in 2014. He told BuzzFeed News that clients who went to an affiliated outpatient program paid a lower weekly rent than those who didn't. He is a certified medical assistant, and he said those outpatient programs paid him between \$150 and \$250 a week to conduct “aftercare” visits with their mutual clients.

Boyd had trouble describing exactly what his aftercare services entailed. “I basically just check on them and see how well they're doing — it's just a basic assessment,” he told BuzzFeed News.

The kickbacks Harshbarger describes are a symptom of a much larger issue, one that is taking its toll on the Florida rehab industry's reputation. For instance, the mega-insurer Cigna, [citing rampant health care fraud](#), pulled out of the Florida health care exchanges for 2016.

One woman, who requested to remain anonymous for fear of repercussions within the community, told BuzzFeed News about getting \$250 a week to do an intensive outpatient program (IOP) in Delray. When her boyfriend, a marketer for the business, failed to bring enough new clients in, the owner cut them off. The woman contacted another marketer, who brought her to a new house.

“They pretty much knew I was only there to get a cut,” the woman told BuzzFeed News. But during her intake at the second house, she says, a doctor inappropriately touched her breasts and pulled down her underwear. A victim of previous sexual assaults, she panicked and demanded to leave.

“After that I told all the body brokers to stay the fuck away from me,” she said. “Even at this point if I relapsed, I would never go back into a halfway or into an IOP.”





Melissa Karnilaw, a flakka addict, approaches a car to ask if it's her ride to a treatment center. Alicia Vera for BuzzFeed News

This layer of cash-only illegal activity creates cracks in the system, where lawbreakers (some with active drug problems) become the rich and powerful gatekeepers to treatment, housing, and even cash.

“We’ve heard it all — we’ve even heard that these [halfway] houses, some of the bad operators are selling drugs in them,” Jeffrey Goldman, the chief of police of Delray Beach, told BuzzFeed News in October.

Marketers pull addicts off the street, said Jessica Bostic, a 26-year-old from Ohio who came to Delray last year for rehab. “There’s a kickback if you’re the person who signs them into detox for referral. I was offered to go into a [rehab center] for two weeks for \$1,000 — they would give you a portion of the referral fee.” But the marketers told her she would have to “do something” to qualify for detox — that is, use drugs.

With addicts in such a vulnerable state, being offered money, drugs, or both, these marketers sometimes use their power to make sexual demands as well.

Bostic relapsed on and off for her first month in Florida. One day she overdosed on the beach where she’d slept the night before. A friend revived her, took her to the hospital, and called Jameal Bost, a well-known marketer around Delray Beach. Bost knew Bostic was “running” — still using — and looking for a safe place to stay.

He set up Bostic and her friend in Redemption House, a halfway house where Bost was a house manager. She overdosed again in the bathroom that night, and Bost helped revive her.

After Bostic left Redemption, Bost sent her dozens of Facebook messages between July and September 2015, ranging from offers of cash to assistance in finding another halfway house. Once Bostic told the marketer she was not interested, he responded defensively:

“look girlfriend you’re not my type nor on my level I have 15 months clean what would I [do] with u? What can you do for me I don’t want you!!”

“Lol ok,” Bostic responded. “Later.”

The next day Bost messaged her again, repeatedly asking her out and then getting angry when she told him to leave her alone. “Pissssh you ain’t no body [in] town but another junkie that don’t want shit in life,” he responded. “U ow[e] me a big apologie but that’s too good for u.”



Jameal Bost / Via Facebook: jameal.bost.5

Bostic says a big part of the problem is how easy it is for addicts with very little clean time to suddenly start making big money selling people they know to rehab centers.

“Everybody needs to make money,” she told BuzzFeed News. “But when you’re in it for the money and you could give a shit less about the person, it’s very dishonest.”





Jessica Bostic, a former heroin addict, brushes her hair in her room at her halfway house in Lake Park, Florida. Alicia Vera for BuzzFeed News

Bostic's story is not unique, according to Susan Ramsey, a West Palm Beach lawyer who often represents people in the recovery community in South Florida.

She knows of dozens of legal cases of sexual assault or misconduct throughout the recovery industry in South Florida, many involving techs or counselors having sex with residents.

"They don't all bring cases —in fact most of them don't," Ramsey told BuzzFeed News. "Frankly, there's a double stigma — because people don't think drug addicts can be sexually assaulted, plus any time a woman says this, unless there's video, it's a problem."

One of Ramsey's clients, an alcoholic with a pending DUI case, was allegedly encouraged to drink by a technician at her halfway house, and then sexually assaulted by him. When she reported it, she was interrogated by the staff and forced to sign a written retraction. She left, and spent the night in a parking lot. The facility did not contact the police.

Some members of the recovery industry even become pimps, like [Kenny Chatman](#). The *Palm Beach Post* reported in December 2015 that Chatman, who ran several halfway houses in Palm Beach County, was actively pimping women out, getting them high and listing them on a local prostitution site. According to the [police report](#), at least one woman was kept there against her will.

Florida has struggled to regulate the recovery industry. The last legislative session saw several laws passed, including one that says rehab centers can only refer clients to halfway houses certified by the Florida Association of Recovery Residences to meet a certain standard. There are many people in South Florida who are honestly trying to help addicts recover, and follow strict codes of ethics around how to behave.

But legal experts say relying on goodwill isn't enough. The Florida Department of Children and Families (DCF), the body tasked with regulating rehab and detox centers, is woefully underfunded, they say, and doesn't have staff to enforce its own regulations. And it doesn't have any power over halfway houses.

Lynne, the Delray Beach lawyer, hates when his clients ask him what the risk is if they engage in illegal marketing. “I can only tell you what I know to be true — there is no DCF police out there, there’s no DCF money out there, and the police aren’t prosecuting,” he told BuzzFeed News. “It does violate the law. But they come to me and say, ‘Jeff, if I don’t do it, I can’t even be in the game.’”

DCF says it reports all alleged patient brokering to the attorney general, but otherwise has no power to do anything about it.

“DCF does not deny patient brokering exists,” Michelle Gladly, the agency’s press secretary, told BuzzFeed News by email. “DCF does not have legal authority to investigate patient brokering and can only legally revoke a license if minimum standards are not met.”

Ultimately, the worst problems may come from the fact that so many addicts are searching for recovery in a place where drugs — [and their consequences](#) — are easy to find and hard to avoid.

“People die every week,” Bostic, the 26-year-old from Ohio, said.

And they’re not just dying in Delray Beach. Nationwide, [125 people die of drug overdoses every day](#). Politicians pay lip service to “evidence-based treatment.” But the truth is, nobody knows the best way to get an addict off drugs.

There are few numbers on how many addicts get clean in rehab, and even fewer on how many stay clean. By nature, it’s a transient population, difficult to track for the multiple years required to get solid evidence of efficacy. And there’s little incentive for rehab centers to shine a light on [relapse rates](#), which likely [hover around 90%](#).

Carrie Schoewe, a 41-year-old originally from Ohio who got sober in South Florida, told BuzzFeed News she thinks that short stays in sober homes can be beneficial, but that many get trapped in the cycle of relapsing with other addicts in early recovery.

“I think for a small period of time, people who understand where you are and what you’ve been through can be really supportive,” she said. “But it’s not staying stuck in a place, it’s what you do after. And there don’t seem to be afters for a lot of people.”

[Pee Scams, Kickbacks, And Overdoses Plague South Florida Rehabs](#)

[buzzfeed.com](#)

[After Overdose, Almost All Pain Patients Keep Their Opioid Prescriptions](#)

[buzzfeed.com](#)

[Feds To Doctors: Stop Prescribing Addictive Painkillers For Chronic Pain](#)

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Nebraska Pharmacists Association
Annual Convention –
Interdisciplinary Opioid Program

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July 16, 2016
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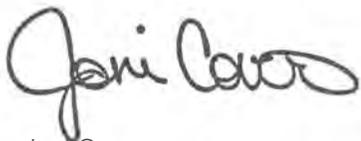
Join Us

Dale Mahlman, Nebraska Medical Association (NMA) Executive Vice President, and I would like to invite you to attend an *Interdisciplinary Opioid Program* on Saturday, July 16, 2016, at The Cornhusker Marriott Hotel, in Lincoln, Nebraska. We are excited to provide this interdisciplinary comprehensive overview of opioid issues impacting Nebraska.

For the first time, the Nebraska Pharmacists Association (NPA) has expanded their annual convention to include all healthcare professionals. The NPA and the NMA have worked together to make Saturday's opioid programming possible, and continue to ensure that all healthcare professionals collectively meet the everyday challenges of Nebraska's healthcare.

By attending Saturday's *Interdisciplinary Opioid Program*, you bring expertise, vision, knowledge, and experience that strengthens the healthcare team, of which we all play a key role, and provide the best patient care to all Nebraskans.

We look forward to seeing you in July!



Joni Cover
Chief Executive Officer
Nebraska Pharmacists Association



Dale Mahlman
Executive Vice President
Nebraska Medical Association



Contact Us

For questions about the program or help with registration, contact the NPA at 402-420-1500 or info@npharm.org.

Handouts

Handouts will be available on the NPA website at www.npharm.org

Registration

Registration and check-in will open at 7:30 am in The Cornhusker Marriott Hotel, 1st Floor Atrium.

Lodging

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A block of rooms has been reserved for \$110 per night (subject to state/local tax). The room block expires on June 23, 2016. Be sure to tell them you are with the Nebraska Pharmacists Association's convention group.

Saturday, July 16, 2016

8:05 am – 8:15 am

Convention Welcome

NPA President, Lyndell White, PharmD

8:15 am – 9:15 am

Appropriate Use of Opioids for Non-Cancer, Acute and Chronic Pain

Liane Donovan, MD, Interventional Pain Physician, Nebraska Spine & Pain Center

ACPE UAN 0128-0000-16-320-L01-P/T Knowledge Based Activity

Program Objectives:

1. Describe the best practices for the treatment of acute and chronic pain.
 2. Explain the role of opioid and non-opioid analgesics in the management of acute and chronic pain and recommend specific dosing regimens.
 3. Define the role of adjuvant analgesics in the management of acute and chronic pain and recommend specific dosing regimens.
-

9:15 am – 9:30 am Break

9:30 am – 10:30 am

Cognitive Behavioral Management of Acute and Chronic Non-Cancer Pain

Thomas Guck, PhD, Professor and Vice-Chair, Director of Behavioral Science, Department of Family Medicine, Creighton University School of Medicine

ACPE UAN 0128-0000-16-321-L01-P/T Application Based Activity

Program Objectives:

1. Describe Cognitive Behavioral strategies for the management of acute pain.
 2. Describe Cognitive Behavioral & Acceptance and Commitment Therapy (ACT) interventions for the management of chronic non-cancer pain.
 3. Provide case examples that allow participants to: a) generate hypotheses that explain lack of patient progress toward functional goals, and b) develop treatment plans to address the reasons for lack of progress.
-

10:30 am – 10:45 am Break

10:45 am – 11:45 am

Identification of Overdose

Kenneth Zoucha, MD, Medical Director, Hastings Juvenile Chemical Dependency Program

ACPE UAN 0128-0000-16-322-L01-P/T Application Based Activity

Program Objectives:

1. Identify risk factors of opioid dependence, addiction, withdrawal and overdose.
2. Describe the physical signs and symptoms of opioid overdose and withdrawal.

3. Recall the steps for treating an opioid overdose, including the use of naloxone.
 4. Discuss strategies for engaging and educating patients about potential opioid misuse or overdose and effectively triaging them to appropriate recovery options.
-

11:45 am – 1:00 pm Lunch

1:00 pm – 2:00 pm

What's Happening in Nebraska?

Doug Peterson, JD, Nebraska Attorney General

ACPE UAN 0128-0000-16-323-L03-P/T Knowledge Based Activity

Program Objectives:

1. Describe the scope of opioid abuse and diversion in Nebraska.
 2. Identify the current drug use trends in Nebraska.
 3. Explain law enforcements' greatest challenges in combating illegal substances (include heroin).
 4. Describe federal and state legislative initiatives to combat drug addiction and overdose in Nebraska.
-

2:00 pm – 2:15 pm Break

2:15 pm – 3:15 pm

Treatment of Addiction

Donald Teater, MD, Medical Advisor, National Safety Council

ACPE UAN 0128-0000-16-324-L01-P/T Knowledge Based Activity

Program Objectives:

1. List the medications used to treat opioid use disorder.
 2. Identify strategies for the treatment of opioid addiction.
 3. Describe non-pharmacological treatment options for specific populations, including comorbidities.
 4. Identify medications and treatments for babies born to addicted moms.
-

3:15 pm – 3:30 pm Break

3:30 pm – 4:30 pm

Resources for Healthcare Providers

Topher Hansen, JD, President and Chief Executive Officer, CenterPointe

ACPE UAN 0128-0000-16-325-L04-P/T Knowledge Based Activity

Program Objectives:

1. Identify resources that are available in Nebraska to individuals battling addiction.
2. Explain the risk factors and behaviors associated with the disease of addiction in pharmacy and medical professionals.
3. Describe the Mandatory Reporting laws and the Licensee Assistance Program.
4. Explain the responsibility/legal ramifications for prescribers and pharmacists.
5. Illustrate strategies for raising awareness of the risks associated with addiction.

Registration



Please print

Name _____ Phone _____

Badge Name _____ Email _____

Mailing Address _____ City/State/Zip _____

Spouse/Guest Name (if applicable) _____

Payment

Check (Payable to the NPA)

Check # _____

Credit Card

Exp. Date ____/____/____ Sec. Code _____

Signature _____

Please send receipt.

	Early Bird On or Before 6/30/2016	On or After 7/1/2016	Registration Sub Totals
Saturday Registration			
Healthcare Professional	\$ 98	\$138	\$ _____
Spouse/Guest	\$ 98	\$138	\$ _____
REGISTRATION TOTAL			\$ _____

Cancellation & Refund Policy

We understand that circumstances arise that require you to cancel or send a substitute. Cancelled registrations must be in writing. Cancellations received on or before July 5, 2016, will receive a refund in the amount paid less a 25% administrative fee. No refunds will be made after July 6, 2016. Please notify the NPA of any changes prior to the event to help facilitate the check-in process.

Continuing Medical Education

Bryan Medical Center is accredited by the Nebraska Medical Association's Commission on Medical Education to provide continuing medical education for physicians.



Programming for Saturday, July 16, 2016

Bryan Medical Center designates this live activity for a maximum of 6 AMA PRA Category 1 Credit(s). Physicians should claim only the credit commensurate with the extent of their participation in the activity.



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The Association Between Receipt of Guideline-Concordant Long-Term Opioid Therapy and All-Cause Mortality

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PURPOSE: For patients receiving long-term opioid therapy (LtOT), the impact of guideline-concordant care on important clinical outcomes—notably mortality—is largely unknown, even among patients with a high comorbidity and mortality burden (e.g., HIV-infected patients). Our objective was to determine the association between receipt of guideline-concordant LtOT and 1-year all-cause mortality.

METHODS: Among HIV-infected and uninfected patients initiating LtOT between 2000 and 2010 through the Department of Veterans Affairs, we used Cox regression with time-updated covariates and propensity-score matched analyses to examine the association between receipt of guideline-concordant care and 1-year all-cause mortality.

RESULTS: Of 17,044 patients initiating LtOT between 2000 and 2010, 1048 patients (6%) died during 1 year of follow-up. Patients receiving psychotherapeutic co-interventions (hazard ratio [HR] 0.62; 95% confidence interval [CI] 0.51–0.75; $P < 0.001$) or physical rehabilitative therapies (HR 0.81; 95% CI 0.67–0.98; $P = 0.03$) had a decreased risk of all-cause mortality compared to patients not receiving these services, whereas patients prescribed benzodiazepines concurrent with opioids had a higher risk of mortality (HR 1.39; 95% CI 1.12–1.66; $P < 0.001$). Among patients with a current substance use disorder (SUD), those receiving SUD treatment had a lower risk of mortality than untreated patients (HR 0.47; 95% CI 0.32–0.68; $P < 0.001$). No association was found between all-cause mortality and primary care visits (HR 1.12; 95% CI 0.90–1.26; $P = 0.32$) or urine drug testing (HR 0.96; 95% CI 0.78–1.17; $P = 0.67$).

CONCLUSIONS: Providers should use caution in initiating LtOT in conjunction with benzodiazepines and untreated SUDs. Patients receiving LtOT may benefit from multi-modal treatment that addresses chronic pain and its associated comorbidities across multiple disciplines.

KEY WORDS: Opioid analgesics; practice guideline; quality of health care; mortality; pain.

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Opioid analgesics, medications once primarily prescribed in palliative care and postoperative settings, are now widely prescribed for chronic pain in specialty and general medical settings.¹ Yet despite the risks posed by opioids, including the risk of addiction and overdose, long-term opioid therapy (LtOT; typically defined as receipt of opioids for ≥ 90 days)^{2–6} is rarely provided in accordance with clinical practice guidelines.^{3,7–16} Among the potential barriers to the provision of guideline-concordant LtOT are ambiguity and disagreements over which recommendations are important to patient outcomes and how they should be prioritized given time constraints and the competing demands of patient care.^{17–19} The majority of recommendations promulgated by leading medical societies, including the American Pain Society and American Academy of Pain Medicine,^{3,7} are supported by low-quality evidence, and none are supported by evidence deemed to be of high quality.^{3,9,19,20} In 2009, a multidisciplinary expert panel identified 37 key areas pertaining to patient care and LtOT where critical weaknesses in the literature exist;¹⁹ to date, the majority of these gaps in the literature have gone unaddressed.^{19,20} Because it remains unclear which recommendations offer the greatest benefit to patient outcomes, clinicians may be relying on anecdotal evidence and individual experience when determining which, if any, LtOT recommendations to implement.^{17,18}

Therefore, with the overarching goal of contributing to an evidence base to guide future quality improvement efforts targeting opioid-related adverse events, we examined the association between guideline-concordant LtOT and all-cause

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mortality using the Veterans Aging Cohort Study (VACS), a well-established, validated sample^{21–24} of HIV-infected patients demographically matched (1:2) to uninfected patients engaged in care. VACS researchers have previously reported that opioid receipt is common in this sample, and that HIV-infected patients are more likely to receive high-dose prescriptions (≥ 120 milligrams morphine equivalents [mEq] per day).⁶ Thus, the VACS provides a robust sample in which to explore mortality associated with guideline-concordant LtOT.

We examined the impact of guideline-concordant LtOT on all-cause mortality in patients at the beginning stage of LtOT, a critical time when guideline-concordant care may be most important,³ and clinicians may thus be more diligent in delivering higher-quality care.²⁵

METHODS

Study Overview

In a large sample of outpatients initiating LtOT between 2000 and 2010, we examined the association between receipt of guideline-concordant LtOT and 1-year all-cause mortality. To address the potential for confounding by indication,^{26,27} we examined these associations using a propensity-matched design.

Data Source

We abstracted administrative, clinical, laboratory, and pharmacy data from the Department of Veteran Affairs (VA) electronic medical record system for patients participating in the VACS. As previously described,^{21–24,28} VACS is a prospective cohort of HIV-infected patients matched (1:2) by age, sex, race, and VA site of care to uninfected controls.²⁹ VACS is HIPAA compliant and has received approval from the review boards for the VA Connecticut Healthcare System and the Yale School of Medicine; the requirement for informed consent was waived.

Study Population

From the VA Pharmacy Benefits Management database, we captured outpatient prescriptions for oral and transdermal opioids filled or refilled between October 1, 1999 (fiscal year 2000) and September 30, 2010 (fiscal year 2010). Consistent with prior studies, we defined LtOT as receipt of at least a 90-day supply of opioids.^{2,4,6,16} We allowed for no more than a 30-day window between prescription refills. Finally, because our focus was on chronic pain, we excluded data on methadone and buprenorphine prescribed for opioid use disorder, but retained data on methadone prescribed for the treatment of pain.⁶

From the approximately 120,000 patients enrolled in the VACS (as of fiscal year 2012),²⁹ as detailed in Figure 1, we identified 26,931 patients filling or refilling prescriptions for 90 or more days of opioids as outpatients between 2000 and

2010. We excluded from this cohort those filling opioid prescriptions within the prior 90 days in order to focus on incident versus prevalent cases of LtOT. We also excluded patients with fewer than 90 days of follow-up, including those who did not meet the 90-day criteria for LtOT due to death. We also excluded those receiving a palliative/end-of-life care ICD-9-CM³⁰ (*International Classification of Disease, 9th revision*) diagnostic code on or before the opioid start date. The final analytic sample consisted of 17,044 patients.

Indicators of Guideline-Concordant Care

The independent variables of interest were indicators of guideline concordance derived from national clinical practice guidelines^{3,7–9} for the management of LtOT related to receipt of primary care visits, urine drug testing, psychotherapeutic co-interventions, rehabilitative therapies (i.e., occupational, physical, and rehabilitation therapies), and benzodiazepine co-prescriptions. Among patients with a current substance use disorder (SUD), we also examined receipt of inpatient or outpatient SUD treatment. In Table 1, we provide the operational definition for each indicator.

The decision regarding which indicators to examine was based on group consensus, relevance of indicator to patient safety, and accessibility of data in the electronic medical record system. Further details on the process and rationale for the inclusion of selected indicators can be found in a previous publication.¹⁶

Surveillance for guideline concordance began at the same time for all patients (LtOT start date) and continued for 180 days; this period was chosen because the initial months of LtOT represent a period during which the risks for adverse events are particularly high.³ For patients not completing 180 days of LtOT, the surveillance ended (either through death or censoring) when the opioid exposure ended, which was determined by either the opioid prescription stop date or, when applicable, date of death. Differences in the length of eligibility (i.e., LtOT duration) for receipt of indicators (opioid therapy duration) were accounted for in the analysis using time-dependent methods (see "Statistical Analyses").^{31,32}

Primary Outcome

The outcome of interest was all-cause mortality.³³ Consistent with our goal of understanding the association between guideline-concordant care and mortality in a diverse patient population, we examined this outcome for the sample in its entirety, and not stratified by particular patient sub-populations (e.g., HIV-infected). Specifically, we identified all patient deaths occurring in the 12-month period that began once patients completed the first 90 days of LtOT. Data on patient deaths were obtained from the Beneficiary Identification Records Locator Subsystem Death File, which was obtained from the Veterans Health Administration Vital Status File; these data are comparable to the National Death Index in terms of accuracy and completeness.^{34,35}

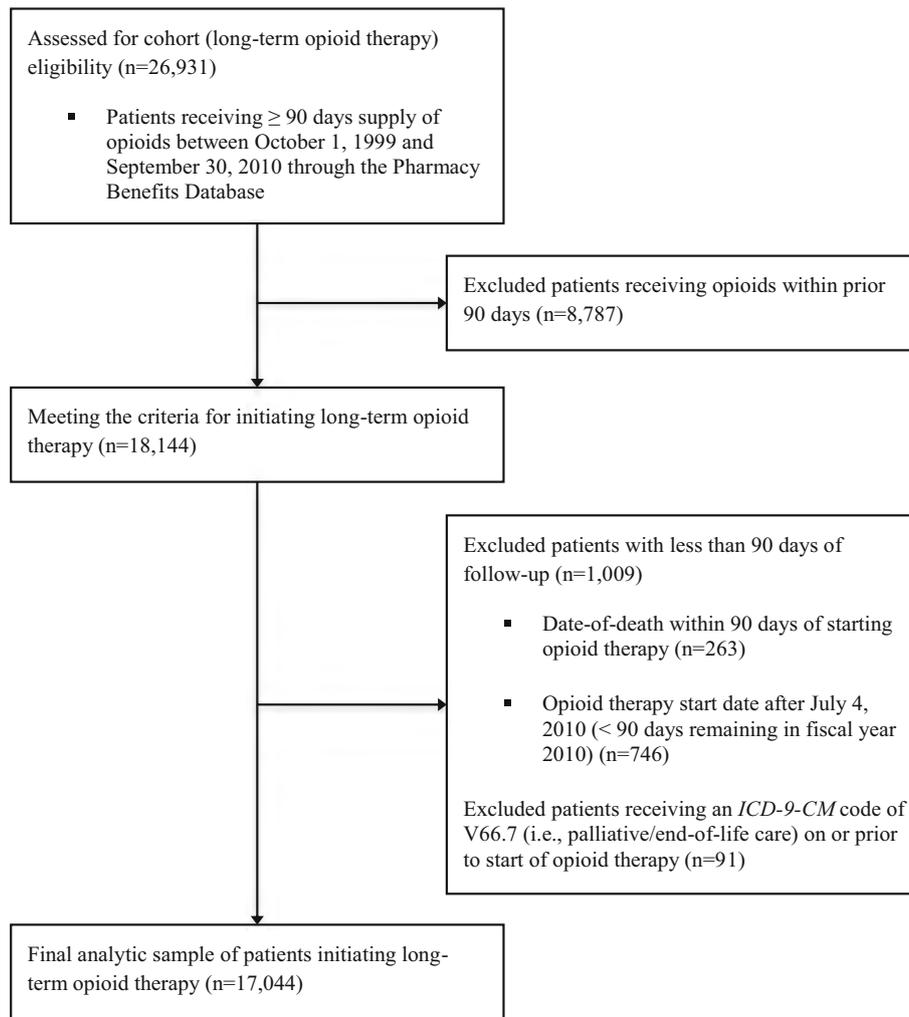


Figure 1 Study flow diagram.

Covariates

We used data from the VA National Patient Care Database³⁶ to characterize the sample at baseline, and used ICD-9-CM codes, pharmacy data, and laboratory results, when applicable, to describe clinical characteristics. A diagnosis of an alcohol use disorder was based on AUDIT-C (Alcohol Use Disorders Identification Test-Consumption) scores ≥ 4 or ICD-9-CM codes. Administrative codes were used to identify treatment. As a measure of overall severity of illness, we used the VACS Index, which incorporates age, HIV-1 RNA viral load, CD4 count, hemoglobin, FIB-4, estimated glomerular filtration rate, and hepatitis C virus. The VACS Index is a validated prognostic measure,^{28,29,37–40} which is predictive of morbidity and mortality in both HIV-infected and uninfected patients (in calculating the index, the assumption is made that uninfected patients have a CD4 count > 500 cells/ μL and viral load < 20 copies/ml).^{29,41} Higher scores are indicative of higher all-cause mortality risk.

Statistical Analyses

Descriptive statistics were used to characterize the sample at baseline and according to receipt of guideline-concordant care. Differences according to demographic/clinical characteristics and treatment status were assessed with χ^2 tests for categorical variables and, as appropriate, t , ANOVA, or Wilcoxon rank-sum tests for continuous variables.

To control for confounding by indication,^{26,27} we generated propensity scores to reflect a patient's conditional probability of receiving the treatment of interest (i.e., guideline-concordant care). Specifically, for each indicator, we developed a multivariable logistic regression model that included clinical covariates associated with both the treatment of interest and the outcome. These covariates were chosen from an extensive pool of mental health, major medical, and pain comorbidities that are prevalent in this study population, including major depression, bipolar disorder, post-traumatic stress disorder, psychosis, schizophrenia, schizoaffective disorder, alcohol and drug use disorders, HIV, hepatitis C, and diabetes. Pain comorbidities included those for acute pain

Table 1 Operational Definitions for Indicators of Guideline-Concordant Long-Term Opioid Therapy

Guideline indicators	Operational definition(s)	Source
Monitoring		
Clinicians should conduct a follow-up visit within 2–4 weeks of LtOT initiation. This initial phase should be considered a therapeutic trial, for which opioid-naïve patients* are particularly at risk. [†] Clinicians should routinely reassess all patients on LtOT every 1–6 months for risks and benefits of treatment for duration of LtOT [†]	1. Any documented outpatient PCP visit between LtOT start date and end of 180 days of LtOT (or LtOT stop date for patients on LtOT < 6 months).	APS/ AAPM ^{3,7} VA/DoD ^{8,9}
As part of a comprehensive patient assessment, clinicians should obtain a UDT to assess for aberrant drug-related behaviors in all patients prior to initiating LtOT. Clinicians should routinely confirm adherence to LtOT plan of care in all patients through periodic UDTs.	2. Laboratory documentation of UDT between LtOT start date and end of 180 days of LtOT (or LtOT stop date).	APS/ AAPM ^{3,7} VA/DoD ^{8,9}
Co-prescription of high-risk medications		
Clinicians should avoid co-prescription of sedatives and LtOT.	3. Pharmacy documentation that patient was prescribed benzodiazepines (≥ 7 days so as to exclude prescriptions for acute indications [e.g., pre-operative sedation]), carisoprodol, or barbiturates between LtOT start date and end of 180 days of LtOT (or LtOT stop date).	VA/DoD ^{8,9}
High-risk patients		
Clinicians may consider LtOT for patients with a history of SUD [‡] only if they are able to implement more frequent and stringent monitoring parameters. Clinicians should initiate LtOT with caution in patients with a history of SUD, and should never initiate LtOT in patients with a current disorder [§] who are not in SUD treatment.	4. Among patients with a current SUD, documentation of SUD treatment (1 inpatient bed days or 1 outpatient SUD-specialty clinic visit) between LtOT start and end of 180 days of LtOT (or LtOT stop date).	APS/ AAPM ^{3,7} VA/DoD ^{8,9}
Chronic pain co-interventions		
Clinicians should avoid relying exclusively on opioids for the management of chronic pain, and should routinely take a multidisciplinary approach to pain management that includes the integration of non-opioid pharmacotherapies, rehabilitation or functional restoration, and psychotherapeutic interventions.	5. Physical rehabilitation therapies: Any documented outpatient visits to a VA physical therapy, occupational therapy, or rehabilitation clinic anytime between LtOT start date and end of 180 days of LtOT (or LtOT stop date).	APS/ AAPM ^{3,7} VA/DoD ^{8,9}
	6. Psychotherapeutic co-interventions: Any 2 documented outpatient visits to a VA mental health clinic between LtOT start date and end of 180 days of LtOT (or LtOT stop date).	

Abbreviations: AAPM, American Academy of Pain Medicine; APS, American Pain Society; DoD, Department of Defense; LtOT, long-term opioid therapy; PCP, primary care provider; SUD, substance use disorder; UDT, urine drug test; VA, Veterans Administration.

*All patients in the current study were considered opioid-naïve (i.e., incident LtOT patients).

[†]Only the VA/DoD guidelines specify an exact time period.

[‡]Lifetime history.

[§]SUD diagnosis received between LtOT start date and end of 180 days of LtOT (or LtOT stop date).

(e.g., abdominal or chest) and chronic pain (e.g., headache, back pain, arthritis, neuropathy), as previously described.⁶ We also identified other covariates as potential confounders, including those for cardiac, pulmonary, liver, and renal disease. Additional covariates were then added to the models as necessary to adjust for receipt of other LtOT indicators (we demonstrated in previous analyses¹⁶ that HIV-infected patients are more likely to receive guideline-concordant care for certain indicators), opioid dose and schedule (for Schedule II, categorized as short- vs. long-acting), and to balance demographic and clinical characteristics. Finally, interactions were included to improve the fit of the model. C-statistics, a measure of a model's ability to predict patient treatment exposure status (i.e., discrimination), and goodness-of-fit tests (i.e., calibration) were used to evaluate the logistic regression models. Additional diagnostics included an evaluation of histograms (stratified by treatment status) for the propensity scores and plotting the observed versus expected outcomes from the Hosmer-Lemeshow goodness-of-fit tests. All logistic

regression models were found to have good fit (Hosmer-Lemeshow p value $\geq .05$)^{42,43} and acceptable (0.75–0.80) to excellent (0.80–0.90)⁴⁴ c-statistics.

For each indicator, we then matched patients on propensity scores using a SAS greedy algorithm macro,⁴⁵ designed to match on as many as five digits. For example, a patient with a low (or high) probability of receiving treatment was matched to another patient with a similar probability, yet only one of these patients received the treatment. The difference in the outcome (e.g., time to death) between these patients (or groups of patients) could then be attributed to the treatment, based on the covariates we included in the regression models. Further details on the methods and rationale for propensity-score matching in observational research are available elsewhere.^{26,46}

Once 1:1 matching was completed, we then assessed for associations between guideline-concordant care and mortality using Cox proportional hazards regression with time-updated covariates. Time-updated methods were employed to account

for differences in exposure to long-term opioids in cases where patients died or discontinued opioids prior to 180 days of therapy, and thus had less time to receive guideline-concordant treatment (i.e., indicators). Such methods correctly classify patients' time to receipt (determined by variables reflecting initiation date) of a particular indicator as unexposed; once the indicator is obtained, the patient is thereafter classified as exposed. Upon a patient's death, proper estimates can then be obtained because the treatment status of those in the risk set has been properly classified.^{31,32}

In secondary analyses, in addition to *matching* patients based on propensity scores, we examined the association between each of the indicators and mortality by *adjusting*⁴⁷ with the propensity scores using both individual five-digit scores and scores categorized into quintiles (i.e., five strata).^{47–49} Overall, the results were similar whether we used the propensity scores for matching or regression-adjustment;⁴⁷ thus, we present here the unmatched and propensity-matched results.

We conducted a sensitivity analysis specific to primary care visits to determine whether there was an association between mortality and receipt of multiple visits (i.e., 0 vs. ≥ 2 visits; 0 vs. ≥ 3 visits), for which we found no association. Thus, we present the results from the main analysis.

All analyses were performed using SAS software, version 9.4 (SAS Institute, Cary, NC, USA). A two-sided statistical significance level of 0.05 was applied to all analyses.

RESULTS

We identified 17,044 patients who initiated LtOT between 2000 and 2010. Patients were primarily male (98%), of white (47%) or black (43%) race, with an average age (SD) of 50.2 (9.3) years (Table 2). In general, prior to matching on propensity scores, patients receiving each of the indicators were slightly older, HIV- and HCV-infected, and with a diagnosis of diabetes, serious mental illness, or SUD. These patients also had a higher mean VACS Index, indicating higher all-cause mortality risk. For the matched samples, select demographic and clinical characteristics according to each of the LtOT indicators can be found in Table 3 and in online Appendices 1A and 1B.

Receipt of Guideline-Concordant Care

In the 180 days following LtOT initiation, 86% of patients received a primary care visit, 20% a urine drug test, 32% psychotherapeutic co-interventions, and 30% rehabilitative therapies. Co-prescriptions for benzodiazepines were received by 21% of patients, and receipt did not differ according to SUD history (22% vs. 22% for those with and without SUDs; $p=0.41$) or current SUD status (21% vs. 21%; $p=0.89$). Among those with a current SUD, 45% were engaged in SUD treatment.

Guideline-Concordant Care and All-Cause Mortality

Unmatched Analyses. During 1 year of follow-up, there were 1048 (6%) deaths, with a median (interquartile range [IQR]) time to death of 227.5 (154.0–328.5) days. In unadjusted analyses on an unmatched sample (Table 3), we found that psychotherapeutic co-interventions (hazard ratio [HR] 0.57; 95% confidence interval [CI] 0.49–0.66; $P<0.001$) and rehabilitative therapies (HR 0.60; 95% CI 0.52–0.70; $P<0.001$) were associated with a decrease in mortality, whereas benzodiazepine co-prescribing was associated with an increase in mortality (HR 1.63; 95% CI 1.43–1.86; $P<0.001$). Among patients with a current SUD, SUD treatment was also associated with a decrease in mortality (HR 0.38;

Table 2 Patient Characteristics at Baseline

Characteristic	Overall sample (n = 17,044)
Age, mean (SD), years	50.2 (9.3)
Male Sex, n (%)	16,638 (98)
Race, n (%)	
White	7976 (47)
Black	7390 (43)
Hispanic	1164 (7)
Other	514 (3)
HIV, n (%)	5236 (31)
Hepatitis C, n (%)	4809 (28)
Diabetes, n (%)	5080 (30)
BMI, mean (SD)	28.4 (6.4)
Smoking status, n (%)	
Never	3548 (22)
Current	10,269 (63)
Former	2508 (15)
Chronic pain, n (%) ^a	10,073 (59)
Acute pain, n (%) ^b	2306 (14)
Major depression, n (%)	3221 (19)
Bipolar disorder, n (%)	1757 (10)
PTSD, n (%)	2797 (16)
Psychosis, n (%)	1613 (9)
Active substance use disorder, n (%)	3329 (19.5)
VACS Index, median (IQR)	18.0 (11.0–34.0)
Average daily opioid dose, mean (SD), mg MEQ ^c	39.7 (139.8)
Average daily opioid dose, median (IQR), mg MEQ ^c	15.7 (9.5–30.9)
Long-term opioid therapy duration, mean (SD), days ^d	233.3 (105.6)
Long-term opioid therapy duration, median (IQR), days ^d	205.0 (134.5–365.0)
CD4 count, median (IQR), cells/ μ L ^e	357.0 (182.0–567.0)
HIV-1 RNA, log ₁₀ viral load, < 500 copies/ml, n (%) ^e	2174 (58)

Abbreviations: BMI, body mass index; IQR, interquartile range; PTSD, post-traumatic stress disorder; MEQ, morphine equivalent; VACS, Veterans Aging Cohort Study.

^aChronic pain: ICD-9-CM codes for headache, temporomandibular disorder, neck, back, extremity, arthritis, neuropathy, other.

^bAcute pain: ICD-9-CM codes for abdominal, chest, fracture, kidney stones.

^cAverage daily opioid dose calculated by dividing the total morphine equivalents received in the year since starting long-term opioid therapy by total days' supply.

^dDuring first year of long-term opioid therapy.

^eAmong HIV-infected patients.

Table 3 Patient Characteristics According to Treatment Receipt in Matched Samples: Primary Care Visits and Urine Drug Tests

Characteristic	Primary care visit*			Urine drug testing*		
	No (n = 2341)	Yes (n = 2341)	P value	No (n = 2579)	Yes (n = 2579)	P value
Age, mean (SD), years	49.6 (10.0)	49.7 (10.0)	0.43	49.4 (7.9)	49.4 (8.1)	0.56
Male sex, n (%)	2250 (96)	2244 (96)	0.66	2523 (98)	2518 (98)	0.64
Race, n (%)			0.76			0.98
White	1146 (49)	1145 (49)		1025 (40)	1013 (39)	
Black	971 (41)	986 (42)		1351 (52)	1357 (53)	
Hispanic	135 (6)	119 (5)		147 (6)	151 (6)	
Other	89 (4)	91 (4)		56 (2)	58 (2)	
HIV, n (%)	297 (13)	310 (13)	0.57	893 (35)	896 (35)	0.93
Hepatitis C, n (%)	512 (22)	526 (22)	0.62	1063 (41)	1047 (41)	0.65
Diabetes, n (%)	585 (25)	574 (25)	0.71	677 (26)	673 (26)	0.90
BMI, mean (SD)	28.4 (6.1)	29.0 (6.8)	0.07	27.7 (6.2)	27.5 (6.1)	0.54
Smoking status, n (%)			0.84			0.01
Never	517 (24)	531 (24)		422 (17)	354 (14)	
Current	1360 (62)	1356 (62)		1735 (70)	1853 (74)	
Former	321 (15)	311 (14)		324 (13)	302 (12)	
Chronic pain, n (%)	893 (38)	909 (39)	0.63	1806 (70)	1763 (68)	0.19
Acute pain, n (%)	210 (9)	226 (10)	0.42	451 (17)	487 (19)	0.19
Major depression, n (%)	365 (16)	388 (17)	0.36	614 (24)	641 (25)	0.38
Bipolar disorder, n (%)	236 (10)	229 (10)	0.73	374 (15)	376 (15)	0.94
PTSD, n (%)	369 (16)	387 (17)	0.47	512 (20)	522 (20)	0.73
Psychosis, n (%)	211 (9)	227 (10)	0.42	315 (12)	338 (13)	0.34
Alcohol use disorder, n (%)	626 (27)	669 (29)	0.16	1200 (47)	1173 (45)	0.45
Drug use disorder, n (%)	478 (20)	500 (21)	0.43	1155 (45)	1118 (43)	0.30
VACS Index, median (IQR)	15.0 (6.0–27.0)	16.0 (10.0–28.0)	0.71	22.0 (12.0–35.0)	22.0 (11.0–35.0)	0.78
Average daily opioid dose, mg mEq, median (IQR)	14.8 (9.0–28.1)	14.4 (8.7–26.7)	0.42	18.6 (10.6–43.1)	18.6 (10.8–40.5)	0.81

Abbreviations: BMI, body mass index; IQR, interquartile range; PTSD, post-traumatic stress disorder; MEQ, morphine equivalent; VACS, Veterans Aging Cohort Study.

*Percent of overall sample (n = 17,044) matched: primary care visit, 27.4 %; urine drug test, 30.2 %.

Note: Results for the remaining indicators can be found in online APPENDIX 1A (Psychotherapeutic Co-Interventions and Rehabilitative Therapies) and online APPENDIX 1B (Benzodiazepine Co-Prescriptions and Substance Use Disorder Treatment).

95% CI 0.29–0.50; $P < 0.001$). We did not detect an association between mortality and receipt of either primary care visits (HR 1.08; 95% CI 0.91–1.28; $P = 0.37$) or urine drug testing (HR 1.10; 95% CI 0.95–1.28; $P = 0.20$; Table 4).

Propensity-Matched Analyses. As shown in Table 3 and in online Appendices 1A and 1B, the propensity-matched samples were well balanced on demographic characteristics as well as medical, mental health, and SUD comorbidities. These matched samples support the associations from the unmatched analyses:

psychotherapeutic co-interventions (HR 0.62; 95% CI 0.51–0.75; $P < 0.001$) and rehabilitative therapies (HR 0.81; 95% CI 0.67–0.98; $P = 0.03$) were associated with a decrease in mortality, whereas benzodiazepine co-prescribing was associated with an increase in mortality (HR 1.39; 95% CI 1.12–1.66; $P < 0.001$). Among patients with a current SUD, engagement in SUD treatment was also associated with a decrease in mortality (HR 0.47; 95% CI 0.32–0.68; $P < 0.001$). For primary care visits (HR 1.12; 95% CI 0.90–1.26; $P = 0.32$) and urine drug tests (HR 0.96; 95% CI 0.78–1.17; $P = 0.67$), there remained no significant associations (Table 4 and Fig. 2a–c).

Table 4 Cox Proportional Hazards with Time-Updated Analyses of Time to Death According to Treatment Status in Unmatched and Propensity-Matched Patients

Indicator	Unmatched*		Matched†	
	Hazard ratio (95% CI)	P value	Hazard ratio (95% CI)	P value
Primary care visit	1.08 (0.91–1.28)	0.37	1.12 (0.90–1.40)	0.32
Urine drug testing	1.10 (0.95–1.28)	0.20	0.96 (0.78–1.17)	0.67
Psychotherapeutic co-interventions	0.57 (0.49–0.66)	< 0.001	0.62 (0.51–0.75)	< 0.001
Rehabilitative therapies	0.60 (0.52–0.70)	< 0.001	0.81 (0.67–0.98)	0.03
Benzodiazepine co-prescribing	1.63 (1.43–1.86)	< 0.001	1.39 (1.12–1.66)	< 0.001
Substance use disorder treatment	0.38 (0.29–0.50)	< 0.001	0.47 (0.32–0.68)	< 0.001

*Unmatched samples: N = 17,044 for all treatments except substance use disorder treatment (n = 3329).

†Propensity-matched samples: primary care visit, n = 4682; urine drug testing, n = 5158; psychotherapeutic co-interventions, n = 7592; rehabilitative therapies, n = 9222; benzodiazepine co-prescriptions, n = 6756; substance use disorder treatment, n = 1656.

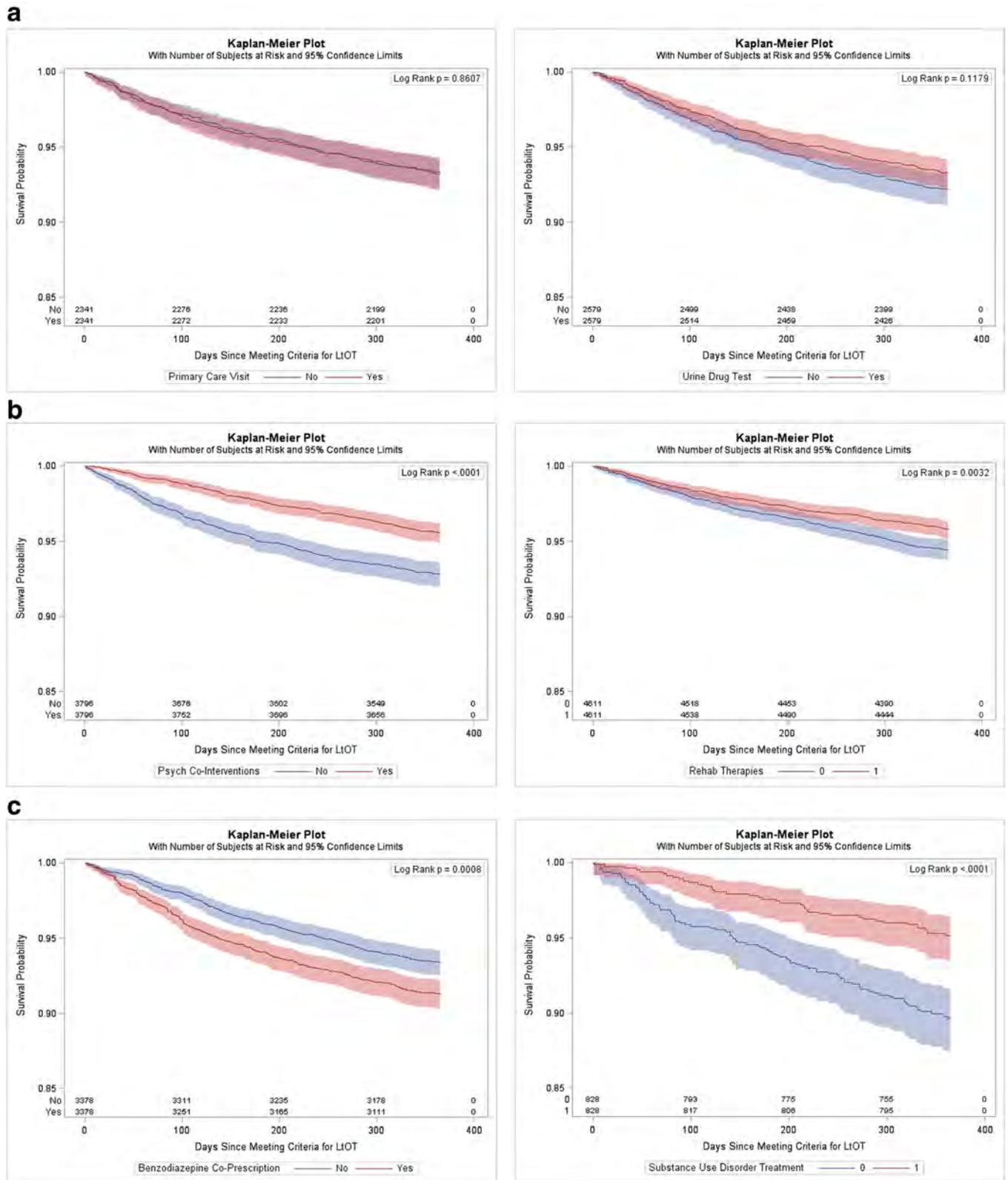


Figure 2 a Propensity-matched Kaplan–Meier plots for time to death (with number of patients at risk) according to treatment status: primary care visits (part 1) and urine drug tests (part 2). b Propensity-matched Kaplan–Meier plots for time to death (with number of patients at risk) according to treatment status: psychotherapeutic co-interventions (part 1) and rehabilitative therapies (part 2). c Propensity-matched Kaplan–Meier plots for time to death (with number of patients at risk) according to treatment status: benzodiazepine co-prescriptions (part 1) and substance use disorder treatment (part 2).

DISCUSSION

Among 17,044 patients initiating LtOT between 2000 and 2010, 1048 (6%) died during 1 year of follow-up. In this sample of patients with a high comorbidity burden, including HIV infection, and high rates of medical, psychiatric, and pain comorbidities, we found that, after extensively controlling for potential confounders, patients receiving psychotherapeutic co-interventions had an all-cause mortality rate nearly half that of patients not receiving these services. Moreover, patients receiving rehabilitative therapies during this same period were approximately 20% less likely to die from any cause than those not engaged in such treatment. Conversely, patients prescribed benzodiazepines concurrent with LtOT were approximately 1.5 times more likely to die. For patients with an untreated SUD, the risk of death was more than twice that of patients engaged in SUD treatment. We did not detect an association between primary care provider visits and all-cause mortality risk. Similarly, we did not detect an association between urine drug testing and mortality. This finding is in keeping with previous studies that have failed to demonstrate an impact of urine drug testing on opioid misuse,^{50,51} an indication that clinicians may not be acting on aberrant results. Indeed, for LtOT guidelines in general, research has shown that clinicians have been slow to integrate recommendations into patient care for those receiving LtOT, even for those at risk for opioid misuse and abuse,^{10–14} all of which speaks to the need^{52,53} for strategies to assist clinicians in caring for patients receiving LtOT. Provider training, in particular, is needed to support clinicians in responding to evidence of unsafe opioid use (e.g., aberrant urine toxicology).⁵⁴

This observational study—the first to examine the association between guideline-concordant LtOT and mortality—lends support to current guidelines that promote a multidisciplinary approach to pain management, as well as to recommendations that caution against initiating LtOT in conjunction with sedatives and untreated SUDs.^{3,7–9} Specifically, the guidelines encourage clinicians caring for patients receiving LtOT to routinely integrate interventions that target biological, psychological, and functional needs.^{3,7–9} Furthermore, for patients with a history of mental health or substance use disorders, the guidelines strongly recommend that clinicians consider co-managing these patients with specialists in mental health or addiction medicine, and according to the VA guidelines, LtOT is contraindicated in patients with a current SUD who are not receiving SUD treatment.^{8,9}

Our study has several limitations. First, although we used propensity score matching to address potential differences between patients who did and did not receive (or adhere to) recommended care, residual confounding may still affect our findings. Additionally, we examined a limited number of indicators related to guideline-concordant care. It may be that indicators beyond the scope of our data (e.g., controlled substance agreements) are associated with reduced mortality in LtOT.^{3,55} Furthermore, because we restricted our sample to patients prescribed 90 or more days of opioids, by definition, deaths occurring in the initial days of opioid exposure, when the risks for LtOT are thought to be

highest,³ were not included in the analyses (these patients had not yet met the criteria for LtOT). There may be a stronger association between receipt of guideline-concordant care and mortality earlier on in treatment, with the mortality benefit diminishing thereafter. In addition, although we excluded patients receiving a palliative/end-of-life care diagnosis on or before initiating LtOT, it is plausible that some of the differences we found in mortality reflect differences in the ability or desire of seriously ill patients or providers to comply with guideline-concordant care. Yet, for each of the indicators examined, a review of baseline characteristics in the matched samples shows that patients who did and did not receive treatment were comparable in terms of severity of illness, even for measures that were not included in the models to establish propensity scores. Furthermore, it was beyond the scope of the current paper to examine other important outcomes that may result from guideline-concordant LtOT, such as the prevention of opioid use disorder or improvement in functional status, pain relief, or patient satisfaction. Importantly, the VA and other state and federal agencies have recently instituted policy and practice initiatives⁵⁶ that may have resulted in improvements in care in the time since our study ended. Finally, with this study, we were interested in the overall impact of guideline-concordant care on mortality and not the differential impact on particular patient subpopulations (e.g., HIV-infected patients). By employing propensity-score matching, we were able to include a range of covariates in the logistic regression models, which is in keeping with our overall research question: understanding the association between guideline-concordant LtOT and all-cause mortality among a diverse group of patients, including those with a high comorbidity and mortality burden. Due to the challenges of external validity inherent in this and other observational research,⁵⁷ we encourage other investigators to replicate our analyses in a variety of patient cohorts.

We opted to focus on all-cause mortality rather than overdose deaths, for several reasons. First, opioids act on a variety of biologic systems and are associated with myriad adverse effects, including cardiovascular, endocrine, immunologic, and gastrointestinal effects—overdose mortality is just one concern.^{25,33,58–64} Moreover, limitations in the basic clinical epidemiology of overdose deaths often results in misclassification of cause of death,^{65–67} which likely precludes an accurate assessment^{68,69} of the association between guideline-concordant LtOT and overdose death. In particular, authorities have noted wide variation in overdose reporting across jurisdictions: medical examiners, coroners, and other practitioners do not use uniform standards and case definitions in conducting surveillance for, or classifying, deaths from overdose.⁷⁰ Finally, we believe caution is indicated when assigning a single cause of death based only on ICD-9 codes to patients with complex medical conditions (e.g., HIV).⁷¹

With this study, our aim was to contribute to the evidence base for clinical practice guidelines promulgated to improve quality of care for patients receiving LtOT. Further research, however, is needed to understand the impact on patient outcomes of targeted interventions⁵⁶ that directly address opioid safety and efficacy,

the optimal timing and frequency of such interventions, and patient subpopulations most likely to benefit. Experimental research, in particular, is needed to determine whether adherence to specific guidelines results in a decrease in mortality and other adverse events. Additional research is also needed to understand the role of guideline-concordant LtOT on cause-specific mortality, especially with regard to overdose deaths.

Our findings from this observational study suggest that adherence to select opioid clinical practice guidelines is associated with lower mortality among individuals initiating LtOT for chronic non-cancer pain. Patients may benefit from interdisciplinary care that extends beyond routine follow-up to encompass multi-modal treatment models—particularly SUD treatment, psychotherapeutic co-interventions, and rehabilitative therapies—that address chronic pain and its associated comorbidities across multiple disciplines.

Author Contributions: Dr. Gaither had full access to all the data in the study and takes responsibility for the integrity of the study and the accuracy of the data analysis.

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Compliance with ethical standards:

Disclosure: The content of this paper is solely the responsibility of the authors and does not necessarily reflect the official views of the National Institutes of Health or the Department of Veterans Affairs.

Conflict of Interest: Dr. Fiellin received an honorarium from PinneyAssociates to serve on an external advisory board to monitor the diversion and abuse of buprenorphine. All other authors declare that they do not have a conflict of interest.

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Assistant Professor at Columbia University's Mailman School of Public Health. Katherine focuses her research on life course epidemiology with particular attention to substance use and psychiatric disorders. Her empirical research has documented a narrowing gender gap in the prevalence and course of alcohol abuse and dependence over time, as well as the effects of changing social norms on birth cohort effects in marijuana and alcohol use in adolescence. Dr. Keyes is an expert on methodological issues in age-period-cohort effect estimation and has conducted age-period-cohort analysis on a range of health outcomes, including autism, obesity, breast cancer, and substance disorders. Her work has highlighted and extended several existing age-period-cohort methods, most notably including the median polish method. Dr. Keyes also has explored the effects of early life exposures on adolescent and adult health, documenting long-term consequences of child maltreatment on internalizing and externalizing psychiatric disorders in adulthood and the sensitizing effects of childhood maltreatment on exposures to stress in adulthood.

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BATTLING NEBRASKA'S OPIOID ADDICTION

Posted: Fri, January 15, 2016

Prescription drug abuse in Nebraska is an extensive problem addressed by local law-enforcement officers, school systems, and medical care providers. Ranging from students raiding the family drug cabinet to a full-fledged addict manipulating the prescription of opiate drugs in order to feed an addiction or sell to the addicted, creating an epidemic in our state.

Unfortunately, Nebraska is one of only two states that currently does not have a mandatory prescription monitoring program (PDMP) in place. This environment makes it easier to doctor shop for pain med prescriptions or falsify a prescription.

The Unicameral is seriously examining changes in policy to combat prescription drug abuse. AG Peterson applauds State Senators Howard and Lindstrom for addressing Nebraska insufficiencies through Nebraska's current legislation.

AG Peterson also commends the Nebraska Medical Association, Nebraska Pharmacists Association, Nebraska Hospital Association, Nebraska Dental Association, and the Nebraska Veterinary Medical Association for collectively addressing opioid addiction by educating their members and participating in the dialogue to develop legislative answers.

"Awareness and education are fundamental in identifying and addressing opioid addiction epidemic in our state," said Peterson, "I appreciate that these organizations are actively addressing concerns through their associations."

Yesterday, Peterson joined 35 Attorneys General^[1] in sending a [letter](#) to the Center for Disease Control (CDC) urging adoption of the CDC's Proposed 2016 Guidelines for Prescribing Opioids for Chronic Pain. The Guidelines provide a foundation for practice in order to reduce deaths and injuries and clear guidance for prescribers to assess the appropriate balance between the potential harms and benefits of opioid use. The letter recognizes doctors will need to adapt the guidelines to meet the individual needs of their patients.

[1] Arkansas, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, and Wisconsin.

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REVIEW ARTICLE

Dan L. Longo, M.D., *Editor*

Treatment of Opioid-Use Disorders

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THIS ARTICLE PROVIDES AN OVERVIEW OF THE CURRENT TREATMENT OF opioid-related conditions, including treatments provided by general practitioners and by specialists in substance-use disorders. The recent dramatic increase in misuse of prescription analgesics, the easy accessibility of opioids such as heroin on the streets, and the epidemic of opioid overdoses underscore how important it is for physicians to understand more about these drugs and to be able to tell patients about available treatments for substance-use disorders.

Opioids include most prescription analgesics as well as products of the poppy plant (e.g., opium, morphine, and codeine).¹ Although opioids usually are prescribed to control pain, diminish cough, or relieve diarrhea, they also produce feelings of euphoria, tranquility, and sedation that may lead the patient to continue to take these drugs despite the development of serious related problems. These problems include the need to escalate doses in order to achieve these desired effects; such levels of opioids can overwhelm respiratory drive and lead to death.^{1,2} Opioid-use disorders are seen in persons from all educational and socioeconomic backgrounds. Recognition of such disorders has contributed to efforts to change physicians' prescribing practices and to train first responders regarding the parenteral administration of naloxone (Narcan or Evzio), a mu-opioid receptor antagonist.²

In the United States, an estimated 400,000 persons have used heroin in the past month and 4 million have reported nonmedical use of prescription pain relievers.³⁻⁵ By some estimates, almost 17,000 deaths per year are related to opioids; drug poisoning is one of the leading causes of accidental death in the United States. Approximately 3 million persons in the United States and almost 16 million worldwide have a current or past opioid-use disorder.⁶ The global burden of disease from opioid-related conditions approaches 11 million life-years lost from health problems, disabilities, and early death.⁷

In the 2013 *Diagnostic and Statistical Manual of Mental Disorders* of the American Psychiatric Association (Table 1), an opioid-use disorder is defined as the repeated occurrence within a 12-month period of 2 or more of 11 problems, including withdrawal, giving up important life events in order to use opioids, and excessive time spent using opioids. A cluster of 6 or more items indicates a severe condition.^{4,8}

The clinical course of opioid-use disorders involves periods of exacerbation and remission, but the underlying vulnerability never disappears.¹ This pattern is similar to that of other chronic relapsing conditions (e.g., diabetes and hypertension) in which perfect control of symptoms is difficult and patient adherence to treatment is often incomplete. Although persons with opioid problems are likely to have extended periods of abstinence from opioids and often do well,⁹ the risk of early death, primarily from an accidental overdose, trauma, suicide, or an infectious disease (e.g., human immunodeficiency virus [HIV] infection), is increased by a factor of 20.¹⁰⁻¹⁵ Legal problems are especially likely in persons with criminal records and high impulsivity.¹³ The risk of adverse outcomes decreases markedly with abstinence from opioids.^{9,16}

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Table 1. Diagnostic Criteria for an Opioid-Use Disorder.*

Use of an opioid in increased amounts or longer than intended
Persistent wish or unsuccessful effort to cut down or control opioid use
Excessive time spent to obtain, use, or recover from opioid use
Strong desire or urge to use an opioid
Interference of opioid use with important obligations
Continued opioid use despite resulting interpersonal problems, social problems (e.g., interference with work), or both
Elimination or reduction of important activities because of opioid use
Use of an opioid in physically hazardous situations (e.g., while driving)
Continued opioid use despite resulting physical problems, psychological problems, or both
Need for increased doses of an opioid for effects, diminished effect per dose, or both†
Withdrawal when dose of an opioid is decreased, use of drug to relieve withdrawal, or both†

* If two or three items cluster together in the same 12 months, the disorder is mild; if four or five items cluster, the disorder is moderate; and if six or more items cluster, the disorder is severe. Criteria are from the *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition.³

† If the opioid is taken only as prescribed, this item does not count toward a diagnosis of an opioid-use disorder.

TREATMENT OF OPIOID-WITHDRAWAL SYNDROMES

Treatment of acute withdrawal syndromes (i.e., medically supervised withdrawal or detoxification)¹⁷ can improve the patient's health and facilitate his or her participation in a rehabilitation program. This treatment also may help patients better consider abstinence from opioids because they can think more clearly once the acute withdrawal phase has passed. However, by itself, medically supervised withdrawal is usually not sufficient to produce long-term recovery, and it may increase the risk of overdose among patients who have lost their tolerance to opioids (i.e., the need for higher doses of the drug to produce effects) and resume the use of these drugs.^{10,12} Repeated misuse of opioids produces tolerance as well as long-lasting craving that usually requires additional treatment in order to avoid a relapse of drug use.

The abrupt discontinuation of opioids after long-term, intense use produces symptoms that are opposite to those of the acute effects that

Table 2. Clinical Opiate Withdrawal Scale for Measuring Symptoms.*

Sign or Symptom	Score
Resting pulse rate measured after patient has been sitting or lying for 1 min — beats/min	
≤80	0
81–100	1
101–120	2
>120	4
Sweating during past half hr not accounted for by room temperature or physical activity	
No report of chills or flushing	0
Subjective report of chills or flushing	1
Flushed or observable moisture on face	2
Beads of sweat on brow or face	3
Sweat streaming off face	4
Restlessness observed during assessment	
Patient able to sit still	0
Patient reports difficulty sitting still but is able to do so	1
Frequent shifting or extraneous movements of legs and arms	3
Patient unable to sit still for more than a few seconds	5
Pupil size	
Normal size for room light	0
Possibly larger than normal for room light	1
Moderately dilated	2
So dilated that only rim of iris is visible	5

Table 2. (Continued.)	
Sign or Symptom	Score
Bone or joint aches†	
None	0
Mild, diffuse discomfort	1
Severe diffuse aching of joints, muscles, or both	2
Patient is rubbing joints or muscles and is unable to sit still because of discomfort	4
Runny nose or tearing not accounted for by cold symptoms or allergies	
None	0
Nasal stuffiness or unusually moist eyes	1
Nose running or tearing	2
Nose constantly running or tears streaming down cheeks	4
Gastrointestinal upset during past half hr	
None	0
Stomach cramps	1
Nausea or loose stool	2
Vomiting or diarrhea	3
Multiple episodes of diarrhea or vomiting	5
Tremor in outstretched hands	
None	0
Tremor can be felt but not observed	1
Slight tremor observable	2
Gross tremor or muscle twitching	4
Yawning observed during assessment	
None	0
Once or twice during assessment	1
Three or more times during assessment	2
Several times/min	4
Anxiety or irritability	
None	0
Patient reports increasing irritability or anxiousness	1
Patient obviously irritable or anxious	2
Patient so irritable or anxious that participation in assessment is difficult	4
Piloerection	
Skin is smooth	0
Piloerection of skin can be felt or hairs standing up on arms	3
Prominent piloerection	5

* For each item, the clinician should record the score that best describes the patient's signs or symptoms. Only signs or symptoms that are related to opiate withdrawal should be rated. For example, if the patient's heart rate is increased because he or she was jogging just before the assessment, the increased pulse rate would not be included in the score. Scores should be entered at time zero, 30 minutes after the first dose of buprenorphine, 2 hours after the first dose, and so forth. A score of 5–12 indicates mild withdrawal, 13–24 moderate withdrawal, 25–36 moderately severe withdrawal, and more than 36 severe withdrawal. Data are from Wesson and Ling.¹⁸

† Only pain that is directly linked to withdrawal from opiates should be scored.

result from physiologic changes during drug use. These changes result in what might be called physical dependence, although physical dependence is not part of the official diagnostic nomen-

clature. Withdrawal syndromes include physical symptoms (e.g., diarrhea and dilated pupils), generalized pain, and psychological symptoms (e.g., restlessness and anxiety) (Table 2).¹⁸ Symp-

toms of abstinence syndromes after discontinuation of shorter-acting opioids such as heroin begin within hours after receiving the prior dose and decrease greatly by day 4, whereas with misuse of longer-acting opioids, such as methadone (Dolophine), withdrawal begins after several days and decreases at approximately day 10. Opioid antagonist–precipitated withdrawal begins almost immediately and lasts approximately an hour after intramuscular or subcutaneous administration of 0.4 to 2 mg of the short-acting antagonist naloxone every 2 to 3 minutes (up to a total dose of 10 mg). Acute withdrawal symptoms are followed by weeks to months of protracted withdrawal syndromes that include fatigue, anhedonia, a poor appetite, and insomnia.^{1,19}

The most effective approach to treating a patient who has withdrawal is to prescribe a long-acting oral opioid (usually methadone or buprenorphine [Buprenex]) to relieve symptoms and then gradually reduce the dose to allow the patient to adjust to the absence of an opioid. However, only licensed addiction-treatment programs (both office-based treatments and inpatient treatments) and physicians who have completed specific training regarding opioid drugs can administer opioids to treat opioid-use disorders.²⁰ Such medically supervised withdrawal can also involve the use of nonopioid medications that help to control symptoms.^{21,22}

This section thus begins with the more generally available but less effective withdrawal regimen with the use of less closely controlled medications than those that are available in specialty clinics.

This review does not describe ultrarapid protocols that precipitate withdrawal with the use of naltrexone in heavily sedated patients because the close medical monitoring of heavily sedated patients is more expensive and more dangerous and produces no better outcomes than the opioid tapers discussed below. Finally, ultrarapid withdrawal protocols by themselves are not likely to increase long-term abstinence from opioids.

DECREASING SYMPTOMS WITH α_2 -ADRENERGIC AGONISTS AND OTHER NONOPIOID AGENTS

As indicated in Table 3, α_2 -adrenergic agonists such as clonidine (Catapres) or tizanidine (Zanaflex) can be used on an off-label basis to decrease anxiety, piloerection, and other signs and

symptoms of autonomic overactivity.²² Anxiety and insomnia are treated with benzodiazepines or other sedating drugs. Diarrhea, nausea, and vomiting are addressed with loperamide (Imodium), prochlorperazine (Compazine), or both, along with sports drinks or intravenous fluids. Pain is mitigated with nonsteroidal antiinflammatory agents such as naproxen (Aleve). Such combination therapies are superior to placebo in alleviating symptoms, but they are not as effective in relieving symptoms as a methadone or buprenorphine taper.

OPIOIDS FOR TREATING WITHDRAWAL

Although methadone and buprenorphine for withdrawal are administered only in specialty programs by physicians with special training, it may be useful for nonspecialists to understand these approaches in order to explain the treatment process to patients whom they refer to specialty programs. Because opioid-withdrawal syndromes are caused by rapidly decreasing drug levels after repeated exposure, symptoms can be reduced by administering other opioids to diminish symptoms and then weaning the patient off the new drug.^{1,4,23} Although any mu-opioid receptor agonist that is long-acting (to create a smoother withdrawal) and oral (for ease of administration) might work, most studies have focused on methadone or buprenorphine.

Methadone Taper

Methadone, an oral mu-opioid agonist, has a half-life of 15 to 40 hours.²³ Controlled trials show that the use of methadone tapers in patients who misuse other opioids is superior to placebo and α_2 -adrenergic agonist-based regimens for managing withdrawal symptoms and retaining patients in treatment programs.²⁴

The condition of patients is first stabilized with a dose that mitigates withdrawal but does not oversedate (Table 4). Then, in outpatients, doses are decreased by 10 to 20% every 1 to 2 days over 2 to 3 weeks or longer.²⁵ The taper can occur over approximately 1 week in inpatients who are going through withdrawal from short-acting drugs such as heroin and, as discussed below, can be as slow as 3% of the dose per week in patients who are discontinuing methadone maintenance.²⁶ Flexible administration of the drug on the basis of a patient's response is important.

Table 3. Opioid-free Treatment of Opioid Withdrawal.*

Medication†	Target Symptoms	Dose‡
<i>α</i> ₂ -Adrenergic agonist		
Clonidine (Catapres)§	Increased pulse rate and blood pressure, anxiety, chills, piloerection	0.1–0.2 mg orally every 4 hr up to 1 mg/day; hold dose if blood pressure <80 mm Hg systolic or <50 mm Hg diastolic; by day 5, start to decrease dose by 0.2 mg/day
Clonidine patch	Increased pulse rate and blood pressure, anxiety, chills, piloerection	The patch is an alternative for patients 100–200 lb (45.4–90.7 kg), with oral dose augmentation, but few data are available
Benzodiazepine		
Temazepam (Restoril)	Insomnia	15–30 mg orally at bedtime
Diazepam (Valium)	Anxiety	2–10 mg orally as needed every 4 hr, up to 20 mg/day
Gut-acting opioid: loperamide (Imodium)	Diarrhea	4 mg orally initially, then 2 mg as needed for loose stools, up to 16 mg/day
NSAID: naproxen (Aleve)	Bone, muscle, joint, or other pain	500 mg orally twice daily as needed (take with food)
Antiemetic		
Prochlorperazine (Compazine)	Nausea and vomiting	5–10 mg orally every 4 hr as needed
Ondansetron (Zofran)	Nausea and vomiting	8 mg orally every 8 hr as needed

* A physical examination should be performed, and abscesses from injections and related conditions should be treated. Human immunodeficiency virus infection, hepatitis, and other infections should be ruled out or treated. The patient should be screened for his or her willingness to participate in a rehabilitation program. NSAID denotes nonsteroidal antiinflammatory drug.

† Medications are administered according to symptoms; not all medications are administered to every patient. Also, there are few definitive data indicating that any drug of a class (e.g., naproxen as an example of an NSAID) is superior to any other drug of the class. The medications listed are examples of only one possible medication. Data are from Kowalczyk et al.²¹ and Gowing et al.²²

‡ Doses are approximate.

§ Clonidine is used on an off-label basis for opioid withdrawal. Tizanidine (Zanaflex) is an alternative *α*₂-adrenergic agonist cited in the literature and used on an off-label basis for opioid withdrawal, and outside the United States, lofexidine at a dose of 0.4 mg every 4 hours (up to 2 mg per day) has been used.

Buprenorphine Taper

Buprenorphine is an analgesic that is available as a sublingual monotherapy or in combination with naloxone as a film strip for sublingual use (e.g., Suboxone or as a generic formulation) or in a buccal dissolving film (Bunavail). This review focuses on buprenorphine itself, which is a mu-opioid receptor partial agonist (binding only partially to the mu-opioid receptor with resulting competitive antagonism of concomitantly administered full agonist drugs), an agonist of delta and opioid-like receptor-1 (or nociceptin) opioid receptors, and a kappa-receptor antagonist.^{27–29} Like methadone, it has advantages of oral administration and a long “functional” half-life. (With a half-life of 3 hours, buprenorphine does not easily disassociate from mu-opioid receptors.)

Methadone and buprenorphine produce similar improvements during opioid withdrawal, although buprenorphine is associated with less sedation and respiratory depression. To avoid

precipitating more intense withdrawal, buprenorphine should be initiated 12 to 18 hours after the last administration of opioids in patients who misuse shorter-acting opioids (48 hours in patients who are receiving long-acting drugs such as methadone), with initial doses of 4 to 8 mg. Additional doses up to 16 mg may be administered, depending on the patient’s response. After the patient’s condition is stabilized for 3 to 5 days, the dose is often decreased over 2 or more weeks; more opioid-free urine samples are seen with a 4-week reduction protocol than with a shorter reduction protocol.

APPROACHES TO REHABILITATION AND MAINTENANCE

BACKGROUND

Once patients express interest in discontinuing or diminishing drug use, the core of care depends on the same kinds of cognitive behavioral approaches that are used for other chronic, relaps-

Table 4. Treatment for Symptoms of Opioid Withdrawal with the Use of a Taper with Long-Acting Opioid Agonists or Partial Agonists.*

Step	Oral Methadone	Sublingual Buprenorphine
Preparation	Perform physical examination	Perform physical examination. Administer buprenorphine approximately 12–48 hr after most recent opioid use and while patient is having early withdrawal symptoms (e.g., score >10 on the Clinical Opiate Withdrawal Scale†)
Initial dose	If patient is participating in a methadone program, verify dose; start taper 10 mg below that level; if patient is not participating in a methadone program, start at 10–30 mg administered in divided doses	4–8 mg
Stabilization at effective dose	7–14 days	2–5 days
Taper	Administer 10–20% of initial dose every 1–2 days over 2–3 wk or more	Decrease dose to 0 by reducing dose 10–20% every 1–2 days over 2 wk or more

* To ensure the patient's health and to relieve withdrawal symptoms, a long-acting opioid agonist or partial agonist can be administered and then slowly tapered. If possible, the patient should be cared for in an inpatient or outpatient rehabilitation program. All doses are approximate for an average patient and vary according to the patient's condition and additional medications. It is very important to check the patient 1 to 3 hours after the medication is administered in order to adjust the dose and avoid doses that are too high or too low for the individual person.

† Scores on the Clinical Opiate Withdrawal Scale range from 0 to more than 36, with higher scores indicating a greater severity of withdrawal.

ing conditions, such as hypertension and diabetes mellitus.^{1,30} These approaches include working with patients to encourage motivation to change, enhance adherence to medication through education, reward cooperation with treatment guidelines,^{30,31} keep motivation high, and teach ways to minimize relapses to drug use. Most of these elements are part of motivational interviewing.³²

Unlike some rehabilitation approaches for some other disorders, patients with substance-use disorders are encouraged to participate in self-help programs such as Alcoholics Anonymous and Narcotics Anonymous.^{30,33} The combination of education, motivational enhancement, and self-help groups, which are incorporated into individual and group counseling approaches in inpatient and outpatient programs, helps patients change how they think about the ways that opioids affect their lives, recognize that change is possible, and work to decrease behaviors that perpetuate illicit-drug use while developing new behaviors that diminish drug-related problems.^{1,30}

NALTREXONE FOR ABSTINENCE-ORIENTED OPIOID REHABILITATION

Naltrexone is a mu-opioid receptor antagonist that blocks opioid effects and helps maintain abstinence from opioids in highly motivated patients.^{23,28} It is available in 50-mg daily tablets with effects lasting 24 to 36 hours. To help maintain adherence to treatment when used as part of an outpatient rehabilitation program, it is also available as an extended-release injectable formulation containing 380 mg of naltrexone (Vivitrol) that blocks opioid effects for 1 month.^{34–36}

Medication treatment is most effective when it is administered as part of a cognitive behavioral approach (to enhance motivation, work toward behavioral changes, and prevent relapse) with patient participation in a self-help group. Side effects of these medications include gastrointestinal upset, fatigue, and insomnia, as well as elevated levels on liver-function tests at higher doses, although naltrexone is relatively safe in persons who consume large amounts of alcohol and those with hepatitis C or HIV infection.^{23,36,37}

Patients who initiate naltrexone treatment must be free of physiological opioid dependence

(e.g., >7 days without acute withdrawal symptoms) (Table 5). Opioid-free status can be established by an opioid-free urine sample and a challenge with 0.8 to 1.6 mg of intravenous or intramuscular naloxone with no withdrawal symptoms over the next 15 to 30 minutes before receiving naltrexone (at a dose of 50 mg) that same day. An alternative challenge is to administer a small dose of naltrexone (e.g., 12.5 to 25 mg) orally, and if no withdrawal is seen over the next 4 hours, administer 50 mg orally. After the patient's condition is stable and he or she is abstinent from opioids, it may be possible to switch to 100 mg orally on Monday and Wednesday and 150 mg on Friday, or to monthly depot injections. If naltrexone is used following abstinence from opioids after methadone or buprenorphine maintenance, the induction might be slower (e.g., 12.5 mg orally on day 1; 25 mg on days 2 and 3; and then 50 to 100 mg thereafter).^{34,38}

Efficacy studies have generally used oral rather than intramuscular doses of naltrexone, but both forms are superior to placebo for maintaining abstinence from opioids, with some evidence that monthly injections are superior to oral doses.^{35,39} However, in most studies of oral naltrexone, approximately 50% of patients discontinued the drug by 6 weeks, with only 15% remaining in the study at 25 weeks in some evaluations.⁴⁰ Higher rates of adherence are seen with opioid maintenance, as described below.^{11,41} In addition, because of the loss of tolerance that occurs with abstinence from opioids, the danger of overdoses that may lead to death is enhanced among patients who discontinue naltrexone and return to opioid use.¹¹

OPIOID MAINTENANCE APPROACHES

Opioid-dependent persons who are reluctant to or unable to discontinue opioids but want to improve their health and life situation can markedly improve their daily functioning with opioid treatment. Oral opioids to avoid past reinforcement associated with needles, as well as relatively inexpensive, long-lasting opioids to avoid daily withdrawal symptoms and enhance adherence, are available.^{10,11,42} Maintenance goals include improving health, avoiding contaminated needles and risks of HIV or hepatitis C infection, improving interpersonal relationships and the ability to work, decreasing craving and the rewarding effects of illicit opioids,

Table 5. Medications for Rehabilitation from an Opioid-Use Disorder, According to the Patient's Treatment Goal.*

Stage or Function	Full Abstinence from Opioids			Opioid Maintenance	
	Naltrexone	Methadone	Buprenorphine†	Methadone	Buprenorphine†
Action	Blocks opioid high	Long-term maintenance with the use of an oral, long-acting opioid	Long-term maintenance with the use of an oral, long-acting opioid	Long-term maintenance with the use of an oral, long-acting opioid	Long-term maintenance with the use of an oral, long-acting opioid
Restriction	Patient must be opioid-free	No misuse of depressant drugs or medical contraindications; can be used only in specialized programs, not in office-based practices	No misuse of depressant drugs or medical contraindications; can be used in offices of physicians with special training	No misuse of depressant drugs or medical contraindications; can be used in offices of physicians with special training	No misuse of depressant drugs or medical contraindications; can be used in offices of physicians with special training
Induction and stabilization	Induction (on day 1): to ensure that drug does not cause withdrawal, administer 12.5–25 mg orally as a test; if no withdrawal, 4 hr later administer 25–50 mg orally; if no withdrawal on day 1, on day 2 initiate 50–100 mg orally daily	Induction and early stabilization (at wk 1 and 2): begin 15–30 mg orally and increase by 10–15 mg every 3–5 days up to 50–80 mg/day in most patients; late stabilization (at approximately wk 3–6): adjust dose according to side effects, craving, and adherence (usual dose, 80–100 mg/day)	Induction and early stabilization (at approximately 7 days): begin with 4–8 mg and increase to 16 mg/day on the second day, with further daily increases by the 7th day (rarely for a total of >30 mg/day); stabilization (at approximately wk 8): increase doses to as high as 32 mg/day, depending on craving and side effects	Induction and early stabilization (at approximately 7 days): begin with 4–8 mg and increase to 16 mg/day on the second day, with further daily increases by the 7th day (rarely for a total of >30 mg/day); stabilization (at approximately wk 8): increase doses to as high as 32 mg/day, depending on craving and side effects	Induction and early stabilization (at approximately 7 days): begin with 4–8 mg and increase to 16 mg/day on the second day, with further daily increases by the 7th day (rarely for a total of >30 mg/day); stabilization (at approximately wk 8): increase doses to as high as 32 mg/day, depending on craving and side effects
Maintenance	If patient is abstinent from opioids and cooperative, consider administration of 100 mg orally on Monday and Wednesday and 150 mg on Friday; may also consider switch to 380-mg depot injection once/mo	From approximately wk 6 to >1 yr; at approximately 8 wk, consider weekend take-home doses if patient is adherent; consider weaning from methadone after >1 yr‡	From approximately wk 6 to >1 yr; at approximately 8 wk, consider weekend take-home doses if patient is adherent; consider weaning from methadone after >1 yr‡	From approximately 9 wk to >1 yr; maintenance begins when the most appropriate dose is achieved, although further adjustments may be needed; consider weaning after approximately 1 yr‡	From approximately 9 wk to >1 yr; maintenance begins when the most appropriate dose is achieved, although further adjustments may be needed; consider weaning after approximately 1 yr‡

* Doses are approximate. All rehabilitation approaches should include cognitive behavioral therapy or similar counseling.
 † This medication contains buprenorphine plus naltrexone in a ratio of 4 mg to 1 mg.
 ‡ Risks of returning to illicit-drug use and overdoses that may lead to death increase when maintenance is discontinued.

and diminishing crimes committed to pay for illicit drugs.

Maintenance programs should include psychological support, require participants to take part in counseling, offer education about how to deal with pain syndromes without misusing prescription opioids, and warn patients to avoid misuse of other drugs such as benzodiazepines and gabapentin (Neurontin) that they might use to create a high while receiving opioid-agonist treatment. It is important to carefully monitor the use of illicit drugs and diversion of the medications for opioid treatment to other users.⁴³ Although, theoretically, any long-acting oral opioid might be used for maintenance, the only approved drugs for this use in the United States are methadone and buprenorphine.

METHADONE MAINTENANCE APPROACHES

Maintenance treatment with methadone, an oral mu agonist, has been widely used and intensively studied worldwide. In the United States, methadone is offered only through approved and closely monitored clinics that initially require almost daily patient participation in order to receive the drug, although some take-home doses are usually allowed for patients who adhere to program guidelines.

To be eligible for methadone maintenance, patients must have a current opioid-use disorder with physiologic features or have high risks associated with relapse (e.g., during pregnancy). In addition, patients cannot be currently participating in another maintenance program and cannot be especially vulnerable to methadone-related medical complications (e.g., they cannot be dependent on a depressant drug or have severe respiratory or cardiac disease). Dangers associated with methadone include overdose if the dose is increased too quickly during the initial stages of treatment and a potential prolongation of the QT interval on electrocardiography that can contribute to cardiac arrhythmias with doses higher than 100 mg per day.⁴⁴⁻⁴⁶ Patients must understand their roles and responsibilities as well as the benefits that the program can and cannot offer.

Methadone maintenance treatment occurs in approximately three phases (Table 5).⁴⁷ The induction and early stabilization phase (beginning at week 1 and continuing in week 2) begins with

initial oral doses of 15 to 30 mg, increasing by 10 to 15 mg every 3 to 5 days to 50 to 80 mg per day. During the late stabilization phase (at approximately weeks 3 to 6), doses are increased as tolerance develops and craving decreases. The most effective dose is 80 to 100 mg per day.⁴⁷⁻⁵⁰ Patients who receive more than 100 mg per day must be closely monitored for side effects.^{44,46,50}

The maintenance phase begins at approximately 6 weeks, with doses adjusted to avoid drug-related euphoria, sedation, or opioid craving. Methadone clinics must be open on weekends in order to meet the needs of most patients,⁵¹ and weekend take-home doses are based on the patient's progress in treatment and determination that he or she is unlikely to divert medications to other persons. The length of the maintenance phase, which depends on the patient's progress in treatment and his or her motivation, can last years to a lifetime.

Tapering off methadone is individualized and may take weeks or months.²⁶ During and after tapering, close contact with the patient should be maintained because discontinuation of maintenance carries high risks of relapse to the use of illicit drugs and overdoses that may lead to death.^{11,52,53}

The effectiveness of methadone maintenance is well established, and this drug is listed among "essential medications" by the World Health Organization.^{11,45} Maintenance programs decrease mortality by approximately 50% among persons with opioid-use disorders, decrease acquisition of HIV infection and hepatitis, decrease crime and illicit-substance use, improve social functioning, and increase the rate of retention in rehabilitation programs.^{15,50,54,55}

BUPRENORPHINE MAINTENANCE

In the United States, the restriction of methadone to specialized clinics contributed to a search for an alternative oral, long-acting opioid. This search resulted in buprenorphine maintenance therapy.^{6,56,57}

Although oral buprenorphine is rapidly destroyed in the liver, it is well absorbed as a sublingual tablet or buccal film.^{6,28} Buprenorphine has effects that last for 24 to more than 36 hours. It reduces opioid-withdrawal symptoms and partially blocks intoxication from other opioids.^{6,28} Physicians who are approved to prescribe bu-

prenorphine for office-based maintenance were initially limited to 30 such patients at a time, a number that was increased to 275 patients in July 2016. They must prescribe buprenorphine themselves (e.g., not through a nurse practitioner), must offer counseling or be able to refer patients for counseling, and must agree to participate in Drug Enforcement Administration inspections.

The risks associated with buprenorphine include overdoses, especially if it is taken along with depressant drugs, and potential illicit diversion of drugs.^{58,59} However, mortality during induction with buprenorphine is lower than that during induction with methadone; this finding contributed to approval for office-based maintenance treatment by physicians with special training and certification.⁶

To discourage the misuse of intravenous buprenorphine, maintenance therapy involves a sublingual or buccal combination of buprenorphine and the short-acting opioid antagonist naloxone, usually in a 4-to-1 ratio across the two drugs.^{6,60} Because of the low doses of naloxone administered and the low proportion of this drug that is absorbed orally, this opioid antagonist does not precipitate withdrawal unless it is injected intravenously, in which case the withdrawal symptoms can be sudden and severe.

Patient selection criteria for buprenorphine maintenance resemble the above-mentioned criteria for methadone maintenance.⁵⁷ Although treatment protocols vary depending on specific patients' needs, the usual process is briefly discussed here.^{56,57,61} The patient must have early signs of withdrawal to avoid precipitating an abstinence syndrome when he or she is taking high doses of the drug of abuse.

The induction phase lasts approximately 7 days in patients who are misusing a short-acting opioid such as heroin. On day 1, typical patients receive 4 to 8 mg of buprenorphine. On day 2, the dose is increased up to 16 mg, with further daily increases by day 7 but rarely a total of more than 30 mg per day. The stabilization phase (at approximately 8 weeks) begins when craving is markedly reduced, opioid misuse is diminished or absent, withdrawal symptoms are absent, and a stable dose has been achieved. If needed, doses can be increased up to 4 mg each week up to a daily dose as high as 32 mg; the condi-

tion of most patients stabilizes at 16 to 24 mg. At doses of less than 8 mg per day, the program may not be effective, and higher doses may be required to achieve the maximum effect.^{6,10,62}

The maintenance phase begins when the most appropriate dose is established. The usual minimum length of treatment is 12 months, although, as with methadone, risks of relapse and overdose increase when buprenorphine is discontinued.⁶³ If the patient and physician decide that a buprenorphine taper should be initiated, doses should be decreased slowly while the dose is monitored and adjusted according to the withdrawal symptoms observed.

Strong and consistent data support the effectiveness of buprenorphine maintenance, as compared with placebo and naltrexone, especially at a dose of 16 mg or more per day.^{6,61,62} Initiating buprenorphine maintenance as soon as possible (e.g., while the patient is hospitalized or after an emergency department visit) can enhance efficacy.⁶⁴ Combining maintenance therapy with a cognitive behavioral approach might improve outcomes.

There are no hard-and-fast rules regarding whether to refer a patient to a clinic for methadone maintenance or for buprenorphine maintenance. Considerations include cost; the availability of methadone clinics and physicians who are trained in administering buprenorphine; the match of demographic factors, educational levels, and socioeconomic backgrounds between the patient and treatment programs; the patient's coexisting medical and psychiatric conditions; and individual clinician and patient preferences.⁶⁵

Direct comparisons between methadone and buprenorphine show that both approaches improve outcomes, but most studies suggest that methadone maintenance might be associated with higher rates of patient retention.^{10,50,65-67} Also, buprenorphine is more expensive than methadone, and the private-office charges for buprenorphine might exceed the usual costs of a methadone clinic. However, buprenorphine is safer than methadone during induction and can be administered in offices of trained clinicians; the availability of treatment in clinicians' offices improves access to opioid maintenance.

Universal agreement on how long a patient should continue to receive maintenance therapies is lacking. Some clinicians prefer to work with patients to attempt to discontinue their medications after approximately 1 year, and others emphasize the high rate of relapse and overdose deaths after leaving these programs and suggest that treatment should be open-ended and potentially lifelong.

Finally, just as this article provides a broad overview of medically supervised withdrawal, this overview of rehabilitation focuses only on the most widely used approaches. Morphine and heroin are used less often than methadone and buprenorphine as maintenance treatments, and fewer data are available regarding their use for this purpose.

CONCLUSIONS

This review describes one person's view of what the usual practicing clinician should know about the current state of treatments for opioid-use disorders. The topics that are likely to be most useful to nonexperts in the field are included. The areas that are not covered (e.g., basic pharmacologic approaches and potential treatments that are still in early stages of development, most of which are not likely to progress to clinical implementation soon) are less likely to have immediate clinical utility.

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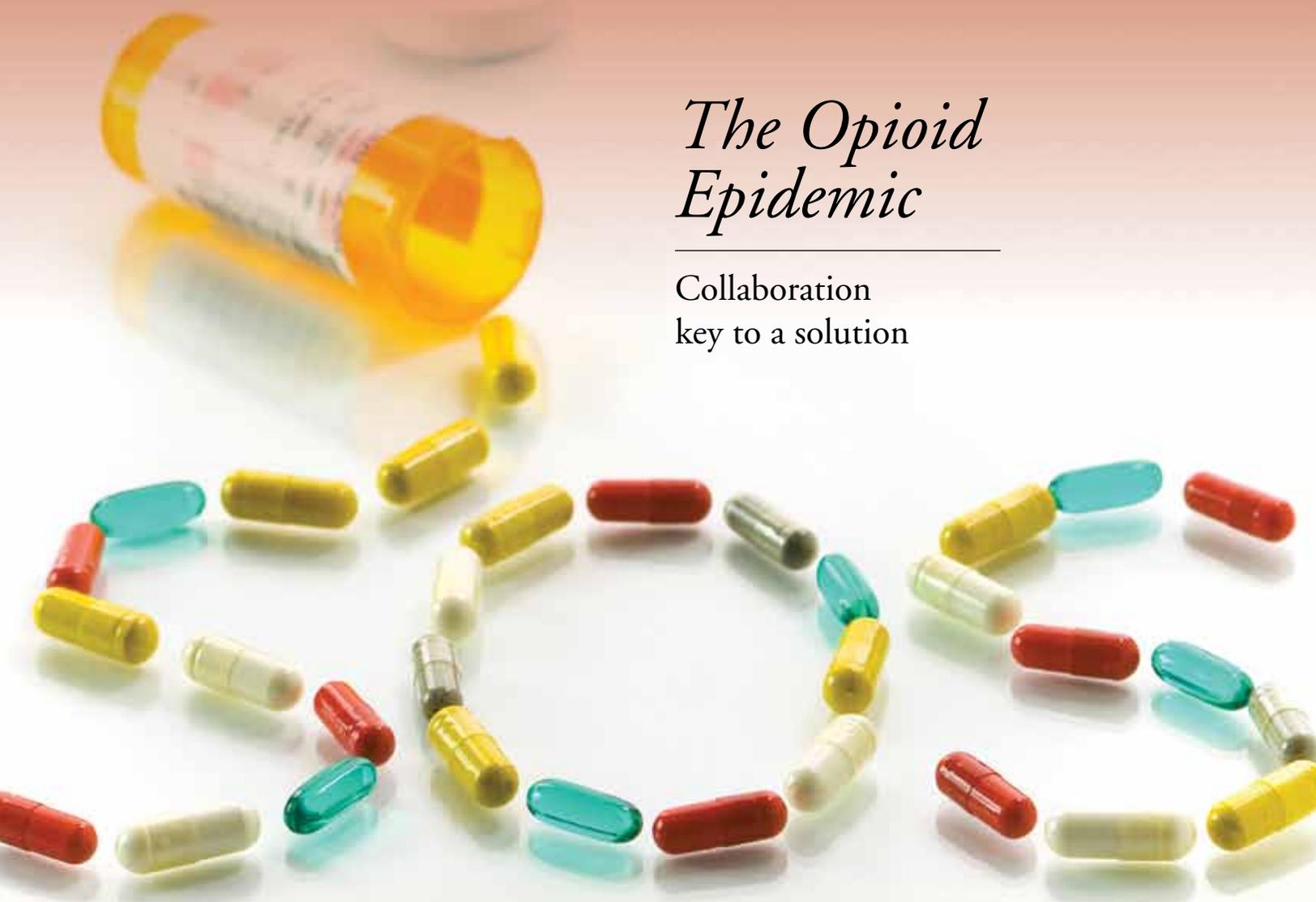
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The Opioid Epidemic

Collaboration
key to a solution



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President's Message

by Harris Frankel, MD
NMA President

I am greatly honored to be the newly elected president of the Nebraska Medical Association. I accept your confidence and willingness to lead this organization in what will surely be another year of opportunities for Nebraska physicians to advocate for not only our profession, but most importantly, our patients.

I would like to express my sincerest thanks to 2014-15 President Richard Blatny, Sr., of Fairbury for the outstanding job he did representing us this past year; a job truly well done.

Let me begin with a quote: "Medicine is in essence, a moral enterprise and its professional associations should therefore be built on ethically sound foundations." (Edmund Pellegrino and Arnold Relman)

Our reputation as an organization is and always has been in your hands as members...to advocate for our patients and the profession of medicine.

We demonstrate our relevance by leading those conversations that our patients, colleagues, the public and legislators are listening to. We need to embrace interprofessional education, clinical care and advocacy. The totality of cooperative and collective influence

can be much greater than the sum of the parts.

As members of our professional organization, as advocates for patients and public health alike, we have the responsibility to shape and influence health policy and not let it define us. We also have the responsibility to educate and advocate. Nothing is more critical to the future success of health care than for physicians to lead.

The big question is: do we have the will to do so?

Medicine has been, remains, and always will be a noble profession... a profession that has engendered trust which we must continue to earn. I have the utmost faith in the future of our profession. However, we are at a crossroads and face tremendous headwinds in the near term.

I would ask each of you to be a mentor. Show your younger partners and/or associates the importance of being involved; the importance of being heard. Ultimately, however, we must act together. Though we can make a difference as individuals, we need the strength of team...and there is no "I" in team.

In closing, I would like to partly quote one of the most famous speeches ever; that by Al Pacino in his role as

coach Tony D'Amato in the movie *Any Given Sunday*:

"On this team we fight for that inch.

On this team we tear ourselves and everyone else for that one inch.

We claw with our fingernails for that inch. Cause we know, when we add up all those inches that's going to make the difference between winning and losing; living and dying.

I'll tell you this, in any fight, it is the guy who is willing to die who is going to win that inch. And I know, if I am going to have any life anymore, it is because I am willing to fight and die for that inch...because that's what living is... the six inches in front of your face. I can't make you do it. You gotta look at the guy next to you. Look into his eyes. Now I think you are going to see a guy who will go that inch with you. You will see a guy who will sacrifice himself for the team because when it comes down to it, he knows you'll do the same for him. That's a team gentleman. Either we heal as a team or die as individuals. That's football guys. That's all it is. Now what are you going to do?"

So I ask you, what are you going to do? □



Executive Vice President's Message

Perspective

by Dale Mahlman
NMA Executive Vice President

Perspective is always interesting when it comes to politics and our everyday life. The past couple of years have provided me several opportunities to

keep my perspective in balance and as a result, I think I have a better understanding of what I think about different things.

Regarding the political world, having 15+ candidates for the Republican nomination for the Presidency meant watching multiple televised debates and hoping one of the candidates will jump out as the "best" option. However, my perspective on this is that the circus environment will continue until a few more drop out and one of the frontrunners begins to draw support from the whole party. For now, watching Mr. Trump proves to be entertaining and my hope is that all candidates, Republican and Democrat alike, have the end goal of making America great again. Nevertheless, as the caucuses and primary approach, let the posturing continue.

In viewing the local political environment, my perspective is term limits have motivated many good candidates

across the state to consider a run for the Nebraska Legislature. Our interest as an organization has been to get a physician elected to the Legislature. The last physician in office, Senator Joel Johnson, MD, of Kearney, left the Legislature in 2008. This year, we have TWO excellent candidates in District 25, Southeast Lincoln and rural Lancaster County, running against each other so while we like our chances better than in past years, we still have the difficult task of determining which of these excellent NMA members, Dr. Les Spry or Dr. Dale Michels, might advance to the November 2016 general election. The next four to five months until the primary will be critical for both candidates but knowing them both well, they will get their message to their constituents effectively.

With regards to health and wellness, two years ago the Nebraska Medical Association participated in a wellness conference in Nebraska City which focused on living a healthy lifestyle and the importance of healthy eating and exercise. Since that time I personally have had a new perspective on both, and the NMA has been active with Teach a Kid to Fish and Husker Sports Marketing promoting the ENERGY message created by Teach a Kid to Fish at Husker Sport-

ing activities, both in venue and on radio. Having heard Dr. Ali Khan, dean of the UNMC College of Public Health, recently describe his goal to make Nebraska the healthiest state in the nation, (we are currently ranked #10), makes a strong case that all Nebraskans, young and old alike, can do more individually and collectively in making Nebraska an example for all to follow.

What's next for organized medicine in 2016? Health care delivery and transformation will continue on many levels, and the NMA will be actively involved in the discussion. Medicaid will see the introduction of THREE managed care companies statewide and that will be a change. Practice transformation resulting from CMS grants will be occurring and for most of our practices it will be business as usual. The NMA will be engaged and active with all these efforts.

Lastly, dues statements for 2016 have been mailed. We hope from your perspective that the NMA continues to be a value to you and you continue to support the mission of the NMA, "To serve our physician members as advocates for our profession, for our patients and for the health of all Nebraskans." With all of you on our team, we can accomplish that goal. □



What can Physicians do to Reduce the Epidemic of Prescription Drug Abuse?

by John R. Massey, MD
State Representative American Academy
of Pain Medicine
Lincoln

Nebraska and Missouri are the last remaining states that have yet to implement a working prescription drug monitoring program. CDC data reports 23,000 prescription opioid / benzodiazepine deaths in 2013, (63/day). An additional 1 million ED visits were for prescription opioid/ benzodiazepine overdoses. Insurance industry analyses indicate the direct medical cost to be in excess of \$15,000 per patient with substance abuse, with far higher indirect costs. The Nebraska Medical Association has been working for years to advocate for legislation and funding to implement a working PDMP. When testifying to the legislative committee I'm always asked: "What are physicians doing to reduce the epidemic of prescription drug abuse?"

Good question. This is an iatrogenic epidemic. As physicians we tend to talk about "drug seekers" and "doctor shoppers." Problematically, the majority of patients who overdose are getting prescriptions from a single prescriber and are taking their medications not for recreational purposes, but in an attempt to treat or eliminate acute or chronic pain.

As medical providers, we are tasked with helping our patients understand the risks and benefits of any treatment we offer. We may differ individually on the nuances of this ongoing evaluation. Nonetheless, we are required by the state to evaluate and document the risk

/benefit ratio of controlled substances whenever we are utilizing them as a portion of care for patients in pain. We tell politicians that they are entitled to their own opinions, not their own facts. As providers, we can differ on the relative risk/ benefit ratio of any given treatment, but we must use data whenever possible to document an understanding of this ratio.

Opioids are often our best weapon for acute pain. They are much less effective at reducing chronic pain. Most studies show an expected 25-30 percent reduction in severity of chronic pain with the use of opioids. Studies differ on the prevalence of substance abuse issues in the population of patients with chronic opioid management. The number is somewhere around 13 percent. Furthermore, opioids tend to show the expected benefit for the first 4-12 weeks in the treatment of a pain state and then can steadily lose efficacy. Many chronic pain states become relatively opioid resistant. This further sets the stage for long-term complications as patients try to maintain the initial benefits they experienced over the course of time.

We can and must do better. When we employ a systematic and data driven approach to measuring the risks versus the benefits of controlled substances, we also increase patient satisfaction, pain relief and safety. While at the same time we reduce physician and staff frustration as well as time burden. With a small investment in education and organization we can leverage data collection to improve our care for these patients.

This process is called **Universal Precautions for Opioid Prescribing**. Just as in universal precautions are utilized to reduce the risk of blood borne pathogen transmission, this process utilizes validated metrics to assist in clinical decision making. It stratifies risk for prescribing before opioid therapy is initiated, as well as longitudinally during the management of these patients to monitor for subsequent development of problematic medication use. This process also utilizes the 4 As: Analgesia, Adverse effects, Activity, Aberrant behaviors. Documentation of these four factors correlates with best practice and not coincidentally is required by state statutes to be evaluated and documented for all patients who received these medications. As physicians we most commonly focus on patient reports of analgesic efficacy and adverse effects.

Activity maintenance and improvement has been shown to more closely correlate with long-term success or failure of treatment with opioids. Aberrant behaviors are commonly seen and are very commonly misidentified or overlooked by clinicians. The accumulation of aberrant drug taking behaviors becomes an indication of loss of control of the use of medications. These are often misunderstood or overlooked by prescribing clinicians. As such we miss the opportunity to intervene on behalf of our patients.

It is never possible to treat pain in the face of unrecognized substance abuse. A

(continued on Page 16)



The Emergency Room perspective

by Jason Kruger, MD
Lincoln

Prescription drug abuse is at epidemic levels across the United States. Death rates from prescription drug overdoses have increased dramatically since the late 1990s. As physicians we sometimes face a dilemma when prescribing controlled substances. First, we want to believe our patients. Most of our patients tell the truth and use their medications for the appropriately prescribed reasons. As physicians, we want and need the ability to treat acute pain in our patients. As physicians, we must balance this duty to treat with our duty to do no harm. Patients who struggle with addiction are often not entirely truthful. As an emergency medicine physician, I typically do not have a long-term established physician/patient relationship with the patients I see and treat in the emergency department. When I go through a history and physical exam with my patients, often the only information I have on their past and current medical history is the information they tell me. Again, most of



the time our patients participate in their health care in an honest and forthright manner. However, patients who struggle with addiction will give limited or false information in an attempt to further fuel their addiction. As an emergency physician, I need to be able to appropriately treat pain, but I do not want to further fuel a patient's addiction problem.

As an emergency physician in Nebraska, I practice in one of only two states that do not currently have a functioning prescription drug monitoring program (PDMP). In the spring of 2011, our state Legislature passed LB 237, a bill that was intended to establish a PDMP in the state of Nebraska. The bill passed unanimously and the Governor signed the bill into law that year. Unfortunately, there was no funding attached to the bill and Nebraska remains without a functioning PDMP.

Every day in the emergency department we see and treat patients with acutely painful conditions. Patient safety is a critical concern for all practitioners. It is impossible to tell if someone is abusing prescription controlled substances by simply looking at them. Providers need

information to make an informed decision on how best to safely treat a patient. With good information, we can appropriately intervene with patients who are using controlled substances in an unsafe manner. Frequently, friends and family members are unaware when their loved one is dealing with issues of addiction. Addiction is a treatable condition if it is identified and early treatment is preferable for success. Without the independent information available in a PDMP, providers are left guessing as to whether the patient in front of them is providing a full and accurate history.

It is challenging to prescribe potentially addictive pain medications to patients without the ability to independently verify their past controlled substance prescription drug history. Both prescribers and dispensers of controlled substances need the ability to independently verify prescription controlled substance histories to safely and effectively do their jobs. We do not want to harm our patients who struggle with addiction by giving them more addictive medications. When addiction goes unrecognized, the end result too frequently is death. □

Chasing the Dragon... The Resurgence of Heroin

by Jane Theobald, MD
Methodist Health Systems

There is nothing like the illness of a loved one to motivate a physician's quest for knowledge. Sadly, this is my story. I am a psychiatrist specializing in treatment of those with pain disorders and cancer. I see a fair amount of addiction. I believed for so long these stories belonged to my patients, but not to me. A year ago that belief came crashing down around me as I stumbled upon my own family's melee with heroin. My story is like thousands of others. But it is mine.

Until recently, heroin was viewed as a drug that's allure had peaked in the 1960s. It was the untouchable leper of recreational drugs only a very few individuals would ever dare try because consequences were viewed as so dangerous and unforgiving. Then OxyContin (oxycodone) and all her sisters came to town and deceptively changed the landscape.

Not long ago, there was an air of urgency in addressing and alleviating pain. In 1996 pain was dubbed "the 5th vital sign" by the American Pain Society and clinicians were urged to "optimize analgesic use." Patients and their loved ones viewed pain as unacceptable and often demanded aggressive treatment. Prescribing of opiates skyrocketed with the unintended consequence of addiction following in the wake.

While marijuana has often been viewed as the gateway drug for "harder" drugs, prescription opiates have proven to be the thoroughfare for heroin's resurgence. Patients prescribed opiates for legitimate pain concerns inadvertently get caught in the web of addiction as they find the medication numbs their emotional

pain. Kids as young as 12 or 13, oblivious of potential consequences, begin experimenting by sampling right from mom and dad's medicine cabinet. New heroin users are now more likely to be young, white and from affluent families. Average age of first use is often in the early 20s and typically follows dependency on prescription opiates. Users are frequently college educated and holding down full time jobs.

Where there is a market, there is a business opportunity, and opiate "pill mills" began cropping up across the landscape in the early 2000s. Eventually, the FDA intervened with a crackdown on such operations and there was a push to educate clinicians about safer prescribing. However, the horse was out of the barn. As opiates became increasingly expensive, a new business opportunity was ripe for the taking. OxyContin on the black-market can bring around \$80 per tablet. Heroin is cheap to produce and an equivalent dose costs only about \$10. Individuals facing a costly psychological dependency on OxyContin with brutal physical withdrawal symptoms, often find the switch to heroin an easy decision to make. Distribution networks are well established by worn pathways of the marijuana trade which has become less profitable as more and more states have legalized it in one form or another.

It was once believed heroin was the most addictive substance known. This has since been questioned. However, there is one key difference between this drug of abuse and others. One single miscalculation of dosage due to variability in potency can be fatal. Again, one single miscalculation of dosage can be **fatal**... and often is. The number of heroin overdoses across

the U.S. has skyrocketed over the last five years. This does not exclude Nebraska. The trenches are deep here in the Midwest. According to Sgt. Dave Bianchi, spokesman for the Omaha police department, heroin users are now much younger and located in the city's wealthy neighborhoods. Deaths from overdose have occurred across the state, from metropolitan areas to tiny burghs. Visiting drug treatment centers in the state reveals history of heroin use is no longer an anomaly.

Education of physicians and vulnerable populations has been slow in coming. Affordable and effective treatment options for heroin use disorder remain elusive. There is little evidence supporting conventional chemical dependency treatment program or support group effectiveness. Structured individual cognitive behavioral therapy may be helpful, but it is often hard to find. Programs shown to reduce risk of morbidity and mortality include needle exchange, medically supervised injection centers, methadone and buprenorphine/naloxone (Suboxone) maintenance, and increasing naloxone (Narcan) availability. Naltrexone, not to be confused with naloxone, has shown promise in the medical management of opiate cravings. This includes an oral daily form (Revia) and a long acting injectable form (Vivactrol). Portugal's policy of decriminalization of heroin use in favor of aggressive treatment has shown surprising success.

As my colleagues, I encourage you to ask your patients about heroin use. Directly. They just might tell you. And if they do tell you, you might be able to

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Nebraska Department of Health and Human Services
HEALTH ALERT NETWORK
Advisory

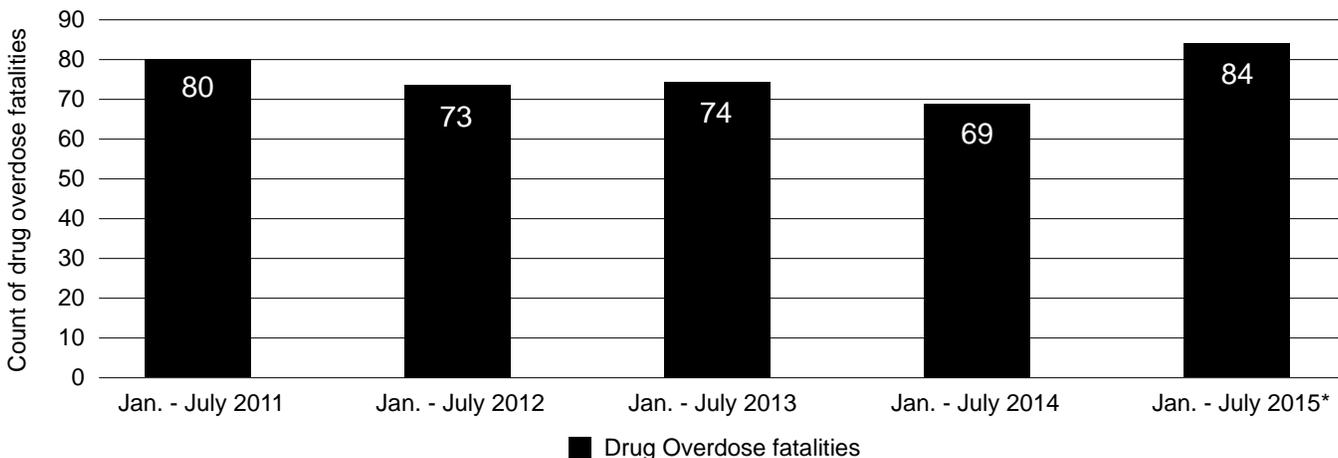


TO: Primary care providers, anesthesiologists, ERs, pharmacies, and public health
 FROM: Thomas J. Safranek, M.D.
 State Epidemiologist
 PHONE: 402-471-2937
 E-MAIL: tom.safranek@nebraska.gov
 RE: **Notification - LB 390 Expanded use of Naloxone**
 DATE: September 22, 2015

Background

During January–July 2015, 84 drug overdose fatalities have been identified in Nebraska (12 deaths/month) representing the highest number of deaths for this time period in the past five years. (Figure).

Figure 1. Number of Drug Overdose Fatalities January - July Nebraska 2011-2015*



Data Source: Nebraska Vital Records, 2011-2015 *preliminary results for July 2015

Case definition – if underlying cause of death included one of the following ICD-10 codes X40-X44, X60-X64, X85, Y10-Y14 or if any contributing cause field contained one of the following ICD-10 codes; T36-T39, T40.1-T40.4, T41-T43.5, T43.7, T50.8, T50.9

The majority of all 2015 overdose deaths have been reported as unintentional (81%) and occurred among males (58%) and persons aged 45-64 years (55%); most involved either a prescription or illicit opioid.

New Legislation:

On May 27, 2015 Governor Ricketts signed LB390 (Statute 28-470 <http://nebraskalegislature.gov/laws/statutes.php?statute=28-470&print=true>). This law allows health professionals to prescribe, administer, or dispense naloxone to persons experiencing an opioid-related overdose **or to a family member or friend in a position to assist such individuals**. This law also authorizes emergency responders and peace officers to administer naloxone to persons experiencing this type of overdose.

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Health Alert Network Advisory *(continued)*

Persons at high risk of opioid overdose include:

- a. People who mix prescription opioids with alcohol or benzodiazepines such as Klonopin, Valium, and Xanax.
- b. Persons who are opioid naïve or have a low drug tolerance (limited ability to process a certain amount of a drug) from either never using the drug before or after taking a break from use either intentionally (e.g., while in drug treatment or on methadone detoxification) or unintentionally (e.g., while in jail or the hospital¹).

Therapeutic Intervention: Consider prescribing naloxone along with the patient's initial opioid prescription

With proper education, patients on long-term opioid therapy and others at risk for overdose may benefit from having a naloxone kit in the event of overdose. Patients who are candidates for such kits include those who are:

- Taking high opioid doses for long-term management of chronic malignant or nonmalignant pain.
- Receiving rotating opioid medication regimens and are at risk for incomplete cross-tolerance.
- Discharged from emergency medical care following opioid intoxication or poisoning.
- At high risk for overdose because of a legitimate medical need for analgesia, coupled with a suspected or confirmed history of substance abuse, dependence, or non-medical use of prescription or illicit opioids.
- Completing mandatory opioid detoxification or abstinence programs.
- Recently released from incarceration and a past user or abuser of opioids (and presumably with reduced opioid tolerance and high risk of relapse to opioid use).

Consider having at-risk patients create an “overdose plan” to share with friends, partners, and/or caregivers. Such a plan should contain information on the signs of overdose and how to administer naloxone or otherwise provide emergency care (as by calling 911).

Follow best practices for responsible analgesic prescribing, including:

- o **Prescribe** the lowest effective dose and only the quantity needed for the expected duration of pain.
- o **Plan** with your patients on how to stop opioids when their treatment is done.
- o **Provide** your patients with information on how to use, store, and dispose of opioids.
- o **Avoid** combinations of prescription opioids and sedatives unless there is a specific medical indication.

For more information on safe prescribing tools please go to:

<http://www.cdc.gov/drugoverdose/prescribing/tools.html>

ADDITIONAL RESOURCES

- Naloxone guidelines for pharmacists: https://cpnp.org/_docs/guideline/naloxone/naloxone-access.pdf
- SAMHSA Opioid overdose toolkit: http://store.samhsa.gov/shin/content/SMA13-4742/Overdose_Toolkit_2014_Jan.pdf
- Harm Reduction Coalition: <http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/opioid-od-risks-prevention/>
- CDC Prescription Drug Overdose What Health Care Providers Need to Know: <http://www.cdc.gov/drugoverdose/epidemic/providers.html>
- SAMHSA Opioid Overdose Prevention toolkit, pg. 11: http://store.samhsa.gov/shin/content/SMA13-4742/Overdose_Toolkit_2014_Jan.pdf

Which of Your Patients is Likely to Overdose on Opioids?

by Marcia Muetting, Pharm.D., R.P.
Nebraska DUR Director
Nebraska Pharmacists Association

Newspapers and professional journals have been flooded with articles highlighting the issues of substance abuse and overdose in the United States.



We have all read about pill mills, doctor shopping and the epidemic of drug abuse. While Nebraska ranks lowest among the states for prescription drug overdose, each year the number increases. In 2008, the rate of death due to drug overdose was

5.5 per 100,000. That number increased to 6.7 per 100,000 in 2010.^{1,2} Data from the Nebraska Regional Poison Center shows that the number of reported exposures to analgesics has increased from 3,156 in 2010 to 4,141 in 2012.³ These statistics parallel the increase in prescribing of opioid pain relievers across the United States with a fourfold increase in sales from 1999 to 2010.¹

While the above statistics do not distinguish the use of opiates for terminal cancer or end of life, the focus of this article is on the use of opioids in the treatment of chronic, non-cancer pain.

Factors that Increase Risks of Death Due to Overdose in Patients with Chronic, Non-Cancer Pain

Certain opioids are associated with a higher risk of death from overdose. Methadone tops the list of drugs with the highest risk, followed by oxymorphone and fentanyl.⁴ Approximately 33 percent

of deaths due to opioid overdose involved no other medications.⁵

Specific drugs, when added to opioids, also increased the risk of overdose death. Approximately 50 percent of all deaths in the United States due to opioid overdose involved another drug and 16 percent involved drugs that were not specified. Benzodiazepines, in combination with opioids, were involved in 17 percent of the overdose deaths. Cocaine or heroin, in combination with opioids, was involved in 15 percent of deaths, and benzodiazepines with cocaine or heroin were involved in 3 percent of deaths.⁵

The opioid dose is a risk factor. In the CONSORT study, patients who received more than 100 mg per day morphine equivalent dose (MED) of opioids were nine times more likely

to experience an overdose (fatal and non-fatal). In this study, it was observed that the patients who received the highest doses were most often male, smokers, had a history of treatment for depression or had a history of substance abuse. More total overdoses occurred, however, in patients taking lower doses, because the total number of patients taking lower doses was higher.⁶ While higher doses are considered a risk factor, even patients taking lower doses are at risk for overdose.

The information in Table 1 can be used to calculate the MED for the listed opioids. A patient's total daily dose of each opioid taken per day is multiplied by the factor listed and added together to calculate the approximate MED.

Patients were at an increased risk of overdose if they had recently received a sedative-hypnotic medication. In comparison to the patients not taking a sedative-hypnotic in the study, patients taking a sedative-hypnotic were 30 times more likely to experience an opioid overdose. The risk did not increase with the frequency of receiving sedative-hypnotics.⁶

Strategies to Monitor Patients

Patients who must be treated long-term with opioids should be supervised closely and be instructed in the appropriate use of opioids.⁶

Prescribers should ask patients about their use of alcohol and other drugs. When possible, patients with a history of mental health issues or substance abuse should be referred to a specialist. Successful pain management will address treatment of any existing mental health issues.⁷

Prescribers should consider "pain contracts" or opioid treatment agreements. These agreements should address at a minimum: how often a patient can obtain

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TABLE ONE

Drug Name	Factor to Calculate MED
Codeine	0.1499
Dihydrocodeine	0.1499
Fentanyl Patch	6.02
Fentora	0.07
Hydrocodone	1
Hydromorphone	4
Levorphanol	7.5
Meperidine	0.1
Methadone	7.6923
Oral fentanyl (except Fentora)	0.06
Oxycodone	1.4925
Oxymorphone	3.03
Tapentadol	0.2

Too Many Lives Destroyed

by Doug Peterson
Attorney General

I have never had to shout at my friend. In fact, I can't remember a time where I've ever had to shout in anger at any friend. But on this day it was necessary to make it clear to Jack¹, he could no longer continue to indirectly enable his son to feed his prescription drug addiction. For two years I watched Jack do everything he could to try to help his son in spite of the fact that Devon² was stealing jewelry from his mother, clothing from his two sisters, and actually breaking into the homes of family friends. His son's prescription drug addiction had turned their family life into an absolute nightmare. Jack had to let Devon crash. It was through this traumatic experience that I witnessed, firsthand, the reach of destruction caused by prescription drug abuse in Nebraska.

Prescription drug abuse is an extensive problem addressed by local law-enforcement officers, our school systems, and our medical care providers. The problem ranges from junior high and high school students raiding the family drug cabinet to see what they can bring to a pharm party³, to a full-fledged addict manipulating the prescription of opiate drugs such as oxycodone, hydrocodone, hydromorphone, and methadone⁴ in order to feed an addiction or sell to the addicted.

Unfortunately, Nebraska is one of only two states that does not have a mandatory prescription drug monitoring program (PDMP)⁵. This lack of a program creates an environment that makes it easier to "doctor shop" for pain med prescriptions or falsify a prescription. It

creates a situation where pharmacists are unable to see if the person is abusing. As a result, the problem of pharmaceutical drug abuse in Nebraska continues to get worse, and outside buyers now perceive Nebraska as a safer place to obtain their supply.⁶

The U.S. Center for Disease Control and Prevention (CDC) has classified prescription drug abuse as an "epidemic."⁷ The Office of National Drug Control Policy called prescription drug abuse "the nation's fastest growing drug problem."⁸ This misuse and abuse is particularly true among young people. According to studies, young people tend to believe that prescription drugs are not as dangerous as street drugs because of the fact that they are prescribed by a physician.⁹ Furthermore, dependency can easily occur when patients are properly prescribed opiate drugs for pain management, but develop a dependency on the pain management and soon find themselves addicted. As a result, each year we are seeing a concerning increase in the number of Emergency Department visits involving nonmedical use of opiates and opioids.¹⁰ In 2010, enough opioid pain relievers were sold to medicate every adult in the United States with the equivalent of a typical dose of 5 mg of hydrocodone every four hours for one month, a 300% increase in the sales rate over 11 years¹¹. Clearly, such a usage rate does not correlate with an actual medical need. The challenge is to reduce the likelihood of opiate misuse, while not creating barriers to legitimate use of pain management between the patient and treating physician.

In order to address this problem in Nebraska, the Nebraska Medical Associa-

tion, the Nebraska Pharmacists Association, Nebraska Hospital Association, representatives from Health and Human Service agencies, and the Nebraska Attorney General's Office have been meeting to move forward with a mandatory PDMP. The National Drug Control Strategy and CDC have identified PDMPs as a key strategy for reducing prescription drug misuse.¹²

State Senators Sara Howard, Brett Lindstrom, John Kuehn, and Kathy Campbell, are to be applauded for working to change our laws to make a PDMP possible. My hope is that this collaborative effort will allow physicians, dentists, clinics, and pharmacists to work together in real time to better identify the individuals who are abusing the drugs.

It will take more than just a PDMP to solve the prescription drug abuse problem. It will also include ongoing education in our high school systems and in our communities about the dangers of pharmaceutical drug abuse. Our office is committed to do whatever we can to further this initiative. It will be critical that all health care providers across Nebraska join in the effort. Too many lives have already been destroyed. It is imperative that we all work together for solutions. □

1. Not actual name.

2. Not actual name.

3. <http://www.lockthecabinet.com/why/why-lock-the-cabinet/>, <http://www.chicagotribune.com/sns-health-kids-raiding-medicine-cabinet-story.html>

4. <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Provider-Education-Toolkits/Downloads/prescription-opioids-booklet0814.pdf> (pages 4-5)

5. <http://www.namsdl.org/library/6D4C4D9F-65BE-F4BB-A428B392538E0663/> (slide 2, footnote 1)

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Preventing Prescription Drug Overdoses in Nebraska

by Senator Sara Howard
Legislative District 9

The CDC tells us that in 2013, of the 43,982 drug overdose deaths in the United States, 22,767 over 50 percent were related to pharmaceuticals. And of those 22,000 plus deaths, over 70 percent involved opioid analgesics known to most of us as prescription pain killers.

There are many factors in which providers agree might be driving up the use of prescription pain killers. Some of them include that health care providers in different parts of the country don't agree on when to use prescription painkillers and how much to prescribe. Some increased demand for prescription painkillers is from people who use them non-medically (using them without a prescription or just for the high they cause), sell them, or get them from multiple prescribers at the same time. Due to the lack of a PDMP in our state, Nebraska has become a hub of sorts where people from out of state come to fill prescriptions in order to sell them on the street. Too many families have fallen victim to losing a loved one because of prescription drug abuse. This problem continues to grow and it is time that we as a Legislature produce a real solution to this problem.

This is not the first time that we have talked about this issue. In 2011, my mother, Senator Gwen Howard, first began the conversation with her bill, LB 237. LB 237 established a system of prescription drug monitoring that the Department

of Health and Human Services would create in collaboration with the Nebraska Health Information Initiative, also known as NeHII. Implemented in 2009, NeHII is a statewide information exchange that allows users of its system to look at a complete health history of a patient, including prescription drug history. LB 237 passed in 2011 and was signed in to law.

Because of language in the original bill restricting use of state funds to establish the program and the continual rise in prescription drug abuse, the issue was again brought to the table by Senator Steve Lathrop of Omaha in 2013 and 2014. LB 535 (in 2013) was used as the conversation starter. He then introduced LB 1072 in 2014 which originally had language for a task force component, but due to the potential fiscal impact the language was stricken. As amended, LB 1072 allowed Nebraska to accept outside sources of funding, including grant dollars to assist with their efforts in creating a PDMP.

Because of the importance of this issue I have again brought this subject to the Legislature through LB 471. I believe that the time is now to get this program implemented and working to prevent further tragedies from occurring in our state. My legislation will still use NeHII as the vehicle for the prescription drug monitoring program. There are many other states who are moving toward health information exchanges to house their PDMPs as they see the benefits that it provides as a hub for patient health information.

Currently, LB 471 is being held in the Health and Human Services Committee where we will again take up the issue this

January once the legislative session starts. I believe that for our system to be the most effective it must have the following components:

- Prohibit patients from opting out of the system;
- Require all prescribed and dispensed prescriptions of controlled substances to be entered into the system, including those of cash pay patients not using a third-party payor such as an insurance company - many patients who are accessing multiple physicians and pharmacies will pay cash to avoid questions of why they are doing so;
- Allow all prescribers and dispensers of prescription drugs to access the system at no cost to them;
- And ensure that the system includes information from all payers including the Medical Assistance Program

The Department of Health and Human Services has recently been awarded two grants, one from the Centers for Disease Control and the other from the U.S. Department of Justice. Combined, these two grants will fund our PDMP for the next five years so that we can provide this service to providers and dispensers at no cost. One of the best ways to ensure usage of this system is by providing it at no cost so that our health care professionals can all access the program.

There are states that have seen the positive effects of an active Prescription Drug Monitoring System. New York saw a 75 percent drop in patients who were seeing multiple prescribers to obtain the same drugs, which would put them at higher

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Physicians Leading Fight against Opioid Crisis

by *Patrice A. Harris, MD, MA, chair, American Medical Association Task Force to Reduce Opioid Abuse*

Deaths from prescription opioid and heroin related overdose have become a public health crisis in America — currently outpacing the number of deaths from car accidents, federal statistics show. While over the last few years there has been some headway on the national front to begin turning the tide on this crisis, with 44 people still dying each day, from overdose of prescription opioids, and many more becoming addicted, this epidemic demands increased attention from the entire medical community as well as intensified efforts and new funding from all levels of government.

This includes a focused national push to increase the availability and access to comprehensive pain treatment options as well as a comprehensive approach to ensure more consistency in the governance of individual states' physician drug monitoring programs, (PDMPs) — such as ensuring privacy protections when sharing data between states. Additionally, strong steps must be taken to eliminate illegitimate pill mills.

We recognize that there is no one-size-fits-all approach that will turn the tide, but strong leadership and swift action from our nation's physicians inspires hope that we will heal this public health crisis. This is the driving force behind the work being done by the AMA Task Force to Reduce Opioid Abuse to identify the best practices to combat this public health crisis and move quickly to imple-

ment these practices across the country.

As physicians, we recognize that it is our responsibility to work together to provide a clear road map that will help bring an end to this public health epidemic.

By taking five critical actions, physicians can make a significant difference and save lives:

1. Register for and use state-based prescription drug monitoring programs (PDMP). Physicians should register for and consult these databases to identify patients at risk for opioid misuse and help patients with substance use disorders get appropriate treatment.
2. Discuss with patients available treatment options. When caring for patients with pain, physicians should understand the best possible options available for treatment. Physicians should ensure patients in pain are not stigmatized by having open and honest conversations on whether opioids should be considered as the preferred course of treatment or if other pain management is appropriate.
3. Take advantage of educational opportunities. Robust education is key to ensuring patients receive appropriate care to meet their individual needs. Physicians must be kept abreast of the tools and resources that meet the needs of their specialties, practices and patient populations to deliver the most comprehensive and appropriate pain treatment, while safeguarding against opioid overdose.

4. Reduce the stigma of pain and of having a substance use disorder. America's patients who live with acute and chronic pain deserve compassionate, high-quality and personalized care. As physicians, we must do everything we can to also reduce the stigma associated with substance use disorders that discourages patients from seeking addiction treatment and strive to create health care responses that ensure patients live longer, fuller and productive lives.



5. Increase access to naloxone and support Good Samaritan protections. Access to these have been shown to save tens of thousands lives across the country. Nebraska physicians can now prescribe, dispense or distribute naloxone not only to patients at risk for opioid overdose, but also to their family members friends who are concerned about their loved ones' risk of overdose.

There is still much work to be done and we recognize that it will take time to turn the tide, but we know that physicians in Nebraska and across the nation are committed to showing the leadership our patients need and deserve to once-and-for-all bring an end to this deadly epidemic.

Learn more about the AMA Task Force to Reduce Opioid Abuse: www.ama-assn.org/go/endopioidabuse □

Preparing Prescribers to Confront the Opioid Crisis

U.S. Capitol Visitor Center, SVC 212-10

October 6, 2015

Remarks by ONDCP Director
Michael Botticelli

The Administration's Progress to Date

Since the start of the Obama Administration, the Office of National Drug Control Policy (ONDCP) has worked to address the drug problem beyond the scope of public safety. In word and action, we have made it clear that a public health – and public safety approach are essential if we want to be successful in reducing drug use and its consequences.

In 2011, the Administration released its plan to address prescription drug abuse. The Plan laid out a strategy to address the epidemic – which was ravaging our Nation. And since the introduction of the plan we have also worked to expand access to medication assisted treatment and naloxone.

The Plan's four pillars include education of parents, patients and prescribers, effective monitoring of prescription drugs, secure and responsible drug disposal, and law enforcement. Prescribers play a role in the first three areas.

Education

Education is the first pillar.

Educating parents – patients – and prescribers.

Parents should understand the importance of keeping track of any medications they have in the house. And understand how dangerous it can be if any members

of their family misuse opioids.

Educating patients is important so that they know to ask questions if they are prescribed opioids, particularly if a patient has a substance use disorder or is already on another medication.

And it is vitally important to our efforts that we train health care providers in proper opioid prescribing. In four years of medical school, medical students receive on average only 11 hours of pain medication training.ⁱ And virtually none on the treatment of substance use disorders.

Various Federal agencies are leading the way by making certain that their workforce is properly trained. Prescribers at the NIH Clinical Center take continuing education on safer prescribing when they are hired.

Over 1,000 providers have been trained by the Indian Health Service on pain, diversion, screening for substance use disorder, and alternatives to opioids for pain.

In the Department of Justice's Bureau of Prisons, virtually all of the supervisory medical staff and dentists have completed an online training program.

The Department of Defense is developing policy that will require prescribers in all branches to take the Military's "Do No Harm Training".

The Food and Drug Administration (FDA), through its voluntary Risk Evaluation and Mitigation Strategy (or REMS), provides a training program on extended-release/long-acting opioids.

Thousands have taken this program.

But does prescriber education work?

Researchers in Massachusetts recently published an evaluation of a REMS program produced at Boston University called "Scope of Pain."ⁱⁱ The evaluation showed provider knowledge gains after the program. More important, 86 percent of providers reported implementing changes in their clinical practice when asked about it two months later.

And states are leading the way in this important effort. Today, 10 states (Connecticut,^{iiiiv} Delaware,^v Iowa,^{vi} Kentucky,^{vii} Massachusetts,^{viii} New Mexico,^{ix} Nevada,^x Tennessee,^{xi} Utah,^{xii} and West Virginia^{xiii}) have passed legislation mandating training for prescribers.

Monitoring

The Plan's second pillar concerns expanding and improving prescription drug monitoring programs (PDMPs). Today all but one state – Missouri – has a PDMP. PDMPs are databases that allow prescribers to check on drug-interactions and alert them to early signs of opioid use problems or diversion.

Kentucky,^{xiv} New Jersey,^{xv} New Mexico,^{xvi} New York,^{xvii} Oklahoma,^{xviii} and Tennessee^{xix} all require their prescribers to use their state's PDMP prior to prescribing in certain circumstances. In Tennessee, where the requirement to check the PDMP went into effect in 2013, there was a drop in the number of high utilizers of opioid pain relievers from the fourth quarter of 2012 to the fourth quarter of 2013.^{xx}

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Preparing Prescribers to Confront the Opioid Crisis *(continued)*

And while PDMPs are important, we need to make sure they receive adequate resources to ensure that they are easy to use. In addition, we need to make sure PDMPs can operate across state lines. We are pleased that today that at least 30 states have some ability to share data with other states. And the Departments of Health and Human Services and Justice are working to expand data sharing capability.

In 2014, the Department of Veterans Affairs finalized a rule authorizing VA physicians to access state PDMPs in accordance with state laws and to develop mechanisms to begin sharing VA prescribing data with state PDMPs.^{xxi} As of last April [2015], 67 VA facilities were sharing information with PDMPs in their respective states. VA providers have also begun registering and checking the state databases.

Although PDMP reporting is not required by Indian Health Service (IHS) facilities, many tribal nations have declared public health emergencies and elected to participate with the PDMP reporting initiative. As of March 2014, IHS is sharing its pharmacy data with PDMPs in at least 19 states^{xxii} and negotiating data-sharing with more states.^{xxiii}

Disposal

The third element of our plan is disposal. The majority of individuals who begin misusing prescription drugs get them from family and friends. For this reason, we must make it easier to dispose of unused medications.

The Drug Enforcement Administration (DEA) has partnered with hundreds of state and local law enforcement

agencies and community coalitions, as well as other Federal agencies, to hold 10 National Take-Back Days since 2010. With the most recent Take Back taking place just last month, DEA collected and safely disposed of millions of pounds of unneeded or expired medications.

In September 2014, DEA published the final regulations on controlled substance disposal. Now ONDCP and our Federal partners and stakeholders are beginning to inform the public about the regulations and looking at ways to stimulate local disposal programs in partnership with pharmacies and law enforcement. The DEA regulations allow for many options, including mail-back programs, which may help with unique state situations that would otherwise require a legislative solution.

Medication Assisted Treatment

The fact is, we cannot afford to wait to address the opioid crisis. We need early identification and evidence based treatments and it must happen now. Recent data show the high proportion of fatal overdoses involving prescription opioids leveling off in this country but, at the same time, a dramatic 39 percent increase in overdose deaths involving heroin from 2012 to 2013.^{xxiv,xxv}

We know that medication assisted treatments, when combined with other behavioral supports, are effective at treating opioid use disorders. Medication Assisted Treatment saves lives while increasing the chances a person will remain in treatment and learn the skills and build the networks necessary for long-term recovery.

The President's 2016 Budget Request

includes millions of dollars in additional funding for treatment efforts. The Health Resources and Services Administration has offered \$300 million in supplementary grants to support medication assisted treatment expansion in Health Centers. And the Substance Abuse and Mental Health Services Administration gave an additional \$11 million in FY 2015 to support medication assisted programming.

We cannot expect attitudes to improve if we fail to intervene in the medical system where the problem can be addressed at the highest levels of care by those who can provide the most effective treatments.

Conclusion

You all play critically important roles in finding solutions to our nation's drug problem, and it starts with leveraging the prevention and the medical system for:

- Preventing substance use from ever beginning;
- Identifying those with a potential substance use disorder earlier;
- Ensuring linkage to treatment;
- Engaging people in treatment; and
- Providing access to naloxone and overdose education.

Let's tackle these issues together so we can help all Americans live safer and healthier lives. □

i) Mezei L, Murinson BB; Johns Hopkins Pain Curriculum Development Team. Pain education in North American medical schools. *J Pain*. 2011 Dec;12(12):1199-208. doi: 10.1016/j.jpain.2011.06.006. Epub 2011 Sep 25. PMID: 21945594

ii) Alford DP, Zisblatt L, Ng P, Hayes SM, Peloquin S, Hardesty I, White JL. SCOPE of Pain: An Evaluation of an Opioid Risk Evaluation and Mitigation Strategy Continuing Education Program. *Pain Med*. 2015 Aug 25. doi: 10.1111/pme.12878. [Epub ahead of print]

(continued on Page 24)

What can Physicians do to Reduce the Epidemic of Prescription Drug Abuse? *(continued)*

patient who calls and reports increasing pain and has been taking medications more frequently than prescribed, or running out of medications early, or who has had multiple emergency room visits, or who has gradually lost activity tolerance or who complains of pain despite the lack of objective evidence may well be developing a comorbid substance abuse issue. These are all aberrant medication taking behaviors. All patients may have one or two such behaviors, but the ACCUMULATION of these behaviors signifies a loss of control over the use of medications of abuse and therefore indicates the potential development of a substance abuse disorder. These patients physically experience pain that continuously worsens despite unrelenting dose increases with the use of more and more potent opioids. In these situations the “pain medications” interact with neurotransmitters and paradoxically cause the physical expression of pain in order to maintain CSF dopamine levels. This is no different than self-medicating with alcohol for depression or cocaine except

as physicians we are not prescribing these to our suffering patients. When this occurs, it is inappropriate to blame the patient if we fail to assist them in understanding what is occurring.

Patients do not choose to deceive us or wish to abuse medications. They most often miss the signs themselves because they trust that we would not prescribe for them if it wasn't in their best interest. It is also suboptimal to fire a patient or give them just enough medication to get to another provider who does not have the benefit of longstanding relationship with a patient with longitudinal observation. When this occurs, we owe our patients the honest and respectful communication that **the medication has become part of the problem rather than just an incomplete solution.** When we fail to identify or communicate this to our patients we set the stage for doctor shopping or worse.

Pain agreements (not pain “contracts”) merely serve as an advance means to document that patients and clinicians mutually understand the difference

between appropriate and inappropriate use of medications which could signify the loss of control over the use of medications. They provide no safety role if they do not spell out specific expectations on the part of the patient. They are not true contracts and it is important for clinicians to be willing to change course if patients are not responding to treatment with opioid medications or are losing control of the use of these medications.

As physicians we recognize that undertreatment of pain is a larger problem than substance abuse. But if we remember that it is not possible to successfully treat chronic pain in the background of medication abuse, and that abuse physiology increases the subjective experience of pain in order to maintain CSF dopamine levels, we can more easily understand the need to avoid inappropriate treatment with these medications.

In short, pain treatment and avoidance of prescription opioid abuse are NOT mutually competing goals, no matter what Big Pharma wants us to believe. □

Too Many Lives Destroyed *(continued)*

6. <http://www.ketv.com/news/nebraska-known-for-blackmarket-prescription-drugs/24671974>

7. http://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html

8. <https://www.whitehouse.gov/ondcp>

9. <http://medicineabuseproject.org/news-events/news/national-study-teen-misuse-and-abuse-of-prescription-drugs-up-33-percent-si> “More than a quarter of teens (27 percent) mistakenly believe that “misusing and abusing prescription drugs to get high is safer than using street drugs,”” [https://www.gadoe.org/Curriculum-Instruction-and-Assessment/Curriculum-and-](https://www.gadoe.org/Curriculum-Instruction-and-Assessment/Curriculum-and-Instruction/Documents/Prescription%20Drug%20Abuse%20Prevention%20Program_Grades%205-8%20Lesson%20Plans.pdf)

[Instruction/Documents/Prescription%20Drug%20Abuse%20Prevention%20Program_Grades%205-8%20Lesson%20Plans.pdf](https://www.gadoe.org/Curriculum-Instruction/Documents/Prescription%20Drug%20Abuse%20Prevention%20Program_Grades%205-8%20Lesson%20Plans.pdf) (page 1)

10. <http://www.samhsa.gov/data/sites/default/files/DAWN2k11ED/DAWN2k11ED/DAWN2k11ED.pdf> (page 55) <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse> “For example, the estimated number of emergency department visits involving nonmedical use of opioid analgesics increased from 144,600 in 2004 to 305,900 in 2008”

11. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6226a3.htm>

12. http://www.cdc.gov/HomeandRecreationalSafety/pdf/HHS_Prescription_Drug_Abuse_Report_09.2013.pdf “Equipping clinicians with clinical tools, such as ready access to prescription drug monitoring program (PDMP) data, prescribing guidelines, and electronic health records with integrated clinical decision support can address several drivers of prescription drug abuse. “ (Page 25: Clinical Practice Tools)

Chasing the Dragon...The Resurgence of Heroin *(continued)*

help them. For families struggling with addiction, I recommend the following two books to help them make informed decisions: *Beyond Addiction: How Science and Kindness Help People Change* by Jeffrey Foote, et.al. and *Inside Rehab: The Surprising Truth About Addiction Treatment and How to Get Help That Works* by Anne M. Fletcher.

As a closing thought, I'd like each of you to consider offering a prescription

for naloxone to every appropriate patient. This includes all individuals prescribed opiates as well as those with a history of misuse and/or heroin use. It will save lives. Teach opiate user's families/friends how to administer naloxone. You may not know how to write the prescription. A few short months ago, I didn't either. Naloxone HCL 0.4 mg/ml, 2 x 1 ml single dose vials; Intramuscular syringe, 23 G, 3cc, 1 inch; Sig: for suspected opiate/heroin over-

dose, inject 1 ml IM in shoulder or thigh. Call 911. Repeat in 3 minutes if necessary.

Please do not hesitate to contact me with comments or questions at jtheob1@nmhs.org.

Editor's note: Additional information on naloxone can be found on the Project Dawn website: <http://www.odh.ohio.gov/sites/core/content/HealthyOhio/default/vipp/drug/ProjectDAWN.aspx>. Or, you may Google Project DAWN.

Which of Your Patients is Likely to Overdose on Opioids? *(continued)*

refills, conditions of early replacements for lost prescriptions, storage safety, using one prescriber, the patient will not "share" medication, and monitoring of adherence through urine screens. Patients need to be educated that the agreement is intended to protect them from adverse events and to foster a relationship of collaboration with the prescriber.⁷

In Washington, the Agency Medical Directors' Group partnered with prescribers to establish dosing guidelines for the use of opioids. These guidelines include specific recommendations for initiation, transition, and maintenance of opioids in patients with chronic non-cancer pain.

Specifically, a MED threshold of 120 mg per day was recommended. The guidelines recommend that a patient receiving more than 120 mg MED should be referred to a pain specialist for treatment.⁸ Workers' compensation data was evaluated after the implementation of the guidelines and modest decreases were observed in the volume of Schedule II and III prescriptions and deaths due to prescription opioids.⁹

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1. CDC MMWR Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999--2008 November 4, 2011 / 60(43):1487-1492
2. Centers for Disease Control and Prevention. Prevention Status Reports 2013: Prescription Drug Overdose— Nebraska. Atlanta, GA: US Department of Health and Human Services; 2014.

3. (NRPC) <http://www.nebraskapoisson.com/annual-Reports.aspx>
4. Gwira Baumblatt J, Wiedeman C, Dunn J, Schaffner W, Paulozzi L, Jones T. High-Risk Use by Patients Prescribed Opioids for Pain and Its Role in Overdose Deaths. *JAMA Intern Med.* 2014 Mar 3. doi: 10.1001/jamainternmed.2013.12711. [Epub ahead of print]
5. Warner M, Hui Chen L, Makuc D. Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999-2006. NCHS Data Brief. No. 22. September 2009.
6. Dunn K, Saunders K, Rutter C, et al. Opioid Prescriptions for Chronic Pain and Overdose. *Ann Intern Med.* 2010 Jan 19;152(2):85-92.
7. McLellan AT, Turner B. Prescription opioids, overdose deaths, and physician responsibility. *JAMA.*2008;300 (22):2672-2673.
8. Agency of Medical Directors Group. Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain. (2010 Update)
9. Dept of Labor & Industries. Interim Evaluation of the Washington State Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain. (08/31/2009)

Preventing Prescription Drug Overdoses in Nebraska *(continued)*

risk of overdose, while Florida saw more than a 50 percent decrease in overdose deaths from oxycodone.

While Nebraska is very different demographically from both New York and

Florida, I find it hard to believe that we would not see a positive result from being more stringent with our Prescription Drug Monitoring Program. Nebraska currently has a rate of 79 painkiller prescriptions per

100 people. It is my hope that as a state and through the passage of LB 471, we can work toward ending this devastating type of drug abuse and support a state full of happy, healthy Nebraskans.

2015 Annual Membership Meeting Recap

On Friday, September 18, the NMA held its annual membership meeting and House of Delegates. We were pleased to have so many physicians across all areas of the state and representing many different specialties attend the meeting.

The day was full of activity beginning with the NMA's quarterly board meeting, the Greater Nebraska Medical Caucus and programming that discussed the transformation of health care including a panel discussion by representatives from various entities. In the afternoon the House hosted many guest speakers including former NMA president and Undersecretary for Food Safety at the U.S. Department of Agriculture Richard Raymond, MD; DHHS CEO Courtney Phillips and Calder Lynch, Medicaid Director; Attorney General Doug Peterson; Les Spry, MD and Dale Michels, MD, candidates for Legislature; and Karla Lester, MD, on the Energy campaign project from Teach a Kid to Fish and the NMA among others. Our regular business meeting included a PAC and legislative update and resolutions. Resolution action taken can be viewed on page 20 of this issue.

Our evening festivities included our scholarship presentation and the honoring of our 50 year practitioners and 2015 award winners. After Dr. Frankel's installation, those in attendance were entertained by The Chief Complaints. You can see photos from this year's meeting on the NMA Facebook page, www.facebook.com/nebmed.

Harris Frankel, MD, of Omaha was installed as your 2015-16 president of the Nebraska Medical Association, at the NMA's annual membership meeting.



2014-15 President Richard Blatny, Sr., MD, installs Harris Frankel, MD, as the NMA's 2015-16 president.

Dr. Frankel is a native of Omaha, Nebraska. He obtained his Bachelor of Arts in animal physiology from the University of California, San Diego, in 1982. He then attended the University of Nebraska, College of Medicine and received his MD degree in 1986. Thereafter, he completed a one-year internship in general internal medicine at Creighton University Affiliated Hospitals in Omaha. He then completed a neurology residency at the University of Texas Southwestern Medical Center at Dallas in 1990. During the last year of training Dr. Frankel served as chief resident for the Department of Neurology at Parkland Memorial Hospital and the Dallas VA Medical Center.

Upon completion of his residency training, Dr. Frankel returned to Omaha and joined the private practice of Neurology. After nearly 21 years of private practice, he then joined the Department of Neurological Sciences at the University of Nebraska Medical Center. He is a member of the active staff of the

Nebraska Medical Center and serves as medical director for the UNMC Physicians Clinical Neurosciences Center. In January 2014, Dr. Frankel joined the executive leadership team of Nebraska Medicine and currently serves as senior vice president and chief medical officer.

Dr. Frankel is board certified in the specialty of neurology by the American Board of Psychiatry and Neurology. He is a member of Alpha Omega Alpha and a member of a number of professional organizations including: the American Academy of Neurology, the Nebraska Medical Association and the American Medical Association. He is a past president of the Metropolitan Omaha Medical Society and past president of the Nebraska Health Information Initiative, Inc. (NeHII).

Thank you again to all the NMA members who took time to attend this year's annual meeting! Please save the date for next year's meeting, September 16 in Lincoln. □

2015 Annual Membership Meeting Recap *(continued)*



**YOUNG
PHYSICIAN
OF THE YEAR**
Michelle Sell, MD
Central City



**PHYSICIAN
OF THE YEAR**
Gerald Luckey, MD
David City

DISTINGUISHED SERVICE TO MEDICINE



David Filipi, MD
Omaha



Linda Ford, MD
Bellevue



Chuck Gregorius, MD
Lincoln



**PHYSICIAN
ADVOCATE
OF THE YEAR**
Britt Thedinger, MD
Omaha

STUDENT ADVOCATE OF THE YEAR



R. Logan Jones



Alicia Smith

2015 50 YEAR PRACTITIONERS

- John Allworth Albers, MD
- Kenneth Paul Barjenbruch, MD
- Charles Lawrence Barton, MD
- George Basque, MD
- Dennis Beavers, MD
- Richard Francis Brouillette, MD
- William Carl Bruns, MD
- Colleen Willert Dilley, MD
- Donald Dynek, MD
- Carl Thomas Frank, MD
- Vernon Ford Garwood, MD
- Thomas John Imray, MD
- Joseph Anthony Jarzobski, MD
- David F Johnson, Jr., MD
- Harold Wallace Keenan, MD
- James Robert Newland, MD
- Loren Paul Petersen, MD
- James Joseph Phalen, MD
- Samar Kumar Ray, MBBS
- James Joseph Regan, MD
- Wendell Fred Ropp, MD
- James Scharphorn, MD
- Robert F. Shapiro, MD
- Duane Oliver Sherwin, MD
- Fordyce Edward Stivers, MD
- Rudolf Strnot, Jr., MD
- Donald Angus Swanson, MD
- Noble Leroy Swanson, MD
- Balachandran Wariyar, MBBS
- Ronald Leroy Wax, MD
- Wayne Kirk Weston, MD
- James Jefferson Woodbury, MD

2015 SCHOLARSHIP WINNERS

- Colby Argo
- Clayton Damme
- Karen Dionesotes
- Jason Eckmann
- Alexis Erbstr
- Brett Grieb
- Chantal Heathers
- Meredith Humphreys
- Sydney Johnson
- Aparna Kailasam
- Michaela Klesitz
- Michael Klinginsmith
- Lindsay Leikam
- Katherine Lester
- Joseph Lippert
- Taylor Losey
- Brent Luedders
- Priya Maillacheruvu
- Alicia McCabe
- Ian Parsley
- Elizabeth Rodriquez
- Gregory Rufener
- Lance Schell
- Irsa Shoiab
- Brody Slostad
- Jessica Sonderup
- Nickolas Stasic
- Jenna Stecker
- Diliana Stoimenova
- Leah Svingen
- Stephanie Weed

2015 House of Delegates Resolutions

The following resolutions were submitted for consideration at the NMA's annual membership meeting.

RESOLUTION #1 – INFORMED CONSENT FOR HIV TESTING

Resolved that the Nebraska Medical Association seek to introduce legislation that would repeal Nebraska Revised Statute 71-531. (Nebraska Revised Statute 71-531 was enacted in 1994 requiring specific written informed consent for the performance of Human Immunodeficiency Virus [HIV] testing except in the case of organ and tissue donation, certain insurance underwriting, and certain instances in the Department of Correctional Services.)

Approved by House of Delegates

RESOLUTION #2 – STATEWIDE IMMUNIZATION PROGRAM

Resolved that the Nebraska Medical Association work with the Nebraska Legislature to introduce legislation that would create a system in Nebraska that would provide adequate reimbursement, cost savings and immunization tracking using the Vermont system as a template or requiring that the present system be used more adequately.

Referred to Board of Directors for review and action

RESOLUTION #3 – PRICE TRANSPARENCY IN MEDICINE

Resolved that the Nebraska Medical Association in cooperation with business, industry and the Legislature develop legislation that would not allow future contracts that prohibit price transparency. Such legislation would also develop publically accessible sites that give the citizens of the state of Nebraska accurate, comparable and understandable information regarding the costs of their health-care for tests, procedures and planned hospitalizations.

Approved by House of Delegates

RESOLUTION #4 – MODEL HEALTH CARE ENVIRONMENT FOR REDUCING HEALTH CARE COSTS

Resolved that the Nebraska Medical Association collaborate with appropriate stakeholders including but not limited to Nebraska Department of Health and Human Services, insurance companies, health systems to:

- Enhance transparency with regards to the costs/charges of care at the level of provider order-entry into an electronic health record.
- Track costs/charges of entered orders on a per physician/per practice basis and report that data to those physicians/practices in order to enhance the cost effectiveness of provider prescribing patterns.

- Pilot novel reimbursement systems and structures that incentivizes reduced costs and adherence to cost-effective, evidence-based guidelines.

Motion was made for an addendum to be added to the resolution as follows:

- Pilot novel reimbursement systems and structures that incentivizes reduced costs and adherence to cost-effective, evidence-based guidelines as supported by specialty definition according to the subspecialty or specialty guidance.

Referred to Board of Directors for review and action

RESOLUTION #5 – NMA COMMITTEE OF NEBRASKA PHYSICIAN SPECIALTY/ SUBSPECIALTY SOCIETIES

Resolved that the Nebraska Medical Association will establish and lead a committee of physician leaders of Specialty and Subspecialty Societies in Nebraska; and

Further resolved that the Nebraska Association will share information on health policy issues with the committee; and

Further resolved that the committee will be encouraged to engage their Society members in working with the Nebraska Medical Association on health policy issues that affect Nebraska patients and physicians.

Approved by the House of Delegates

(continued on Page 21)

2015 House of Delegates Resolutions (continued)

**RESOLUTION #6 –
CREATION OF A NEBRASKA
MEDICAL ASSOCIATION
PHYSICIAN SHORTAGE
TASK FORCE**

Resolved that the Nebraska Medical Association establish a task force to investigate and provide recommendations to improve the problem of physician shortages in Nebraska by exploring mechanisms to expand residency training opportunities within Nebraska.

Approved by the House of Delegates

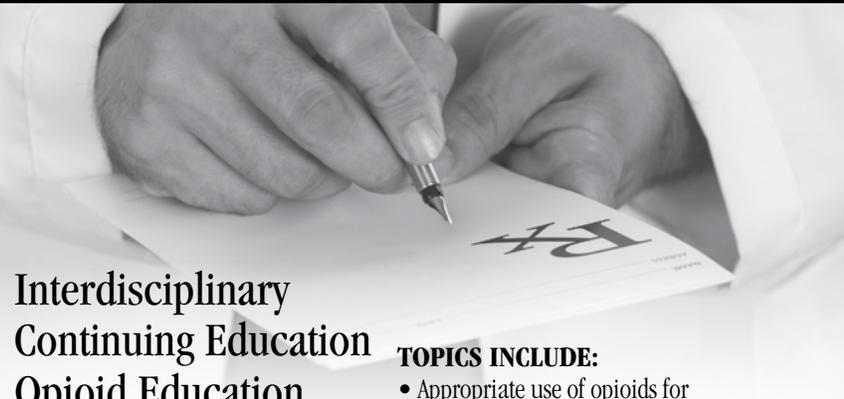
**RESOLUTION #7 –
ELECTRONIC RESIDENCY
APPLICATION SERVICE (ERAS)**

Resolved that the Nebraska Medical Association ask the AMA HOD to study and make recommendations for revisions to the Electronic Residency Application Service (ERAS) to revise access limitations to include medical school staff supporting students.

Approved by the House of Delegates

If you would like full copies of any of the above resolutions, please contact Ranae Bremer at (402) 474-4472 or ranaeb@nebmed.org. Questions may be directed to NMA Executive Vice President Dale Mahlman at (402) 474-4472 or dalem@nebmed.org. □

SAVE THE DATE



**Interdisciplinary
Continuing Education
Opioid Education**

*Saturday, July 16, 2016
Cornhusker Marriott Hotel
Lincoln*

Continuing Medical Education
Credits will be offered

*Hosted by the Nebraska
Pharmacists Association*

TOPICS INCLUDE:

- Appropriate use of opioids for non-cancer, acute and chronic pain
- Non-pharmacological treatments for pain
- Identifying overdose – administration of Naloxone
- Treatment of addiction – Naloxone/Buprenorphine
- Pain psychology
- Methadone treatment clinic
- Law enforcement – what's happening in Nebraska

New Members

Hastings

William David Terrell, MD

Kearney

Amanda Lueshen Davis, MD

Shannon Nichole Hoos-Thompson, MD

North Platte

Amy Christine Short, MD

Omaha

Andrew Irwin Gelbman, DO

Erin Maura Talaska, MD

HelenMari L. Merritt-Genore, DO

Mathagondapally S. Arun, MD

Richard Hamilton Legge, MD

Umasankari Sundaram, MBBS

Yon Jung Chong, MD

Student Members

Joshua Michael Allwardt

Bianca Bendix Christensen

Blake Alan Cover

Anthony Easterday

Nathan Alan Foje

Jonathan A. Greenberg

Haley Danielle Heibel

Shauna Mae Lindstedt

Hannah Elizabeth Malcolm

Alicia Marie McCabe

John Blaine Riley, III

Roman Shrestha

Courtney Smith

Alexandra Lyn Springman

Nicholas John Gray Swingle

Sean Charles Tomes

Alexandria Marie Valdrighi

Austin Michael Wheeler

Necrology

David Rosenberg, MD

Omaha

10/05/15

Thomas Tonniges, MD

Omaha

10/06/15

Ask a Lawyer

What do Physicians need to know about 2015 LB 107?

October 9, 2015

Although there are many similarities between the requirements of LB 107 and prior law, the ability of a qualified nurse practitioner to practice independently of a collaborating physician is a significant change for health care in Nebraska. With the passage of LB 107, a nurse practitioner with sufficient experience can now be licensed and establish his or her own independent practice without having an integrated practice agreement with a collaborating physician.

The new statute is identical to 2014 LB 916, which passed in the previous Legislative session but was pocket vetoed by Governor Heineman. This time, the law was signed by Governor Ricketts on March 5, 2015 and became effective on August 30, 2015.

- As of August 30, 2015, to be licensed as a Nebraska nurse practitioner, an individual must:
- Have a master's degree or doctorate degree in nursing;
- Have completed an approved nurse practitioner program;
- Demonstrate completion of separate course work in pharmacotherapeutics, advanced health assessment, pathophysiology or psychopathology; and
- Submit to the Nebraska Department of Health and Human Services (the "Department") proof of professional liability insurance required under Neb.Rev.Stat. § 38-2320.

Neb.Rev.Stat. § 38-2322 (as amended by 2015 LB 107). Only those individuals, who have not completed the minimum

2,000 hours of supervised or otherwise qualifying practice as a nurse practitioner, will be required to enter into a transition-to-practice agreement with a "supervising provider." If a nurse practitioner meets the minimum experience requirements of the law, he or she may practice without physician supervision or without supervision by another provider.

LB 107 also allows other nurse practitioners to serve as a supervising provider to another nurse practitioner under a transition-to-practice agreement. A "transition-to-practice agreement" must be in writing and provide that a supervising provider and the supervised nurse practitioner will practice collaboratively within their respective scopes of practice.¹ The supervising provider is responsible for oversight of the nurse practitioner to ensure the quality of health care provided to patients.

Formerly, nurse practitioners were limited to having only physicians serve as a collaborating provider under an integrated practice agreement. The difficulty that some nurse practitioners had in identifying willing physicians to serve as collaborators was one of the reasons used in support of LB 107's passage. Now, in addition to physicians, under LB 107, a supervising provider can be another nurse practitioner in the same or a related specialty or the same field of practice as the individual supervised. Such supervision is permitted if the supervising nurse practitioner submits to the Department evidence of having completed 10,000 hours of practice as a nurse practitioner under a transition-to-practice agreement, under a similar type of agreement, through independent practice,

or a combination of these.

"Supervision" is defined in the statute in a similar manner as it was in prior law and Nebraska regulations. See Neb.Rev. Stat. § 38-2310(3)(b) (Reissue 2008); 172 NAC § 100-005.02.2.e. "Supervision" requires "ready availability of the supervising provider" to consult with and direct the activities of the nurse practitioner. Like prior law for nurse practitioners and collaborating physicians, a supervised nurse practitioner and the supervising provider are each responsible for their individual decisions in managing a patient's health care. The nurse practitioner and his or her supervising provider are jointly responsible for the health care provided to a patient based upon the scope of practice of the nurse practitioner and the supervising provider.

LB 107 is now the law. The debate about its potential effects on health care in the state has ended. Time will tell whether proponents' promises or physician concerns about LB 107's significant changes will be seen. □

Ask a Lawyer is a feature of the Nebraska Medical Association newsletter. If you have a legal question of general interest, please write the Nebraska Medical Association. Answers to your questions will be provided by the Nebraska Medical Association's legal counsel, Cline Williams Wright Johnson & Oldfather, L.L.P., 1900 U.S. Bank, 233 South 13th Street, Lincoln, Nebraska 68508-2095. The answer in this issue was provided by Jill Jensen. Questions relating to specific situations should continue to be referred to your own counsel. 4837-9804-4969, v. 1

1) A transition-to-practice agreement form developed by the Department is available at <http://dhhs.ne.gov/publichealth/Licensure/Documents/TransitionToPracticeAgreement.pdf>.



Telemedicine and Liability Issues in Nebraska

By COPIC's Patient Safety and Risk Management Department

Although the definitions of telemedicine and telehealth vary at the state and federal level, "telehealth" in Nebraska has been defined as the use of medical information electronically exchanged from one site to another, whether synchronously or asynchronously, to aid a health care practitioner in the diagnosis or treatment of a patient. It includes services originating from a patient's home or other location, asynchronous services involving the acquisition and storage of medical information at one site that is then forwarded to or retrieved by a health care practitioner at another site for medical evaluation, and telemonitoring.

PHYSICIAN-PATIENT RELATIONSHIP

Formation of a physician-patient relationship is usually clear in the traditional practice setting, but it may not be as clear where a physician has no in-person contact with a patient or where the physician is advising another practitioner who is at the patient's location. Even if the physician is just advising another practitioner, the consultant may be also be considered a "treating" physician if:

- The consultant interprets patient data such as labs, EKGs, or imaging studies.
- The consultant participates in diagnosing the patient and prescribing a course of treatment.
- The treating practitioner must rely on the consultant's expertise rather than exercising his or her judgment in treating the patient.

If a physician is being paid to provide consulting services, that may be a factor

in determining whether the physician has a "contractual" obligation to the patient.

Proper documentation of a telemedicine encounter is important for showing the existence of a physician-patient relationship. A physician providing consultation via telemedicine will want to carefully review any contractual agreements as well as documents used to memorialize a patient's agreement to be treated through telemedicine.

STANDARD OF CARE-MEDICAL LIABILITY

In a medical liability case, a physician is held to the standard of reasonable and ordinary care, defined as "that which health care providers, in the same community or in similar communities and engaged in the same or similar lines of work, would ordinarily exercise and devote to the benefit of their patients under like circumstances."

Although this hasn't been specifically addressed in Nebraska law, a practitioner will likely be held to the same standard of care as in a traditional encounter and not a "telemedicine" standard. The Federation of State Medical Boards, in its model telemedicine policy, takes this approach: "[A] physician using telemedicine technologies in the provision of medical services to a patient (whether existing or new) must take appropriate steps to establish the physician-patient relationship and conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the particular patient presentation. As such, some situations and patient presentations are appropriate for the utilization of telemedicine technologies as a component of, or in lieu of, in-person provision of medical care, while others are not."

Whether approaching a patient differently under the "circumstances" of a telemedicine encounter meets the standard of care will depend on expert testimony and the facts of a case. Some specialty societies have developed telemedicine guidelines.



Although treatment guidelines don't define the standard of care, they may be considered as some evidence of the standard of care if an expert in the same field would reasonably rely upon them when treating a patient.

INFORMED CONSENT

When a patient is being treated remotely, the informed consent process should include any pertinent benefits, risks, and alternatives that are unique to the telemedicine setting.

The patient should understand the limitations of telemedicine and that the physician may decide that it is inappropriate to evaluate and treat, or continue to treat, the patient through telemedicine. While there is no one informed consent process that would be applicable to all telemedicine encounters, the American Telemedicine Association guidelines¹ include some recommendations that are relevant in many cases.

- The provider should set appropriate expectations in regard to the telemedicine encounter. This may include prescribing policies, scope of services (including the structure and timing of services), communication and follow-up.
- Topics to be reviewed with patients include confidentiality and the limits of confidentiality in electronic com-

(continued on Page 24)

Telemedicine and Liability Issues in Nebraska *(continued)*

munication; an agreed upon emergency plan particularly for patients in settings without clinical staff immediately available; the process by which patient information will be documented and stored; the potential for technical failure; procedures for coordination of care with other professionals; a protocol for contact between visits; and conditions under which telemedicine services may be terminated and a referral made to in-person care.

The Nebraska Medicaid program requires a health care practitioner who

delivers a health care service to a patient through telehealth to ensure that certain written information is provided to the patient prior to the initial telehealth consultation. The patient must sign a written statement that the patient understands the written information and that the information has been discussed with the practitioner or his or her designee. A sample form is available via the following link: <http://dhhs.ne.gov/Documents/471-000-10.pdf>

ABANDONMENT

When a physician acts as a primary

treating physician through telemedicine, rather than as a consultant, it is essential that the patient understands how to receive follow-up care and with whom. In the absence of any special agreement limiting the physician's service, a physician may face an abandonment claim if the physician unilaterally ends the physician-patient relationship when a patient requires ongoing care and the patient has not been given proper notice. □

1. <http://www.americantelemed.org/docs/default-source/standards/core-operational-guidelines-for-telehealth-services.pdf?sfvrsn=4>

THE OPIOID EPIDEMIC

Preparing Prescribers to Confront the Opioid Crisis *(continued)*

PMID: 26304703

iii) CONN. GEN. STAT. § 20-10b (2015), available at <http://www.cga.ct.gov/2015/ACT/PA/2015PA-00198-R00HB-06856-PA.htm>

iv) CONN. GEN. STAT. § 20-10b (2015), available at <http://www.cga.ct.gov/2015/ACT/PA/2015PA-00198-R00HB-06856-PA.htm>

v) CONN. GEN. STAT. § 20-10b (2015), available at <http://www.cga.ct.gov/2015/ACT/PA/2015PA-00198-R00HB-06856-PA.htm>

vi) IOWA ADMIN. CODE r. 253-11.4 (2011), available at <https://www.legis.iowa.gov/docs/ACO/chapter/07-22-2015.653.11.pdf>.

vii) 201 Ky. Admin. Reg. 9:250 (2013), available at <http://www.lrc.ky.gov/kar/201/009/250.htm>.

viii) MASS. GEN. LAWS ch. 94C, § 18(e) (2011), available at <https://malegislature.gov/Laws/General-Laws/PartI/TitleXV/Chapter94c/Section18>.

ix) N.M. ADMIN. CODE § 16-10-14 (2012), available at <http://164.64.110.239/nmac/parts/title16/16.010.0014.htm>.

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xxv) Source: CDC/Wonder; data extracted May, 2013



Physician Advocacy Breakfast at the Capitol

On January 12, 2016, the Nebraska Medical Association will host its annual Advocacy Breakfast at the State Capitol.

Wear your white coat and plan to attend.

Let's send a strong message that the leaders of the health care team, Nebraska physicians, are engaged as advocates for physicians and the health of all Nebraskans!

When: January 12, 2016, 7:30-9:00 a.m.

Where: Room 1023, State Capitol

Who: Nebraska physicians across all specialties, residents and medical students

RSVP to Meghan by January 5
at meghanj@nebmed.org or (402) 474-4472.
Register online: www.nmaevents.org

Be assured that health care providers across the entire spectrum are out advocating for their profession. Physicians need a seat at the table to be heard!

**We look forward to seeing you on January 12
and don't forget to wear your white coat!**

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Giving More & Paying Less

Donor-Advised Funds—What's not to like?

by Ross Polking

Provided by the Foster Group

As 2015 starts to wind down, many physicians are thinking about how to positively impact causes and organizations about which they are passionate. A further benefit of this endeavor is the opportunity to lessen one's annual tax burden. A donor advised fund (DAF) is a fantastic tool for gifting and tax mitigation that is worth considering. DAFs are philanthropic vehicles operated by public charities which are relatively uncomplicated, widely available, and cost-effective for charitable pursuits. They are simpler to set up and less capital-intensive than a private foundation. They also allow for greater control and personal input than direct donations.

The premise and process is simple:

- 1) Choose an organization that offers a DAF, and open an account.
- 2) Deposit cash or transfer securities into the account, surrendering your ownership of the assets.
- 3) Provide direction to the DAF on how the account is invested, when and to whom dollars are distributed.

Here are a few of the benefits and inner workings of DAFs:

- **Avoid capital gains taxes on highly appreciated securities.** Making donations using appreciated securities

is one of the most tax-efficient ways of giving. Donors not only get an immediate tax deduction for the fair market value, they also avoid paying any capital gains tax when those shares are liquidated inside the DAF. Many investors have large unrealized gains built up in after-tax portfolios with the market rise over the past few years.

- **Reduce future tax burden on heirs.**

Listing a DAF as a beneficiary of an investment account removes those assets from one's estate at the time of death without subjecting them to gift tax consideration. Consider this so long as heirs are taken care of with other assets.

- **Mitigate large expected tax bills.**

A deduction for a donation to a DAF is taken in the same year as contribution to the fund, rather than the year of the distribution from the fund to a charitable organization. This allows for the flexibility to minimize taxes in years when you expect a large tax bill while still preserving the ability to make a gift at the right time. Additionally, gift amounts that exceed Adjusted Gross Income limits (50% for cash, 30% for property) can carry forward for up to five years.

- **Deductions and capital gains mitigation are more valuable.**

Because of the increase in marginal income and capital gains taxes, limiting their effect is now of even greater benefit. The highest marginal tax rate is near 40%,

while the top capital gains tax rate is 20%. Both have increased in the past year and offer even more incentive to the giver to mitigate taxes with their charitable gifts.

Physicians are sacrificial not only with their time, but with their financial resources as well when it comes to making a greater impact. Giving to charity can be done in many ways. Just be sure you are maximizing every dollar with efficient giving techniques, benefitting the causes you are passionate about as well as your own pocketbook. Stay diversified. □

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The information and material provided in this article is for informational purposes and is intended to be educational in nature. We recommend that individuals consult with a professional advisor familiar with their particular situation for advice concerning specific investment, accounting, tax, and legal matters before taking any action.



FOSTER GROUP PRESENTS

VECTORS & VIEWPOINTS®

2015 NMA Edition

VECTOR: SMALL CHANGES MAKE A BIG DIFFERENCE



Ross Polking
CFP®, AIF, Lead Advisor

Today's question:

How does Charitable Giving fit into a person's financial plan?

As a part of our relationship with the Nebraska Medical Association, we would like to offer you a complimentary Second Opinion. This \$1,500 service is yours at no charge. We invite you to participate in this unique opportunity to acquaint yourself with Foster Group and bring clarity, reduce complexity and increase your probability of financial success.

I think one of the most important parts of a person's financial plan is charitable giving, because of the perspective it gives a family.

Some of my favorite experiences as an advisor involve seeing the freedom that comes when a client begins to see the impact that a small gift can make on the recipient. This can be done through automatic gifts to one's church, random acts of generosity like buying a stranger lunch, or strategic, large-scale gifts to help build the Children's hospital in Iowa City! A favorite book of mine is, "I Like Giving", which is filled with stories of people impacting others through small and large acts of generosity.

You can read some of these stories at www.ilikegiving.com/stories and see how you get inspired!



Contact us today at 844-437-1102 or visit fostergrp.com/NMA.



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- **Concussion Characteristics & Epidemiology**
Facts and myths, special problems with youth concussions, multiple injuries, and after effects.
- **Concussion Symptoms & Signs**



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**COMMUNICATION
AND LEADERSHIP**

**2016 ANNUAL
MEMBERSHIP MEETING
& HOUSE OF DELEGATES**

Friday, September 16, 2016
Holiday Inn Downtown
Lincoln



Nebraska
Medical
Association

PRESIDENT'S MESSAGE



On Friday, September 16, the Nebraska Medical Association will host its 148th Annual Session and House of Delegates, what we now refer to as the NMA's annual membership meeting.

For nearly 150 years, physician members have recognized the importance of convening to make policy and take action on items that affect the medical profession and ultimately the lives of our patients. Physicians and patients alike have benefited from the thousands of members before us who dedicated their time, despite their busy and demanding schedules, to come together to advocate for change and influence our profession and patient care. It's now up to us, current NMA members, to assume leadership roles. It's easy to tell ourselves that we'd love to participate if only...or we sure wish we could, but can't for whatever reason, but I will say this: if we don't take the time, who will?

This year's meeting covers a wide range of topics that are at the forefront of medicine in 2016. Physician burnout, medical marijuana, opioid abuse, physician communication and leadership – these are just a few of the issues talked about in the doctors' lounge or referenced in the media. It can be overwhelming to address these issues on our own so oftentimes it's simply a conversation before we return to our daily tasks. That's where the NMA comes in – bringing medical colleagues from all areas of the state, all specialties, all backgrounds and all opinions together on one day in one place to make a difference.

If you've joined us in the past, we welcome you back! If you haven't attended before, I strongly encourage you to make arrangements now to attend the NMA's annual membership meeting on September 16.

Our time to lead is now.

A handwritten signature in black ink, reading "Harris A. Frankel, MD". The signature is fluid and cursive.

Harris Frankel, MD
NMA President

SCHEDULE OF EVENTS

FRIDAY, SEPTEMBER 16, 2016

7:15 am

Registration

7:15 am – 9:45 am

Continental Breakfast

7:30 am – 9:00 am

Greater Nebraska Medical Caucus Meeting*

** (Greater Nebraska physicians only)*

7:30 am – 5:00 pm

Commercial Supporters Exhibits

9:00 am – 12:00 pm

CME Programming
(3 CME Hours)

9:00 am – 10:30 am

Caring for the Caregiver: How Do We Identify, Reduce and Properly Manage Physician Stress, Burnout and Proper Maintenance of Healthy Personal Relationships?

Scott Humphreys, MD

Senior Medical Director, Colorado Access Program

Program Objectives:

- Discuss and identify unique stressors: work, home, and personal, in a physician's life and explore methods for proper management thereof
- Understand typical stress syndromes of burnout and malpractice stress
- Identify the various occupational hazards of being a physician such as depression, suicide, addiction, poor health, work/life balance, and understand ways to effectively prepare for and cope with such hazards
- Identify common physician traits that tend to interfere with emotional awareness and/or expressions of feelings and familiarize with strategies for addressing and maintaining healthy personal and occupational relationships

(continued)

SCHEDULE OF EVENTS (cont)

10:30 am – 12:00 pm

Medical Cannabis: What Physicians Need to Know - Understanding the Pros and Cons

Scott Humphreys, MD

Senior Medical Director, Colorado Access Program

Program Objectives:

- Identify the pros and cons for use of medical cannabis as it relates to specific medical conditions that have been shown to benefit from its use
- Discuss how the use of medical cannabis is currently viewed by the FDA and the DEA and the relation thereto the prescribing physician
- Review current debates and controversies in marijuana policies across the United States
- Describe the consequences of marijuana use physically, psychiatrically, and cognitively
- Determine what safeguards need to be in place to protect those whose consequences from the treatment would outweigh any potential benefit

12:00 pm – 1:00 pm **Lunch Buffet** (1 CME Hour)

Leadership as Physicians: Acquiring the Tools Necessary for Surviving and Thriving in Transforming Healthcare Delivery and the Payment Delivery System

Michael Hein, MD

President and CEO, Enhance Health Network

Program Objectives:

- Discuss and identify the future of payment and practice reform as it relates to patient-centered health care
- Discuss the MACRA legislation and the impact value-based reimbursement will have on the practice of medicine
- Identify the potential barriers and solutions for implementing effective patient-centered care in your practice
- Outline the steps necessary to work collaboratively and effectively to establish community-based health teams that support and promote high quality, affordable and accessible patient-centered care in your practice
- Describe the skills and competencies necessary to effectively integrate and lead a transformed health care organization
- Discuss the resources available to Nebraska physicians to provide assistance and education in the implementation and collaboration of patient-centered health care and payment transformation

(continued)

SCHEDULE OF EVENTS (cont)

1:00 pm – 5:45 pm **House of Delegates**

1:00 pm – 2:00 pm **Keynote Address** (1 CME Hour)

Physician Leadership in Addressing the Opioid Crisis: A National Perspective

Patrice Harris, MD, MA

Director, Fulton County (Atlanta, GA) Health Services
AMA Board of Trustees

Program Objectives:

- Identify what physicians can do in their practices and communities to focus on ending the opioid overdose epidemic
- Discuss and explain the AMA's Task Force to Reduce Opioid Abuse and 5 Recommendations of the Task Force
- Discuss the national movement to utilize Naloxone as a means in addressing opioid overdose
- Explain the importance of implementing and utilization of an effective Prescription Drug Monitoring Program

2:00 pm – 3:00 pm **House Business**

President's Message –
Harris Frankel, MD

Resolutions

3:00 pm – 3:15 pm **Break Service /
Visit Commercial Supporter
Exhibits**

3:15 pm – 3:45 pm **Maintenance of Certification**

John Moorhead, MD, MS, FACEP
Chair-Elect, American Board of
Medical Specialties

3:45 pm – 4:00 pm **Legislative/Candidate
Election Update**

Kim Robak, JD
Matt Schaefer, JD
Mueller Robak, LLC

4:00 pm – 4:30 pm **PAC Update**

Todd Hlavaty, MD

AMPAC Update

Linda Ford, MD

(continued)

SCHEDULE OF EVENTS (cont)

4:00 pm – 4:30 pm **Medicaid Managed Care Organization Contract Introductions**
Nebraska Total Care –
Chris Stark
Vice President of Contracting
and Network Development
Wellcare –
Tracy Smith
Senior Director of Network Management
United Healthcare –
Mike Horn, MD, MMM
Chief Medical Officer

4:30 pm – 4:45 pm **Prescription Drug Monitoring Program Update**
Kevin Borchert, PharmD
NeHII

4:45 pm – 5:45 pm **What's Happening in Nebraska – Drug Trafficking Trends (1 CME Hour)**

Doug Peterson, JD
Attorney General, State of Nebraska

Chris Kober
Investigator, Nebraska State Patrol

Program Objectives:

- Describe the scope of opioid abuse in Nebraska
- Identify the current drug use trends in Nebraska
- Explain law enforcement's greatest challenges in combating illegal substances (including heroin)
- Describe state legislative initiatives to combat drug addiction and overdose in Nebraska

6:15 pm – 7:00 pm **Commercial Supporter's Social Reception**

Resident Poster Presentations

Residents are invited to present Scientific Posters during this time. Attendees encouraged to vote for their first choice.

7:00 pm – 9:00 pm **Inauguration & Awards Dinner**

7:15 pm **Dinner**

7:45 pm **Awards Program**
Doc Winger – Master of Ceremonies

2016 Scholarship Presentation

2016 50 Year Practitioner Presentation

SCHEDULE OF EVENTS (cont)

2016 Awards Presentation

Young Physician of the Year
Physician of the Year
Physician Advocate of the Year
Resident Advocate of the Year
Student Advocate of the Year
Distinguished Service to Medicine
Friend of Medicine
Resident Poster Award
Harold E. Williamson Award – COPIC

Installation of Todd Pankratz, MD, President

ADDITIONAL ACTIVITIES

8:00 am – 9:30 am **Nebraska Osteopathic Medical Association (NOMA) Meeting**
(1 CME Hour)
(social continental breakfast 8:00-8:30)

Update on Osteopathic Manipulation Therapy

Melinda S. Barratt, DO
Broken Bow Clinic, PC

Program Objectives:

- Understand the use of palpation as a helpful diagnostic tool
- Discuss therapeutic touch and the ability to soothe and comfort patients, affecting them on physical, emotional and spiritual levels
- Understand when and where to use osteopathic manipulative treatment

9:30 am – 1:00 pm **NMA Alliance Meeting**

Current Issues for Safety in Lincoln/ PULSE Point App

Tom Casady, Public Safety Director, City of Lincoln

Effective Efforts to Reduce the Rate of Childhood Obesity

Bob Rauner, MD, Partnership for Healthy Lincoln

Assisting Your Child in Selecting a Career Path

Pat McBride, Associate Dean of Admission
University of Nebraska Lincoln

9:30 am – 1:00 pm **Alliance Childcare**

12:00 pm

Lunch and Packing Tips for Travel

Sherri Travis
Rachel's Boutique

Todd Pankratz, MD President-Elect

Dr. Pankratz began his obstetric and gynecologic practice in Hastings in 1998. He is certified by the American Board of Obstetrics and Gynecology and is a Fellow of the American College of Obstetricians and Gynecologists.



Dr. Pankratz was born in Henderson, Nebraska, and completed his primary education there. He attended Hastings College and received his Bachelor of Arts degree in 1988. After receiving his doctor of medicine degree from the University of Nebraska College of Medicine in Omaha in 1992, he served his residency training at Truman Medical Center/St. Luke's Hospital in Kansas City, Missouri. Following completion of his residency training in 1996, Dr. Pankratz was in private practice in Iowa City, Iowa, prior to returning to Hastings.

Dr. Pankratz has been an active member of the NMA since 1998. From 2005-2011, he served as Greater Nebraska Medical Coalition president and served as treasurer from 2011 until his appointment to president-elect in 2015. Dr. Pankratz has served on numerous NMA committees and commissions including: the NMA Board of Directors, the Maternal and Child Health Committee, the Medical Home Committee, the Nebraska Medical Political Action Committee, the Nebraska Medical Insurance Services, the Health Care Reform Task Force, the Commission on Legislation and Governmental Affairs, and the NMA Foundation. He has served as a delegate from 2002 to present.

Nationally, Dr. Pankratz is a diplomate of the American College of Obstetricians and Gynecologists currently serving as the District VI chair of Nebraska. He has been a member of the American Medical Association since 1996 where he has served as an alternate delegate and delegate to the House of Delegate's Young Physicians Section. He was also an AMA representative to the CAPIR Council for the American Dental Association from 2011 to 2014.

Dr. Pankratz practices at Obstetricians and Gynecologists, P.C., in Hastings. He is a medical staff member of Mary Lanning Memorial Hospital where he has served on numerous committees. He also serves as medical director of Hastings Family Planning. His community involvement includes serving as a charter board member with 5 Points Bank of Hastings, Early Head Start, Rotary, Leadership Hastings, the Hastings Symphony, mentoring pre-med students at Hastings College, and First Presbyterian Church.

Dr. Pankratz and his wife, Jessica Meeske, a pediatric dental specialist, have two children, Robert, 21, and Sophia, 18.

Master of Ceremonies Dwight 'Doc' Winger

Dwight 'Doc' Winger is executive vice-president, external relations of Pinpoint Broadband, Inc. Previously, he served as vice-president for governmental relations and business development for Pinpoint Holdings, Inc.



Before assuming his position at Pinpoint, Winger had more than 30 years of telecommunications policy experience as an employee at the Nebraska Legislature, the Nebraska Public Service Commission and in the telecom industry in Nebraska. He is generally recognized as a preeminent Nebraska expert in rural telecommunications policy and is routinely called on to present seminars to policy makers and their staffs on telecommunications policy and finance history. He holds a Bachelor of Science degree from Nebraska Wesleyan University and a master's of public administration from the University of Nebraska at Omaha.

In addition to his work in telecommunications, Winger is also well known in the athletic community. Since 1988, he has announced more than 1,000 high school and college athletic contests and has been the Public Address Announcer for NSAA state football, girls and boys basketball and baseball championships for more than 20 years. He is also the current PA announcer for the University of Nebraska-Lincoln's men's basketball team.

FEATURED SPEAKERS



Melinda S. Barratt, DO

Dr. Barratt is a native of Lincoln, Nebraska. After high school, Dr. Barratt attended Nebraska Wesleyan University and graduated in 1993 with a Bachelor of Science degree in biology. She then received her medical degree from the Kirksville College of Osteopathic Medicine in Missouri in 1998. Dr. Barratt completed a dual track residency program in family medicine and osteopathy at the Wilson Memorial Regional Medical Center in Johnson City, New York. Dr. Barratt is board certified in both family medicine and osteopathic medicine. Her practice is located at the Sherman County Medical Clinic in Loup City, Nebraska and she has privileges at the Jennie M. Melham Memorial Hospital in Broken Bow. Dr. Barratt is trained in obstetrics, including caesarean, pediatrics, sports medicine, osteopathic manipulation, geriatrics, and all other aspects of family medicine and osteopathic medicine.

Kevin C. Borchert, PharmD

Kevin Borchert is the Prescription Drug Monitoring Program Director for NeHII (Nebraska Health Information Initiative) and is responsible for the implementation of the Nebraska Prescription Drug Monitoring Program (PDMP). Prior to his current position, Kevin was the pharmacy informatics coordinator at Nebraska Methodist Hospital for over 19 years. He has experience in implementing and maintaining automated dispensing systems, barcode medication administration (BCMA), computerized provider order entry (CPOE), and most recently the first implementation of one of the largest EHR systems in the country with electronic prescribing of controlled substances (EPCS). Kevin is a 1986 graduate of UNMC. He has served on the Nebraska Board of Pharmacy and several committees on the National Association of Boards of Pharmacy for 10 years and currently is the pharmacist member on the Board of Health, serving as chair of the Rules and Regulations Committee. Kevin has been involved with several Nebraska Pharmacists Association (NPA) legislative initiatives, including co-chair of the NPA Legislative Committee to help pass LB37, the Prescription Drug Safety Act and LB471, the most recent update to the PDMP.



FEATURED SPEAKERS (cont)

Patrice A. Harris, MD, MA

Patrice A. Harris, MD, MA, who has diverse experience as a private practicing physician, public health administrator, patient advocate and medical society lobbyist, was elected to the American Medical Association Board of Trustees (BOT) in June 2011.



Active in organized medicine her entire career, Dr. Harris has served on the board of the American Psychiatric Association (APA) and was an APA delegate to the AMA. She has also been a member of the governing council of the AMA Women Physicians Congress, testified before and served on AMA reference committees, and has served on AMA work groups on health information technology, SGR and private contracting. The AMA-BOT appointed her to the AMA Council on Legislation in 2003, and she was elected by the council to be its 2010–2011 chair.

Dr. Harris has held many positions at the state level as well, including serving on the board and as president of the Georgia Psychiatric Physicians Association and on the Medical Association of Georgia's Council on Legislation and Committee on Constitution and Bylaws. She was also the founding president of the Georgia Psychiatry Political Action Committee.

A governing theme in Dr. Harris' professional life has been a passion to improve the lives of children. Starting with medical school in West Virginia, followed by a psychiatry residency and child psychiatry fellowship at Emory, and then as a senior policy fellow for the Emory University School of Law, she has worked for children clinically and in the advocacy arena. At Emory she addressed public policy for abused and neglected children before the Georgia legislature and in public education programs.

As past director of Health Services for Fulton County, Georgia, which includes Atlanta, she directed all county health services for a wide range of public safety, behavioral health, and primary care treatment and prevention services. Dr. Harris also served as medical director for the Fulton County Department of Behavioral Health and Developmental Disabilities.

Currently, Dr. Harris continues in private practice and consults with both public and private organizations on health service delivery and emerging trends in practice and health policy.

FEATURED SPEAKERS (cont.)

Michael Hein, MD

Dr. Hein is president and CEO of ENHANCE Health Network, a non-merger network of 59 hospitals and health care systems in western Iowa, northwestern Missouri, and Nebraska. He is a board certified general internal medicine physician and a Fellow of the American College of Physicians.



He has previously served in numerous leadership roles. These include positions in the VA health care system at a local, regional and national level, as well as chief medical officer and vice-president of medical affairs at CHI Health St. Francis in Grand Island, Nebraska. Prior to his service in the VA, Dr. Hein was in private practice in Holdrege, Nebraska, and Yankton, South Dakota.

Dr. Hein received his medical degree from the Sanford School of Medicine at The University of South Dakota and completed his residency in internal medicine at Gundersen Health in La Crosse, Wisconsin. He received his Master of Science in healthcare management from Harvard University, School of Public Health, and a Master of Science degree in exercise physiology from St. Cloud State University in St. Cloud, Minnesota.

Scott Humphreys, MD

Dr. Humphreys received his medical degree from the University of Oklahoma. He went on to train in general psychiatry at John Hopkins Hospital where he served as chief resident. He came to Denver to train in forensic psychiatry through the University of Colorado Denver.



Dr. Humphreys oversees the psychiatric consultation services at Presbyterian St. Lukes and Rose Hospitals, and he is an attending physician on the geriatric psychiatry unit of the Medical Center of Aurora. He continues to be affiliated with the forensic psychiatry training program at the University of Colorado Denver. Dr. Humphreys' primary emphasis in his forensic psychiatric practice is sex offender evaluation, management, and treatment. In addition, he cares for general psychiatric outpatients in his private practice.

Dr. Humphreys sees it as a privilege and a great responsibility to work with the physicians in this state during some of their most trying times to help ensure their health and, subsequently, the health of their patients.

FEATURED SPEAKERS (cont)

Attorney General Doug Peterson

Nebraska Attorney General Doug Peterson was born in Columbus, Nebraska, and grew up in Lincoln. Attorney General Peterson graduated from the University of Nebraska with a business degree in 1981 and from Pepperdine University School of Law in 1985. Following law school, Doug spent two years in North Platte, Nebraska, prosecuting both criminal and civil cases for the Lincoln County Attorney. From 1988 to 1990, he served as deputy to the Nebraska Attorney General's office, representing the State in employment law matters and tort litigation. He was in private law practice from 1990-2014. Doug was sworn in as the 32nd Attorney General for the State of Nebraska on Thursday, January 8, 2015.



Investigator Chris Kober

Christopher Kober has been with the Nebraska State Patrol for over 22 years and has been in investigations for the past 12 years. He is currently assigned to a DEA Task Force that focuses specifically on prescription drug issues. Chris has also served on the U.S. Attorney's Medical Fraud Task Force for the past 10 years. He has worked a wide variety of cases relating to prescription drugs and medical fraud issues to include false, forged, or altered prescriptions, doctor shopping, theft, robbery, burglary, overprescribing, illegal distribution, pill mills, overdose deaths, identity theft, billing fraud, money laundering, and homicides. Chris has a bachelor's degree in criminal justice and has completed the medicolegal death investigations course through St Louis University and the International Association of Identification certification. In 2013, Chris received the Midwest HIDTA Award and the Office of National Drug Control Policy Award for outstanding prescription drug investigations.

CME STATEMENT

Bryan Health is accredited by the Nebraska Medical Association to provide continuing medical education for physicians.



"Bryan Health designates this live activity for a maximum of 6 AMA PRA Category 1 Credit(s). Physicians should claim only the credit commensurate with the extent of their participation in the activity."

Please complete and return registration form at right **NO LATER THAN September 7, 2016**

along with check or payment information made payable to:

Nebraska Medical Association

233 South 13th Street, Suite 1200

Lincoln, NE 68508

Fax (402) 474-2198

Call (402) 474-4472 or (800) 684-9380

with questions.

WE GREATLY APPRECIATE YOUR RSVP FOR MEAL COUNTS.



HOTEL INFORMATION

Holiday Inn Downtown

141 N. 9th St.

Lincoln, NE 68508

Rate: \$165/night

*two night minimum (Friday/Saturday) to receive the contracted rate

Rooms must be booked by August 16, 2016, in the Nebraska Medical Association room block.

There is no guarantee of rooms after August 16 as the room block will be released after that time.

Online booking link is available at www.nmaevents.org

Phone: 1-800-HOLIDAY or 402-475-4011

Group Code: NMA

Group Name: Nebraska Medical Association

Due to the Nebraska Oregon football game on Saturday, hotel rooms will be limited.

We encourage you to reserve your room early.

REGISTRATION

REGISTRATION DEADLINE: SEPTEMBER 7, 2016

We encourage you to register online at www.nmaevents.org.

Attendee Name _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

Email _____

FRIDAY, SEPTEMBER 16, 2016

Greater Nebraska Medical Caucus

NOMA Meeting

NMA Alliance Meeting *Childcare:* Yes No

If yes, please indicate number of children and ages:

Caring for the Caregiver: How Do We Identify, Reduce and Properly Manage Physician Stress, Burnout and Proper Maintenance of Healthy Personal Relationships?

Medical Cannabis: What Physicians Need to Know, Understanding the Pros and Cons

Lunch - Leadership as Physicians: Acquiring the Tools Necessary for Surviving and Thriving in Transforming Healthcare Delivery and the Payment Delivery System

NMA House of Delegates

Cost: None Number of attendees _____

NMA Inaugural Dinner

Cost: \$70.00 per person Number of attendees _____

Guest Name _____

Student Cost: \$35.00 Number of attendees _____

Guest Name _____

Please list any dietary restrictions: _____

TOTAL COST \$ _____

PAYMENT

Check Enclosed

VISA MasterCard AMEX Discover

Total Amount Enclosed \$ _____

Account Number * _____

Expires _____

Name on Credit Card _____

** Credit Card will NOT process unless all information is completed*



Nebraska
Medical
Association

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Applying Population Health Management to Opiate Prescription Medication Misuse

Joe Parks, MD
National Council Senior Medical Advisor

April 13, 2016

- **Medicaid Director**
- **Previously DMH Medical Director – 20 years**
 - ✓ Practicing Psychiatrist
 - ✓ CMHCs – 10 years
 - ✓ FQHC – 18 years
- **Distinguished Professor, Missouri Institute of Mental Health, University of Missouri St. Louis**
- **Adjunct Professor of Psychiatry – University of Missouri Columbia**

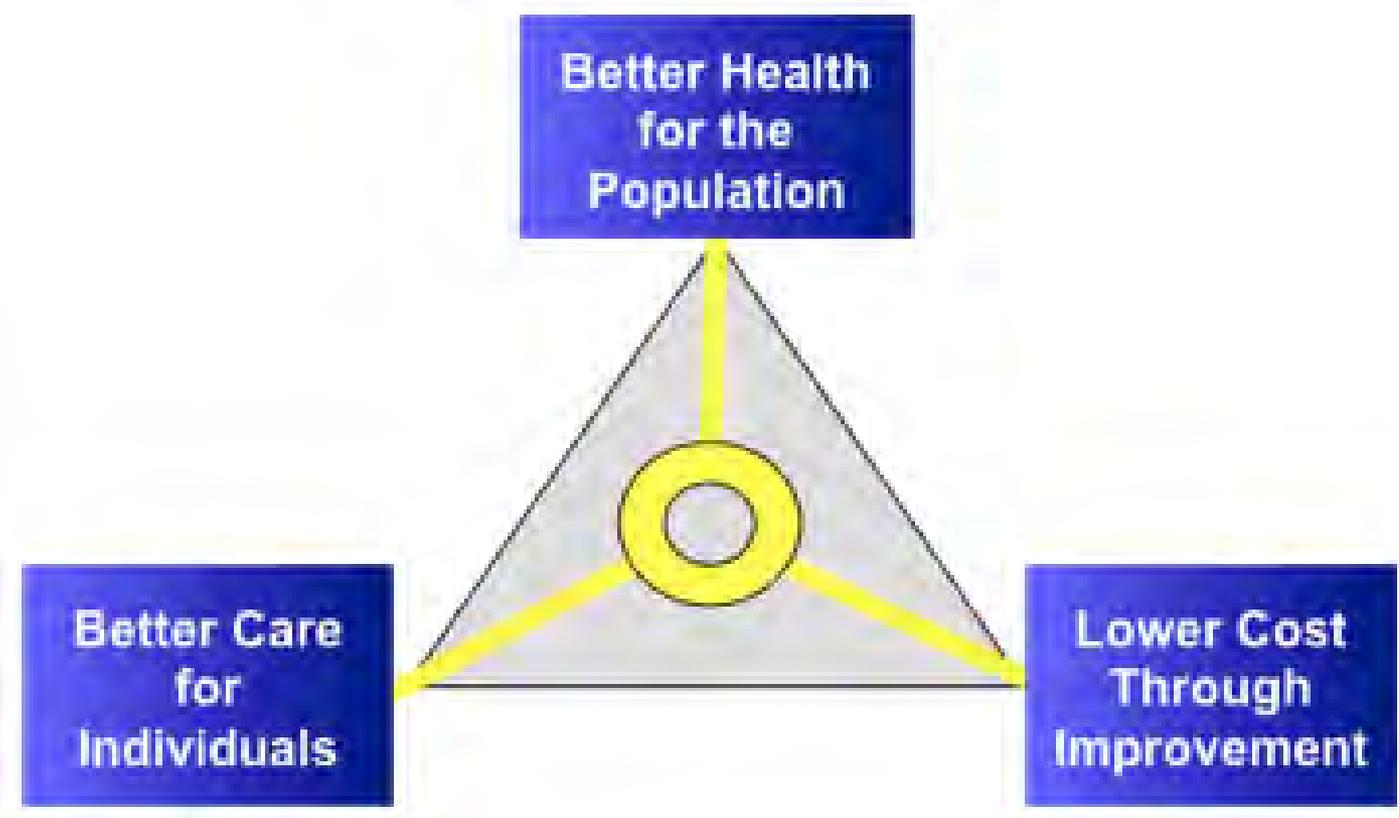
- **What Is Population health**
- **What is population health management**
- **Why do we need it for Perscription Drug Abuse?**
- **Missouriexample**

- **The health of the population as measured by health status indicators and as influenced by social, economic and physical environments, personal health practices, individual capacity and coping skills, human biology, early childhood development, and health services (Dunn and Hayes, 1999).**
- **A conceptual framework for thinking about why some populations are healthier than others as well as the policy development, research agenda, and resource allocation that flow from it (Young, 2005).**



The IHI *Triple Aim*

Better Care for Individuals, Better Health for Populations, and Lower Per Capita Costs



Population Management Principles

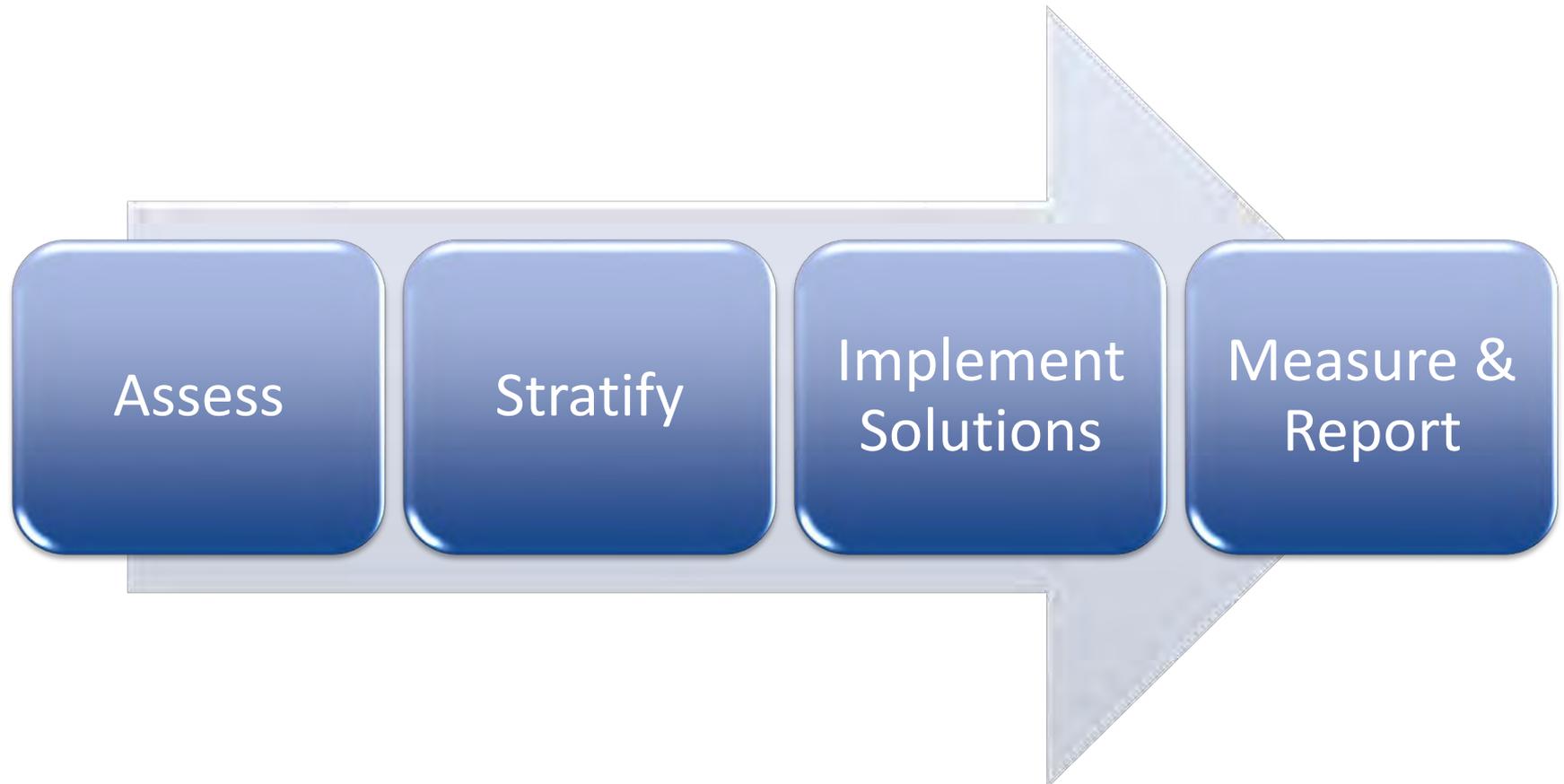
- ✓ **Population-based care**
- ✓ **Data-driven care**
- ✓ **Evidence-based care**
- ✓ **Patient-centered care**
- ✓ **Addressing social determinates of health**
- ✓ **Team care**
- ✓ **Integration of behavioral and primary care**

- **Don't rely solely on patients to know when they need care, what care to ask for and from whom—use data analytics for outreach on high need/utilizer patients**
- **Don't focus on fixing all care gaps one patient at a time - Choose selected high prevalence and highly actionable individual care gaps for intervention across the whole population**
- **The population-based health care provider is the public health agency for their clinic population**

Data-Driven Care



How do you deliver PHM?



- **Selects those from whole population:**
 - ✓ Most immediate risk
 - ✓ Most improvement opportunities
- **Aids in planning:**
 - ✓ Care for whole population
 - ✓ New interventions and programs
 - ✓ Early identification and prevention
 - ✓ Choosing and targeting health education

- **Individual drill-down – care coordination**
- **Aggregate reporting – performance benchmarking**
- **Disease registry – care management**
 - ✓ Identify care gaps
 - ✓ Generate to-do lists for action
- **Understanding – planning and operations**
- **Telling your story – presentation like this**

- **Use the Data you have before collecting more**
- **Show as much data as you can to as many partners as you can as often as you can:**
 - ✓ Sunshine improves data quality
 - ✓ They may use it to make better decisions
 - ✓ It's better to debate data than speculative anecdotes
- **When showing data, ask partners what they think it means**
- **Treat all criticisms that results are inaccurate or misleading as testable hypotheses**

- **Tell your data people that you want the quick easy data runs first. Getting 80% of your request in one week is better than 100% in six weeks**
- **Treat all data runs as initial rough results**
- **Important questions should use more than one analytic approach**
- **Several medium data analytic vendors/sources is better than one big one**
- **Transparent bench marking improves attention and increases involvement**

- ★ **Perfect is the enemy of good**
- ★ **Use an incremental strategy**
- ★ **If you try to figure out a comprehensive plan first, you will never get started**
- ★ **Apologizing for a failed prompt attempt is better than apologizing for a missed opportunity**

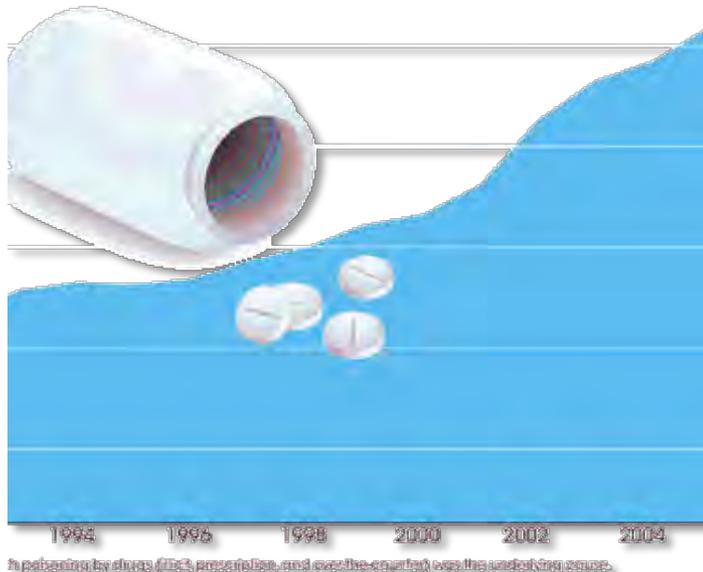


PLANNING

MUCH WORK REMAINS TO BE DONE BEFORE WE CAN ANNOUNCE
OUR TOTAL FAILURE TO MAKE ANY PROGRESS.

- **Methadone is reported by the Centers for Disease Control and Prevention to be involved in 30 percent of prescription overdose deaths**
- **CDC also reports that the death rate from methadone overdoses was 6 times higher in 2009 than in 1999.**
- **While buprenorphine abuse and overdose deaths are much rarer, they are rapidly increasing in number.**

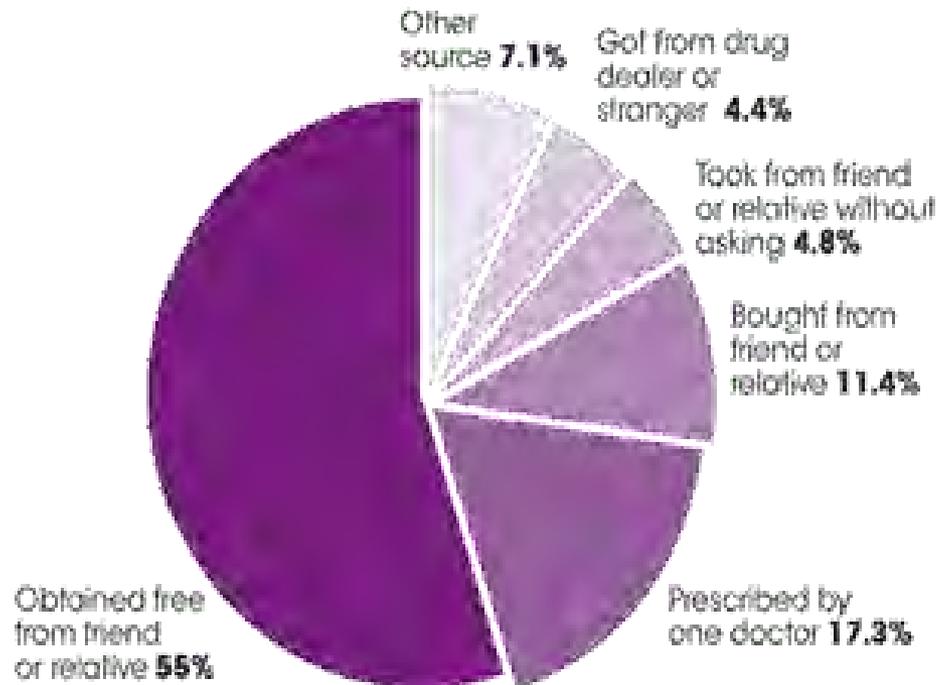
Drug overdose death rates in the US have
tripled since 1990.⁵



- Drug overdose death rates in the US have more than tripled since 1990
- In 2008 more than 36,000 people died from drug overdoses
- 42 people die everyday from prescription painkiller overdose in US
- Most of those deaths were caused by prescription drugs

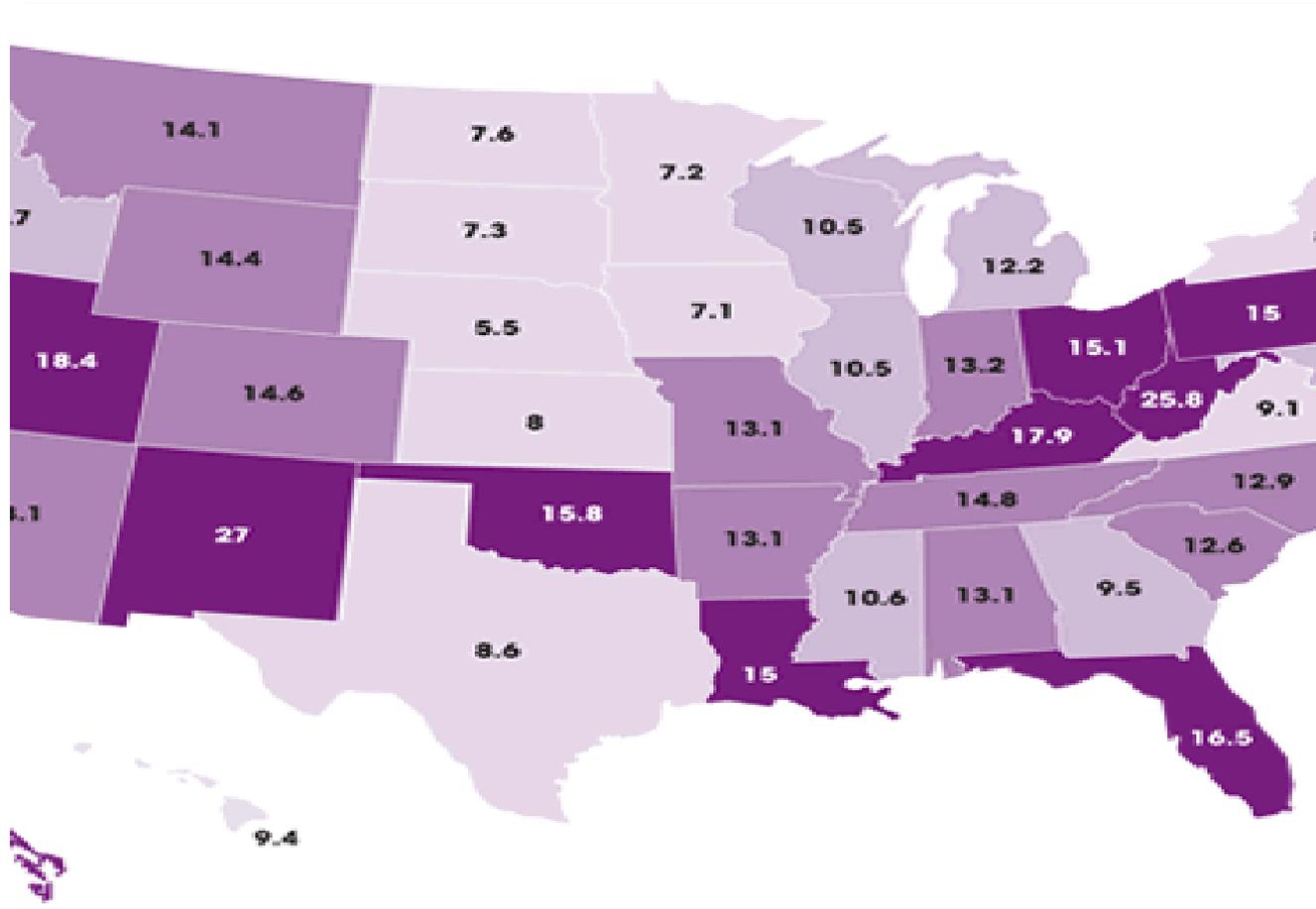
Most Cases of Opioid Misuse Start with a Doctor's Prescription

People who abuse prescription painkillers get drugs from a variety of sources⁷



Opioid Misuse Varies Regionally

www.TheNationalCouncil.org



- **Young age (18-25)**
- **Misuse rising among elderly**
- **Male**
- **Rural area**
- **Living in south, Maine, New Hampshire**
- **Low income, unemployment**

- **Previous or current psychiatric illness**
- **Previous alcohol or other substance abuse**
- **Benzodiazepine use**

Risks for Misuse of Opioids: “Doctor Shopping”

- **Multiple pharmacies**
- **Multiple prescribers**
- **“Lost” pills or prescriptions**
- **Frequent requests for dose increase**
- **Frequent requests for early refill**

Risk for Misuse of Opioids: Prescriber Issues

- **Influenced by patient request**
- **Inadequate training**
- **Ignore PMPs**

REF: McKinlay et al, Med Care, 2014

- **Control of post-traumatic pain**
- **Control of post-surgical pain**
- **Treatment of pain in patients with malignant cancer**
- **Palliative, end-of-life care**
- **Treatment of opioid addiction (methadone & buprenorphine)**

- **Migraine headache**
- **Cough suppression**

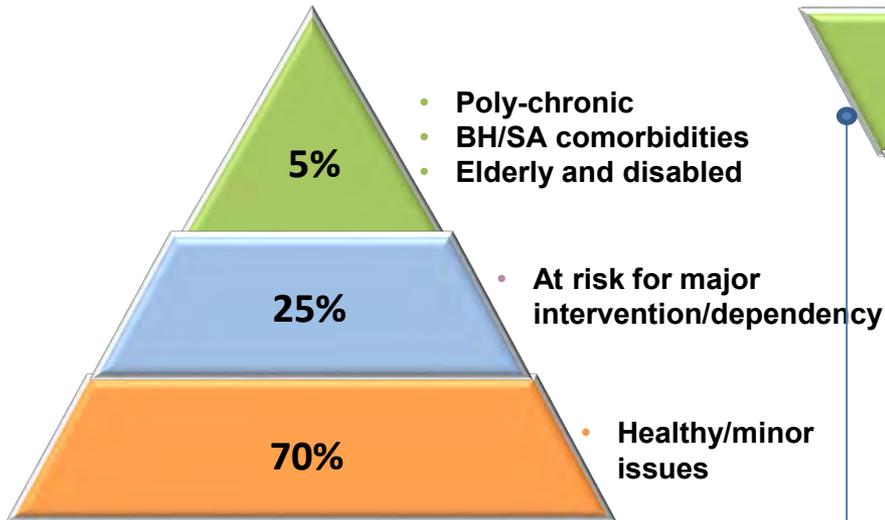
Uncertain Use of Opioid Analgesics

- **Chronic non-malignant pain**
- **Defined as: pain lasting more than three months or past the time of normal tissue healing**
- **One-third of American adults report chronic pain**
- **Neuropathic pain**

REF: AHRQ, 2013

- **Mandatory PMP use**
- **Follow practice guidelines**
- **Screen for substance abuse and psychiatric illness**
- **Do not co-prescribe benzodiazepines**
- **Evaluate prescribing data on a regular basis, including in ED**
- **Use Population Data Based Analytics — Prescription Monitoring Programs (PMP); CMT Model**

Population Stratification

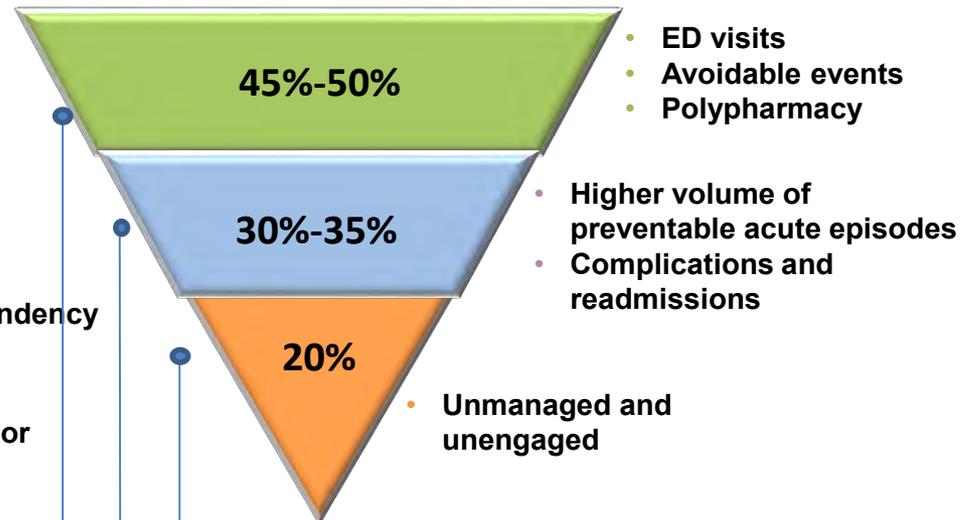


Opportunities for integrative medicine

Opportunities to enhance value through greater BH access and engagement

Opportunities to reduce/prevent dependency; Improve quality of life

Resource Consumption



Source: Blended MarketScan Commercial, Medicare 5% LDS, and representative payer Medicare data

- **Lowered rates of doctor shopping**
- **Improved clinical decision making**
- **Increased discussion with patients about pain/opioid use**
- **Increased referrals for SA and brief intervention services**

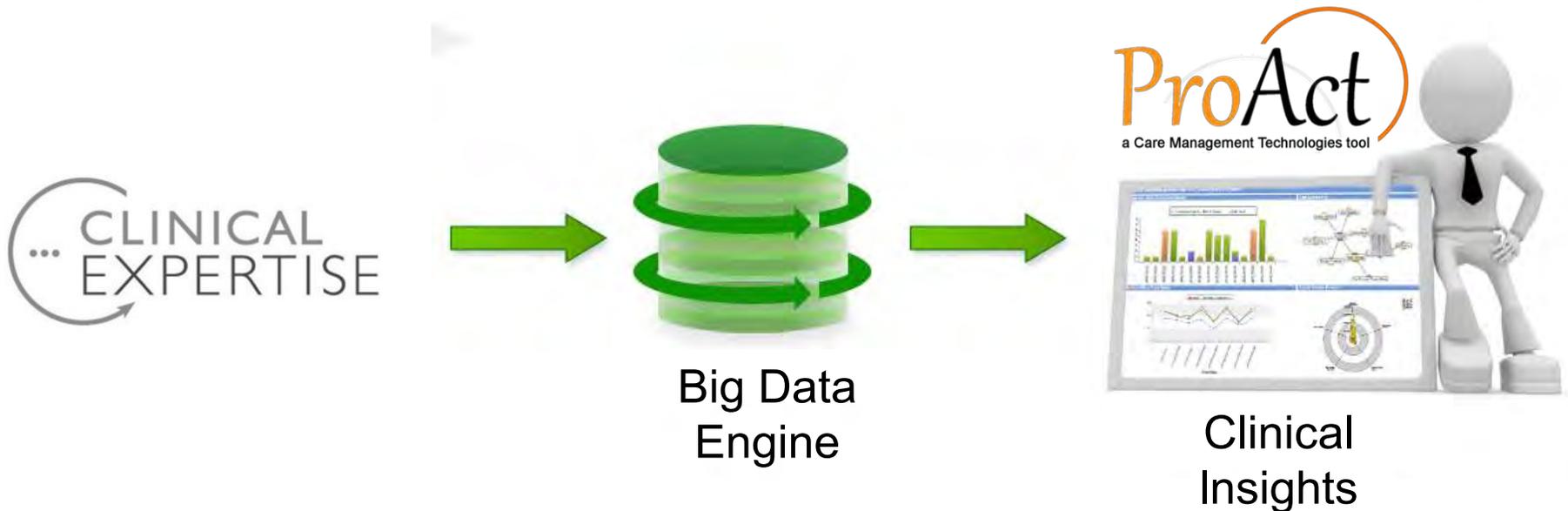
*Sproule, B. "Prescription Monitoring Programs in Canada: Best Practice and Program Review," CCSA, June 2014.

- **Cochrane Review:**
 - ✓ **More efficacious than academic detailing**
 - ✓ **Best value when:**
 - **Includes peer comparisons**
 - **Communicated by a peer-verbally and in writing**
 - **Targeted goals and action plans**
 - **Patient specific information tied to outcomes**

- **Use claims to identify patients who appear to be at high risk for prescription drug abuse**
- **Identify prescribers with high portions of their patients at risk for prescription drug abuse**
- **Identify high risk patients to the prescribers involve and provide benchmark feedback and recommendations for change**
- **Report selected high risk prescribers who did not respond to feedback for regulatory investigation**

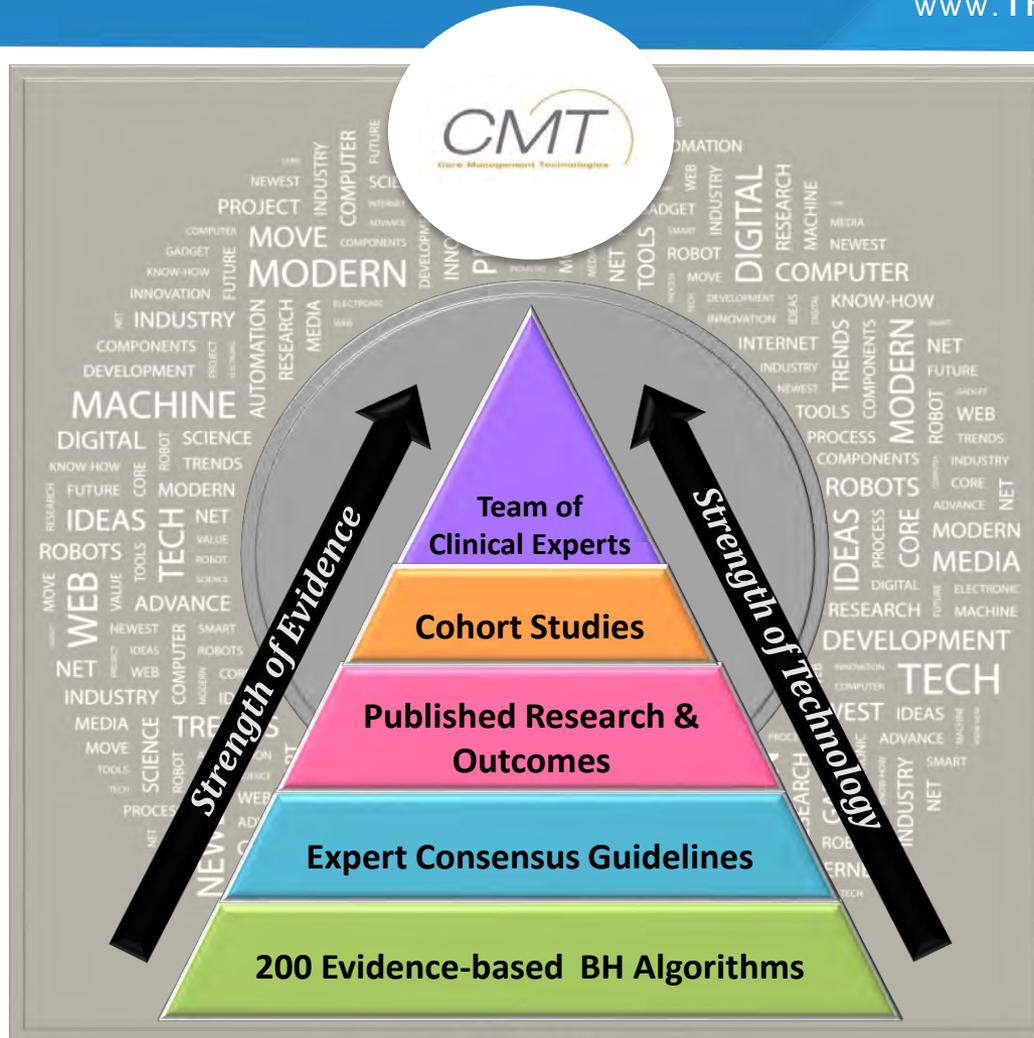
- **Pharmacy Data Alone**
 - ✓ Multiple opiates or benzodiazepines for over 60 days
 - ✓ High-dose benzodiazepines
 - ✓ Multiple opiates prescribers
- **Pharmacy and Claims Data**
 - ✓ Multiple pharmacies filling opiates or benzodiazepines
 - ✓ SUD Related diagnoses
 - ✓ Co-prescribed benzodiazepines and opiates

What gets measured, gets done.



- ✓ **Includes ALL drugs**
- ✓ **Ensure patient, prescriber, pharmacist linkage in data**
- ✓ **Full patient profile available**
- ✓ **Unsolicited reports to stakeholders**
- ✓ **Standard data collection method**
- ✓ **Patient privacy safeguards**
- ✓ **Evaluate intended and unintended consequences**
- ✓ **Allow for encrypted data for research/outcomes analyses**

Core Foundation



Behavioral Pharmacy

164

Age Banded – Child, Adult, Elderly

Opioid Pharmacy

56

Age Banded – Child, Adult, Elderly

- **Evidence or consensus based.**
- **Involve significant cost and/or health and safety.**
- **A small proportion of providers responsible for a large proportion of suspected errors.**
- **Compelling empirical support for the indicator.**
- **Are actionable.**

- **Using multiple prescriber**
- **Using multiple pharmacies**
- **Monthly total methadone equivalent of all opiate prescriptions**
- **Diagnoses of substance use disorders**
- **Diagnoses of factitious disorder, malingering, and somatization**

- **Percent of opioid patients flagged for substance use diagnosis**
- **Monthly average number of opiate prescriptions per opioid patient**
- **Average daily methadone equivalent of opioid prescriptions to SUD flagged patients**

Peer Comparator Unsolicited Report



OPIOID Prescriber Benchmark Summary

July 24, 2014

Dear Dr. Webber:

_____ is committed to providing safe, quality health care for our members. The purpose of the Opioid Prescriber Benchmark is to partner with you to improve both patient safety and quality of care through the sharing of information. Recent paid prescription claims data have identified you as a **High Dose Prescriber of Opioids**. High dose prescribers were identified as those who have prescribed >120 Morphine Equivalent Dose (MED) of opioids to 1 or more members during the reporting period. *Please note members with a known malignant cancer diagnoses and oncologists are excluded from this data set.

The benchmark summary below compares your average prescribed dose of opioids to pain management specialists and non pain management physicians.

Medication	Your Mean Dose	Pain Management Specialists Mean Dose	Non-Pain Management Specialists Mean Dose
FENTANYL	0.00 mgs/day	29.00 mgs/day	59.00 mgs/day
HYDROCODONE	20.00 mgs/day	22.00 mgs/day	30.00 mgs/day
MORPHINE	117.00 mgs/day	30.00 mgs/day	30.00 mgs/day
OXYCODONE	0.000 mgs/day	45.00 mgs/day	30.00 mgs/day
TRAMADOL	22.00 mgs/day	40.00 mgs/day	40.00 mgs/day

Patients receiving ≥ 100 MED have a 9 fold increase in overdose risk.¹

Guidelines from Washington State Agency Medical Directors' Group recommend NOT prescribing more than 120 MED without the patient demonstrating improvement in function and pain OR obtaining a consultation from a pain management specialist.

Please consider one or more of the following responses:

- This information was helpful and I will take into consideration.
- I would like to request a pain management consultation.
- I would like additional information or training materials on this subject.
- Other: _____

If you have checked one or more responses please fax to 888-241-3361

Sincerely,

1. Washington State Agency Medical Directors' Group. Interagency guideline on opioid dosing for chronic noncancer pain: an educational aid to improve care and safety with opioid treatment. Olympia (WA): Washington State Department of Labor and Industries; 2010.

Opioid, Alcohol, or Other Substance Abuse Diagnosis Alert

Use of Opioids for 60 or More Days with a Diagnosis Suggesting Opioid, Alcohol or other Substance Abuse in the Last Year

According to our data, your patient has received opioids for 60 or more days (including possession of an opioid prescription in the last 30 days of the 3-month reporting period). In addition, our data show that a diagnosis suggesting opioid, alcohol, or other substance abuse has been made in the last year. (We estimate that about 3% to 6% of adults receiving any opioid in the last 3 months meet the criteria for this alert.)

We understand that you may be already aware of this situation. In addition, the opioid abuse diagnosis may or may not be clinically accurate. On the other hand, this information would be useful to you if you were not aware of the opioid abuse diagnosis and it is accurate.

Please review the information to assess whether our data are consistent with your understanding of the patient's case. You may wish to consider discussing this matter with your patient.

This indicator identifies adult patients (age 18 through 64 years) who have been prescribed opioids for at least 60 days in the last 3 months, with a diagnosis suggesting opioid, alcohol, or other substance abuse in the last year.

Diagnoses suggesting opioid abuse:

- 304.0* (Opioid dependence)
- 304.7* (Multi-drug [including opioid] dependence)
- 305.5* (Opioid abuse)

Diagnoses suggesting alcohol abuse:

- 291.0* (Delirium tremens)
- 291.1* (Alcohol amnestic syndrome)
- 291.2* (Alcoholic dementia)
- 291.81 (Alcohol withdrawal syndrome)

Diagnoses suggesting other substance (non-alcohol) abuse:

- 292.0* (Drug withdrawal syndrome)
- 292.1* (Drug-induced psychotic disorders)
- 292.8* (Drug-induced delirium, dementia/psychiatric disorders)
- 292.9* (Drug-induced Disorder NOS)
- 304.* (except 304.7*) (Various Substance Dependence)
- 305.* (except 305.1*, .5*, .8*) (Various Substance Abuse)

- **Use of Buprenorphine with another Opioid (prescribed by another physician).**
- **Use of Buprenorphine with a Benzodiazepine (prescribed by another physician).**
- **Patient's use of 5 or more prescribers for Opioid prescriptions.**
- **Use of Opioids for 60 or more days with a diagnosis suggesting Opioid, alcohol or other substance abuse in the last year.**
- **Use of Opioids for 60 or more days with two or more diagnoses of malingering, somatization or factitious disorder.**

- **Use of cough and cold medications containing Opioids - Adult / Child / Elderly**
- **Patient's use of 4 or more pharmacies for Opioid Rxs – Adult**
- **Patient's use of 5 or more prescribers for Opioid Rxs - Child / Elderly**
- **Use of Opioids for 60 or More Days in Absence of a Diagnosis Supporting Chronic Use - Adult / Child / Elderly**

Mailing Date	Patients	Providers	Phase
2/25/2013	2,627	1,786	Original 5 QIs
4/22/2013	3,219	1,273	
6/27/2013	33,780	1,675	5 Original QIs + Expansion QIs
8/30/2013	28,422	1,594	
10/30/2013	27,238	1,566	
12/20/2013	26,093	1,585	
2/14/2014	25,900	1,646	
4/21/2014	27,572	1,603	
6/20/2014	27,897	1,756	

- **Following each mailing, summary reports are emailed to Missouri administrative staff.**
- **Those reports include:**
 - ▶ OPI QI Summary (list of QIs with patient and prescriber counts and percentages)
 - ▶ High Risk Substance Abuse Patient Report
 - ▶ Prescriber Identified High Risk Patients Report
 - ▶ Prescribers More Likely to Treat Patients with SA Report
 - ▶ OPI Intervention Report (selected QIs and counts of patients and prescribers)
 - ▶ OPI CMHC and CMHC-Prescriber Benchmark Reports

Original QIs:

- Estimated savings of \$217,034 in opioid pharmacy cost avoidance – an average of \$20.69 per intervened patient per month for 3,496 individuals eligible for 3 months follow-up.
- Significant decrease of emergency department visits by 37.84%* and hospital admits decreased by 37.82%*
- Average patient usage of 37.1%* fewer opioid prescribers and 31.2%* fewer opioid pharmacies
- Average monthly dose of opioids (in morphine equivalents) dispensed fell 17.9%*
- Three Month Pre/Post analysis includes MO HealthNet clients from the eight OPI mailing interventions from 2/25/2013 through 4/21/14.

* comparing 3 months pre-intervention to 3 months post-intervention | $p < .001$

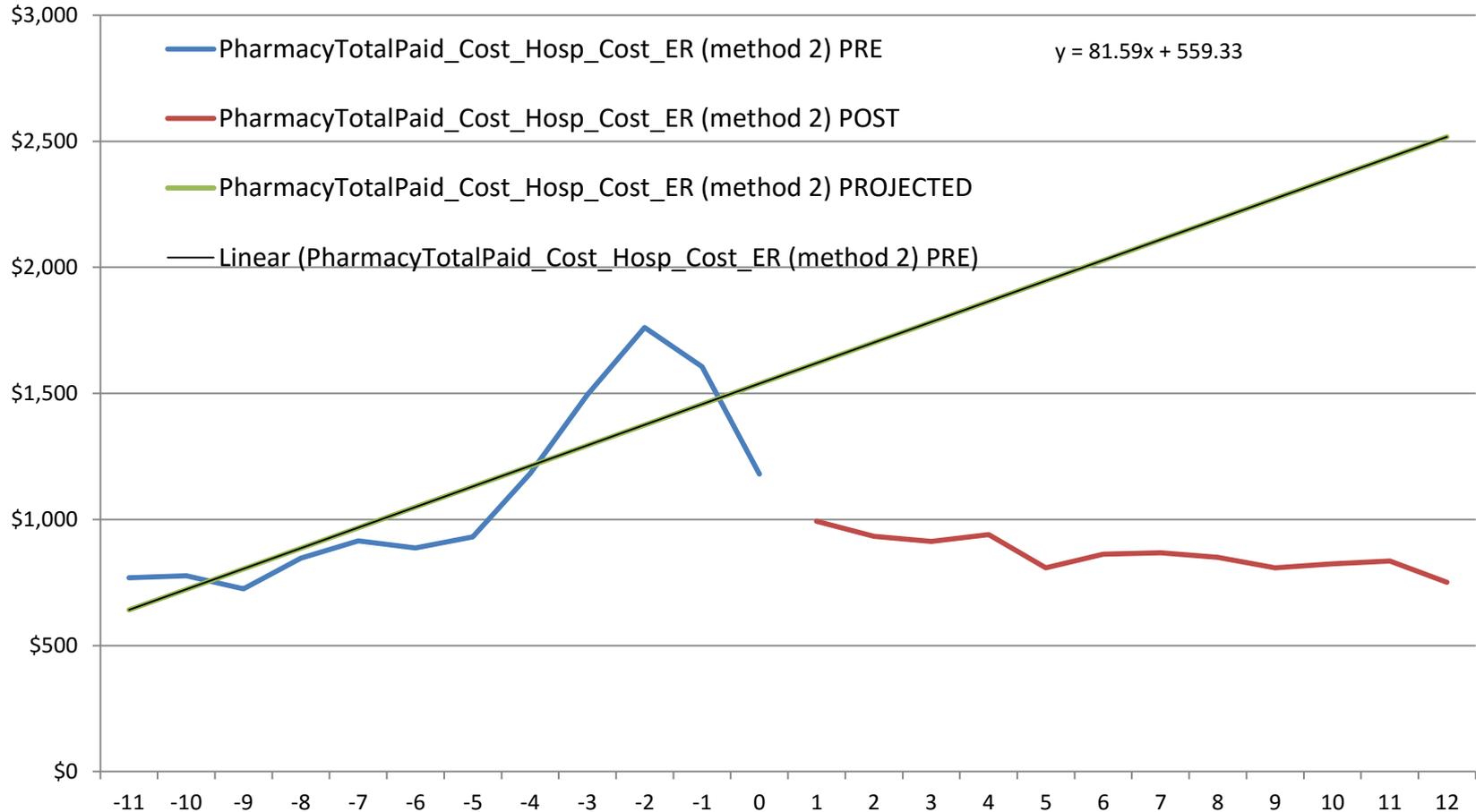
- **Study included eligible adult/child/elderly first intervened in 2013/2014.**
- **Patient/Months in the analysis included where spend is greater than zero or subject is Medicaid-eligible for the entire month.**
- **Study excludes subjects who:**
 - ▶ Were part of a BPM intervention in this report
 - ▶ Were included in any BPM or OPI intervention in 2012
 - ▶ Are dual eligibles
- **End date for claims analysis was 8/22/2014.**
- **Cost avoidance related to Hospitalizations, ER and Opioid Rx estimate is \$40 million.**

Note: A multiple baseline analysis has multiple cohorts and multiple study periods, hence no single reporting period applies to all cohorts.

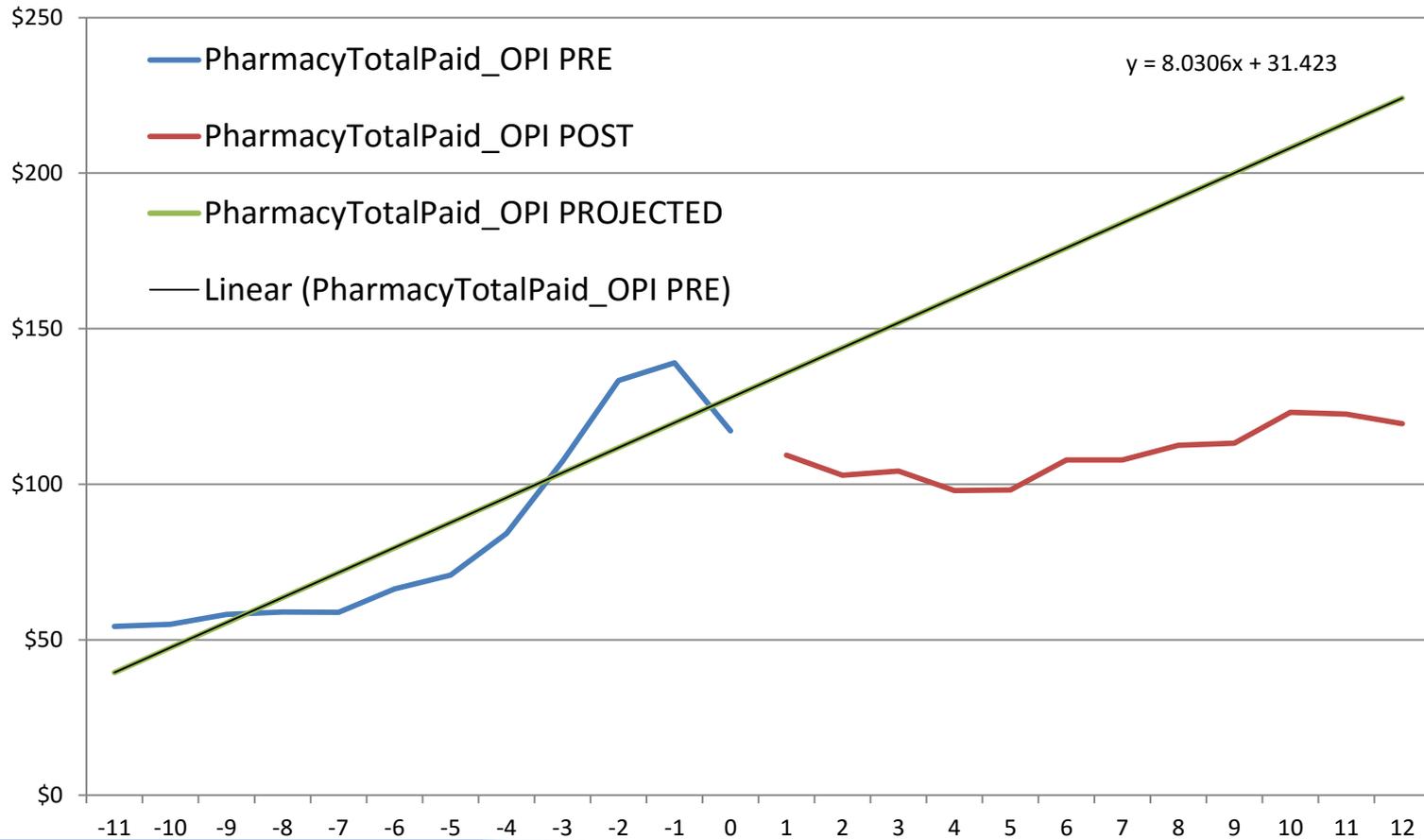
- Multiple Baseline Analysis includes multiple cohorts with variable amounts of follow-up based on eligibility and claims activity.
- Dataset includes up to 12 months of pre/post for each cohort.

Mailing Date	Cohort Total	Eligible Patient-Months After Mailing Date
2/25/2013	788	8,155
4/22/2013	810	8,574
6/27/2013	659	6,894
8/30/2013	403	4,093
10/30/2013	311	2,645
12/20/2013	320	2,216
2/14/2014	306	1,665
4/21/2014	246	921
6/20/2014	328	615
Total	4,171	35,778

Combined Hospital, ER and Opioid Spend PMPM | Original 5 QIs | Adults

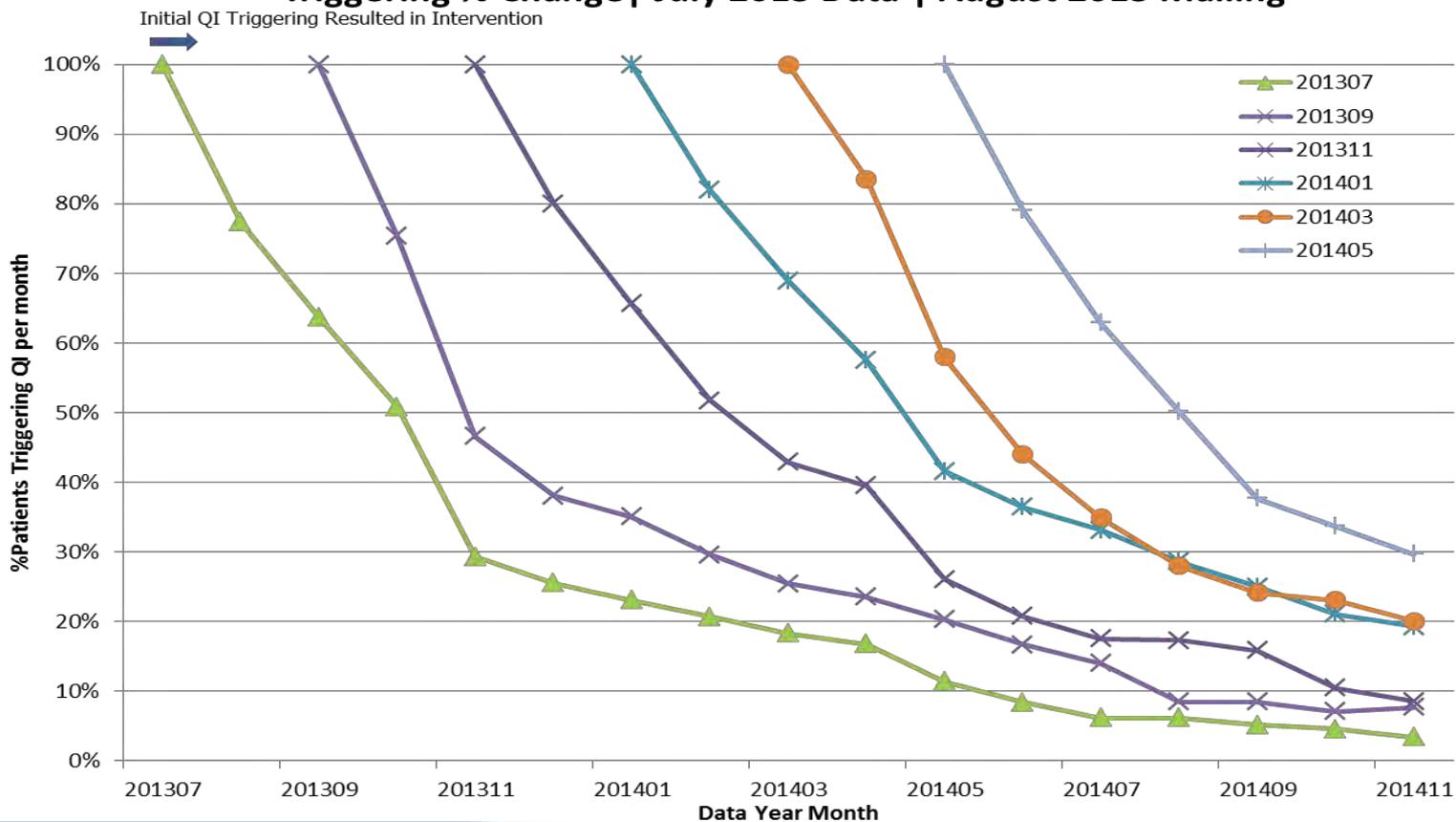


Opioid Spend PMPM | Original 5 QIs | Adults



QI 883: Use of Opioids for 60 or More days with a diagnosis suggesting Opioid, alcohol or other substance abuse in the last year

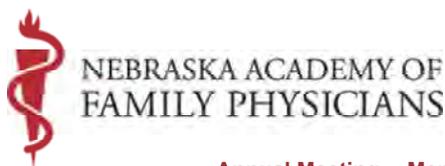
Triggering % Change | July 2013 Data | August 2013 Mailing



- **Expansion started with mailings in June 2013**
 - Substantial increase in mailing volume
 - Approximately 20x as many clients impacted as before per mailing
- **Estimated \$454K savings on Opioids for FY 2013-2014**
 - Adult: \$7.16 PMPM x 17,142 individuals x 3 Months = \$368K
 - Child: \$16.54 PMPM x 1,530 individuals x 3 Months = \$76K
 - Elderly: \$1.36 PMPM x 2,439 individuals x 3 Months = \$10K
- **Cost avoidance related to Hospitalizations, ER and Opioid Rx estimate is \$15.3 million**

- Significant decrease of emergency department visits by 10.2%* for adults and a decrease of 45.3%* for children.
- Significant decrease in hospitalizations by 43.7%* for children.
- Average usage of opioid prescribers dropped by 12.6%* for adults, 11.8%* for elderly and 77.6%* for children
- Average number of pharmacies used to obtain opioids decreased 13.1%* for adults, 77.1%* for children and 10.0%* for elderly.
- Average monthly dose of opioids (in morphine equivalents) dispensed fell 8.1%* for adults, 52.3%* for children and 11.3%* for elderly.

** comparing 3 months pre-intervention to 3 months post-intervention | $p < .001$*



Pain Management & Opioid Abuse

Chronic pain represents a substantial public health issue with tremendous economic, social, and medical costs. As the percentage of the U.S. population utilizing opioid analgesics for pain control grows, so does the rate of abuse, misuse and overdose of these drugs. We recognize the seriousness of the prescription drug abuse problem in the United States. At the same time, we must address the ongoing public health requirement to provide adequate pain management. The American Academy of Family Physicians is actively working toward a solution to America's pain management and opioid abuse epidemics through advocacy, collaboration, and education.

Resources

[AAFP formal position: Pain Management and Opioid Abuse: A Public Health Concern](#)

Position paper: AMERICAN ACADEMY OF FAMILY PHYSICIANS PAIN MANAGEMENT AND OPIOID ABUSE: A Public Health Concern

[AAFP Pain Management & Opioid Abuse](#)

AAFP resources for pain management & opioid abuse.

[Chronic Pain](#)

Resources to help educate patients on chronic pain.

[Collaborative for REMS Education \(CO*RE\)](#)

*CO*RE's mission is to ensure that ER/LA opioids are prescribed, when indicated, in a manner that enhances patient well-being and does not contribute to individual or public harm.*

[CO*RE iBook](#)

3 CME credits are available upon completion of the evaluation and assessment.

[Narcotics Anonymous](#)

Resources for patients suffering from drug addiction.

[National Institute on Drug Abuse Addiction Performance Project](#)

This online tool, developed in cooperation with the AAFP, may help you identify and help drug-abusing patients.

[Opioid Addiction](#)

Resources to education patients on opioid addiction.

[Prescription Drug Abuse in the Elderly](#)

Resources to help identify prescription drug abuse in elderly patients.

[Safe Use, Storage, & Disposal of Opioid Drugs](#)

Resources to help patients use, store, and dispose of opioid drugs.

[Substance Abuse & Mental Health Services Administration](#)

The official U.S. Government website.

[CO*RE Educational Opportunities](#)

*CO*RE offers live, online, and iBook educational opportunities.*

IN THIS SECTION

[Practice Tools & Resources](#)

[Patient-Centered Medical Home](#)

[Accountable Care Organizations](#)

[ICD-10](#)

[Pain Management & Opioid Abuse](#)

[National Registry of Certified Medical Examiners](#)

PSR Prevention Status Reports

Prescription Drug Overdose

PSR NATIONAL SUMMARY

The Prevention Status Reports highlight—for all 50 states and the District of Columbia—the status of public health policies and practices designed to address 10 important public health problems and concerns.



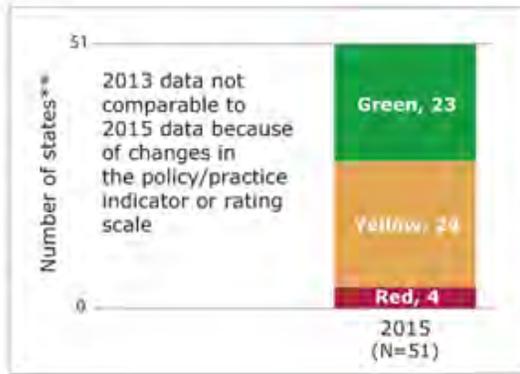
CDC and other agencies continue to identify and evaluate interventions to reduce prescription opioid overdose deaths. This report focuses on two key policies concerning state prescription drug monitoring programs (PDMPs), electronic systems that track the dispensing of controlled substances to patients. The following policies are supported by emerging evidence, expert consensus, and extensive review of the primary drivers of the epidemic (1–3):

- Requiring timely data submission to the PDMP
- Requiring universal PDMP use by prescribers

These policies are especially promising but are not the only interventions needed to address this epidemic. Rather, they should be seen as key pieces in a much larger, multisector approach to preventing prescription drug abuse and overdose. Other important PDMP practices for states to consider include ensuring that their PDMP 1) is easy to use and access (e.g., by allowing delegates of the provider to access the system); 2) can be linked to electronic health records for point-of-care decision making by providers; 3) is accessible to public health agencies for tracking trends; and 4) has the capacity to proactively notify users of high-risk behaviors (1). Also, the Department of Health and Human Services outlines three priority areas to advance a comprehensive approach to reversing the epidemic: improving opioid prescribing practices, expanding use and distribution of naloxone, and expanding medication-assisted treatment to reduce opioid use disorders and overdose (2).

Requirement for timely data submission to prescription drug monitoring program

State-required interval between dispensing a controlled substance and submitting the dispensing data to the state PDMP.



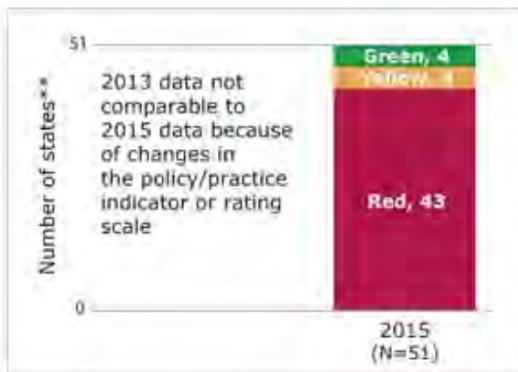
Rating	State dispensing data submission requirement
Green	Within 24 hours
Yellow	More than 24 hours but within one week
Red	More than one week OR no reporting requirement

How These Ratings Were Determined

These ratings reflect data provided by the National Alliance of Model State Drug Laws about state legal requirements for the timeliness of data submission to state PDMPs. CDC translated this information into a rating for each state. The rating does not reflect how fully the state has carried out the law. The “as of” date referenced in the Prescription Drug Overdose state reports (<http://www.cdc.gov/psr/>)—July 31, 2015—is the date CDC assessed the law. The date does not reflect when the law was enacted or became effective.

Requirement for universal use of state prescription drug monitoring program

State requirement that prescribers must consult the patient’s PDMP history before initially prescribing opioid pain relievers and benzodiazepines, and at least every three months thereafter.



Rating	State PDMP use requirement
Green	Prescribers are required to consult the PDMP before initial opioid and benzodiazepine prescriptions and at least every three months thereafter
Yellow	Prescribers are required to consult the PDMP before initial opioid prescriptions and again within one year
Red	Prescribers are not required to consult the PDMP before initial opioid prescriptions, OR such a requirement does exist but there is no required subsequent check and/or the policy includes subjective standards or broad exceptions

How These Ratings Were Determined

These ratings reflect data provided by the National Alliance of Model State Drug Laws and the PDMP Center of Excellence at Brandeis University about state laws requiring prescriber use of state PDMPs. CDC translated this information into a rating for each state. The rating does not

reflect how fully the state has carried out the law. The “as of” date referenced in the Prescription Drug Overdose [state reports \(http://wwwn.cdc.gov/psr/\)](http://wwwn.cdc.gov/psr/)—October 31, 2015—is the date CDC assessed the law. The date does not reflect when the law was enacted or became effective.

For the purposes of this report, a law was deemed to “require” a PDMP check when it applied to most or all prescribers. To be rated green, a state’s policy must have required a check for both opioid and benzodiazepine prescriptions; to be rated yellow, the requirement must have applied to at least opioid prescriptions.

Laws were considered to be requiring a PDMP check even if they had limited exceptions to the requirement (e.g., exempting prescriptions written in emergency departments) or if they exempted short prescriptions (i.e., lasting less than seven days). Laws that applied only to limited classes of providers (e.g., only opioid treatment programs or pain clinics) or that had overly broad exceptions (e.g., exempting prescriptions lasting 90 days or less), were not deemed as requiring PDMP checks in this report and were rated as red. In addition, laws in which the requirement depended on a subjective standard (e.g., the provider was required to check the PDMP only when having a reasonable belief of inappropriate use by the patient or only when treating chronic pain) were rated red.

**State count includes the District of Columbia

References

1. Clark T, Eadie J, Knue, P, et al. [Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices](http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf) [PDF-2.3MB] (http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf). Waltham, MA: Prescription Drug Monitoring Center of Excellence, Brandeis University; 2012.
2. US Department of Health and Human Services. [ASPE Issue Brief: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths](http://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths) (<http://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths>). Washington, DC: US Department of Health and Human Services; 2015.
3. Prescription Drug Monitoring Center of Excellence, Brandeis University. [Mandating PDMP Participation by Medical Providers: Current Status and Experience in Selected States](http://www.pdmpexcellence.org/sites/all/pdfs/COE_briefing_mandates_2nd_rev.pdf) [PDF-285KB] (http://www.pdmpexcellence.org/sites/all/pdfs/COE_briefing_mandates_2nd_rev.pdf). Waltham, MA: Prescription Drug Monitoring Center of Excellence, Brandeis University; 2014.



PRESCRIPTION NATION **2016**

ADDRESSING
AMERICA'S
DRUG
EPIDEMIC



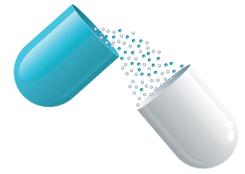
making our world safer®



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EXECUTIVE SUMMARY

This is the most fatal drug crisis on record in United States history, and too many families and communities are left to suffer in its path. These highly addictive medicines have been incorrectly marketed as the most effective method for treating pain and, subsequently, liberally prescribed. Prescription opioids also serve as gateway drugs to heroin, which has a nearly identical chemical makeup and is cheaper and sometimes easier to obtain.

The facts are clear:

- ✓ More than 259 million opioid prescriptions were written in 2012
- ✓ 1.9 million Americans are addicted to opioid painkillers
- ✓ The U.S. makes up 4.6 percent of the world's populations but consumes 81 percent of the world supply of oxycodone
- ✓ 4.3 million adolescents and adults reported non-medical use of prescription opioids in 2014
- ✓ 4 out of 5 heroin users started on prescription opioids

The National Safety Council is committed to ending unintentional injuries and death in our lifetime and has been fighting this drug epidemic for years. State governments also play a significant role in this fight, with state legislators, Governors, and public health officials dictating the strategy.

This report identifies four key actions states can take that could have immediate and sustained impact:

- ✓ Require and expand prescriber education
- ✓ Develop and implement prescriber guidelines
- ✓ Increase access to naloxone, an overdose antidote
- ✓ Expand access to treatment

**Prescription
opioid overdoses
kill 52 people
every day.**

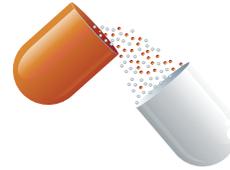
In 2014, the most recent annual statistics available, 18,893 people died as a result of a prescription opioid overdose.

4 Key Actions:

- Require and expand prescriber education
- Develop and implement prescriber guidelines
- Increase access to naloxone, an overdose antidote
- Expand access to treatment

Some states have made significant progress. Others have much more to do while each day people suffer from addiction and die from this epidemic. States were given a rating of “Making Progress”, “Lagging Behind” or “Failing” based on careful evaluation of efforts in six key indicators:

6 KEY INDICATORS



1. Mandatory Prescriber Education

Mandatory prescriber education helps providers make well-informed decisions on medical treatment based on best practice and the latest research, carefully weighing the benefits and risks of opioids and their alternatives. The Centers for Disease Control and Prevention (CDC) has shown that the increase in opioid prescribing has resulted in increased admissions for treatment of opioid use disorder and overdose deaths, despite a lack of a corresponding decrease in reported pain. Additionally, physicians report receiving limited education on pain treatment.



2. Opioid Prescribing Guidelines

Sound, evidence-based prescribing guidelines encourage physicians to incorporate alternative, non-opioid treatments for pain and provide the lowest effective doses and the fewest number of pills when prescribing dangerous opioid medications. The recently released CDC guideline on opioid treatment for chronic pain should be adopted as the state prescribing guideline, but states should also consider the risks for acute pain patients. If followed, NSC believes guidelines that address acute and chronic pain could reduce the number of opioid overdose deaths in the United States.



3. Eliminating Pill Mills

“Pill mills” are a doctor’s office, clinic or health care facility that routinely prescribes controlled substances outside the scope of standard medical practice and often in violation of state laws and greatly increases the risk of abuse and overdose. States should pass legislation that regulates pain clinics and pain management services, requiring such actions as following prescribing guidelines, defining ownership, restricting dispensing of controlled substances and requiring use of state prescription drug monitoring programs.



6 KEY INDICATORS



4. Prescription Drug Monitoring Programs (PDMPs)

PDMPs play an important role in any effective approach to the prescription opioid epidemic. Doctor shopping, or going to multiple providers for prescriptions, and providers who prescribe controlled substances outside the scope of standard medical practice will continue to fuel the opioid epidemic. PDMPs directly address these issues. Nearly every state has an operating PDMP, and states should take steps to simplify registration and utilization, improve reporting response times and upgrade technology to allow data integration into clinical workflows.



5. Increased Access to Naloxone

Naloxone is an opioid antagonist that saves lives by reversing an opioid overdose, with no negative side effects. Naloxone is not a controlled substance and has no abuse potential. States should ensure that naloxone is widely available without a prescription under standing orders and covered by insurance plans, both public and private.



6. Availability of Opioid Use Disorder (OUD) Treatment

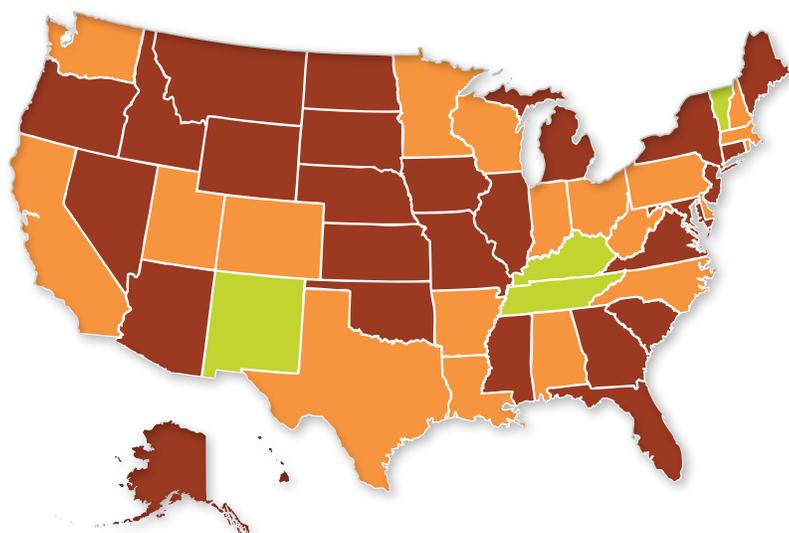
Access to treatment is key to helping those with a substance use disorder. In order to increase this access, states must expand capacity for treatment, including medication-assisted treatments and require both public and private health insurers to cover medication-assisted treatment and remove caps on duration of treatment.



States were evaluated on each of these indicators which are critical to effectively and comprehensively fighting this growing epidemic.

This report provides a roadmap for strengthening laws and regulations. NSC is prepared to assist states with implementation of these evidence-based strategies which can save thousands of lives every year.

A ROADMAP FOR STRENGTHENING LAWS & REGULATIONS



FAILING			LAGGING BEHIND		MAKING PROGRESS	
MEET ZERO INDICATORS	MEETS 1 INDICATOR	MEETS 2 INDICATORS	MEETS 3 INDICATORS	MEETS 4 INDICATORS	MEETS 5 INDICATORS	MEETS 6 INDICATORS
<p>THREE HAVE MET ZERO INDICATORS.</p> <p>Michigan Missouri Nebraska</p> <p>3 STATES</p>	<p>Alaska District of Columbia Hawaii Idaho Kansas Montana Wyoming</p>	<p>Arizona Connecticut Florida Georgia Illinois Iowa Maine Maryland Mississippi Nevada New Jersey New York North Dakota Oklahoma Oregon South Carolina South Dakota Virginia</p>	<p>Arkansas Colorado Delaware Louisiana Massachusetts Minnesota Pennsylvania Texas Utah Washington</p>	<p>Alabama California Indiana New Hampshire North Carolina Ohio Rhode Island West Virginia Wisconsin</p>	<p>Kentucky New Mexico Tennessee Vermont</p>	<p>ZERO HAVE MET ALL 6 INDICATORS.</p> <p>NO STATES</p>

DEADLIEST DRUG EPIDEMIC ON RECORD IN OUR NATION'S HISTORY



The United States is confronting the deadliest drug crisis on record. (CENTERS FOR DISEASE CONTROL & PREVENTION, 2016)

Drug overdoses, mostly caused by opioids, end far too many lives too soon. More than 47,055 families lost loved ones in 2014 to a drug overdose. Opioid pain medications like Vicodin (hydrocodone), OxyContin (oxycodone) or Fentanyl accounted for 18,893 deaths. (CDC NATIONAL CENTER FOR HEALTH STATISTICS, 2015)

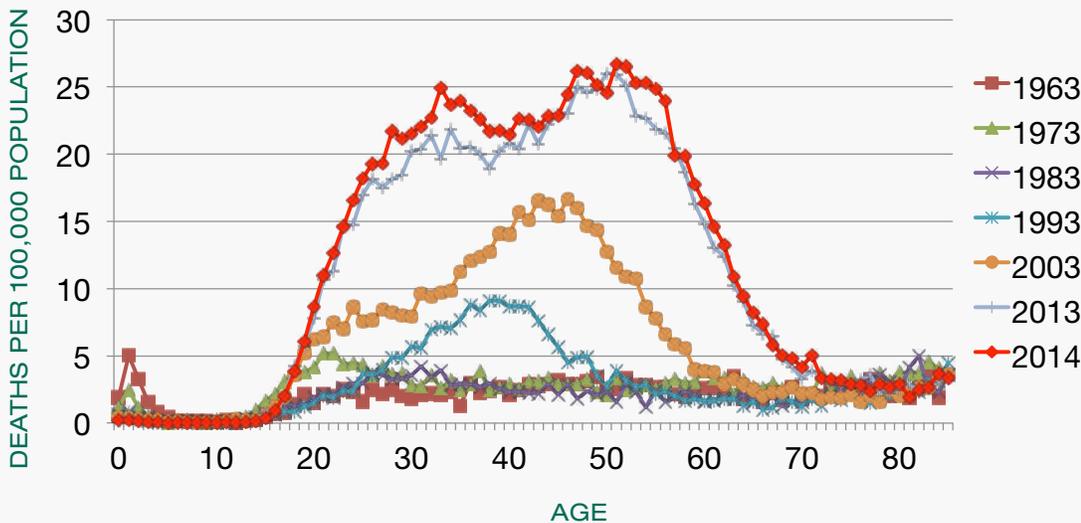
According to the CDC, the increase in opioid-related fatalities and treatment admissions parallels the increase in sales of opioid pain relievers. (PAULOZZI, JONES, MACK, & RUDD, 2011) Opioid prescribing remains high, with more than 259 million prescriptions written in 2012. (PAULOZZI, MACK, & HOCKENBERRY, VITAL SIGNS: VARIATION AMONG STATES IN PRESCRIBING OF OPIOID PAIN RELIEVERS AND BENZODIAZEPINES—UNITED STATES, 2012, 2014)

Opioid pain medications, if taken too long or at a high daily dose, can have deadly and life-changing consequences even when used under the care of a medical professional.

The drug problems of past decades pale when compared to the current opioid epidemic which has killed 165,000 Americans from 2000 to 2014.

Poisoning Death Rates by Age

This graphic shows the rate of poisoning deaths has changed in the past fifty years. In 1963, poisoning deaths peaked in early childhood causing 5 deaths per every 100,000 people.



Today, there has been a **550 percent increase** in the age-adjusted death rate of Americans killed by poisoning. These deaths, primarily from an overdose of an opioid pain medication or heroin, peak around age 50 with a secondary peak around age 30. Especially troubling is that these deaths span from ages 20-70 as it shows an increase in the rate of poisoning death for nearly all working adults.

FACT

➤ From 1963 to 2014 the age adjusted death rate for poisoning increased **550%** from 2.0 to 13.0.



AMERICANS ARE AT GREATER RISK FOR ADDICTION THAN THEY REALIZE



Opioid pain medications have a number of side effects and the risk of addiction may be the most serious. However, it is clear most people do not understand this risk. A 2015 National Safety Council public opinion poll found nearly 90 percent of opioid users were not worried about addiction, even though 60 percent of respondents reported having an addiction risk factor such as personal or family history of alcoholism, depression, use of psychiatric medications, or a history of physical, mental or sexual abuse. More education is needed about who is at risk for addiction from opioid pain medication use.

More than 1.9 million Americans are addicted to opioid painkillers. (SAMHSA, 2015) For some people, their first prescription of an opioid pain medication began an addiction that was never intended or expected. More than 4.3 million people have misused¹ an opioid painkiller in the past month. (SAMHSA, 2015) Seventy percent of people gain access to opioids from people they know. (SAMHSA, 2015) Tragically, about four percent of those who misuse opioid painkillers will transition to heroin. (JONES, 2013)



for Opioid Addiction

- Having depression, anxiety or other mental health illness
- A personal and/or family history of alcohol or substance abuse
 - A history of physical, mental or sexual abuse
- Long term use of opioid pain medications



**STARTED MISUSING
an opioid pain medication
for the first time
TODAY!**

¹ "Misuse" includes use without a prescription or taking the drug for the feeling or "high" it causes. Examples of misuse include using another person's prescription or using "saved" medications from a previous medical condition or surgery.

THE TRANSITION TO HEROIN



Opioid pain medications, like hydrocodone and oxycodone, are chemically similar to heroin and have a similar effect on our minds and bodies.

As opioid pain medication use dramatically increased, the United States also experienced an increase in heroin use and deaths. More than 900,000 people reported heroin use

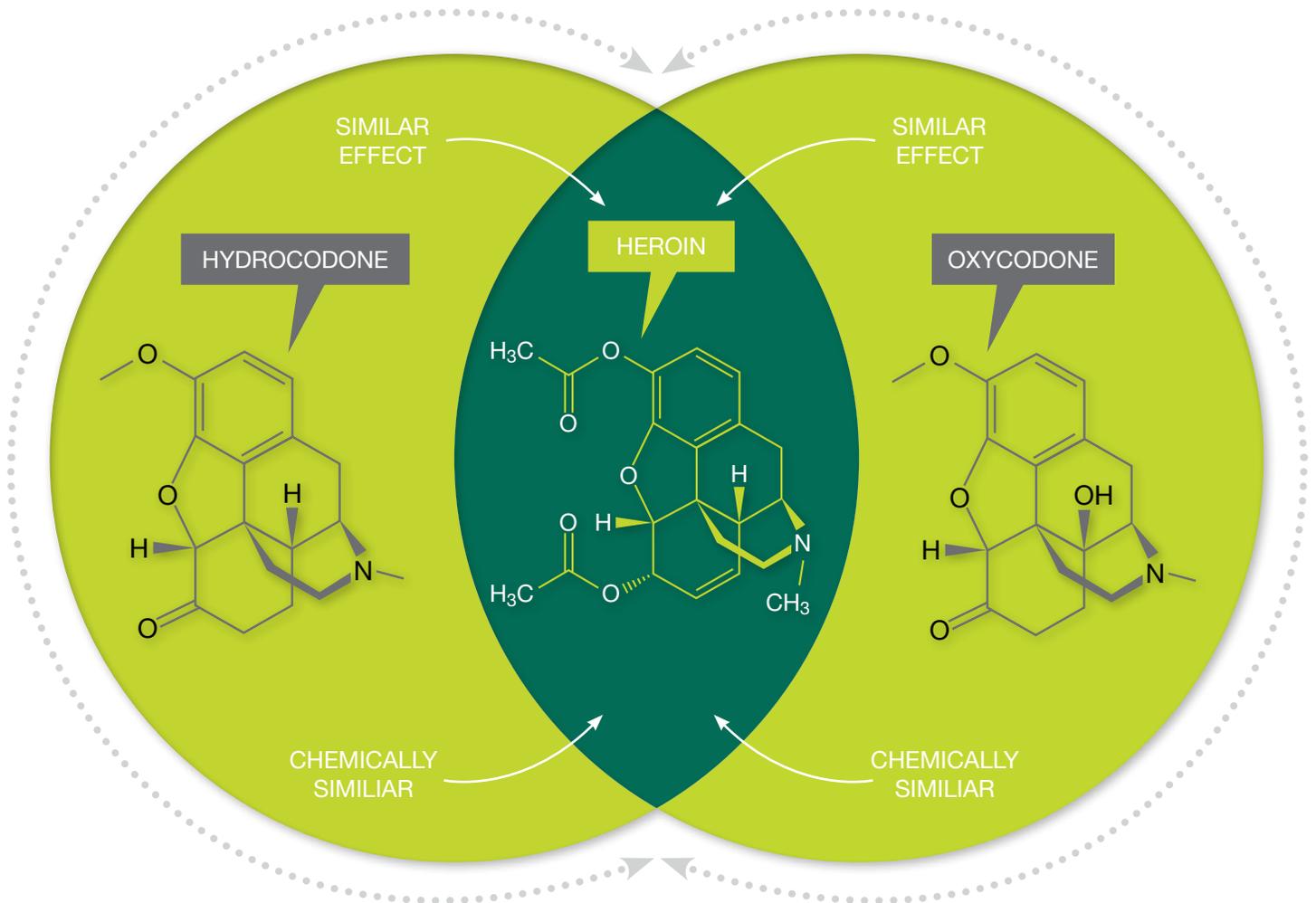
in 2014, a 153 percent increase since 2007. (COMPTON, JONES, & BALDWIN, 2016)

Tragically, heroin deaths tripled in the 5 year period from 2010 to 2014, increasing from 3,300 to more than 10,000 deaths. (CENTERS FOR DISEASE CONTROL & PREVENTION, 2016)

These facts clearly show heroin use patterns have changed. In the 1960's,

80 percent of heroin users reported heroin was the first opioid they used. Today, of the 600 people who begin using heroin, (SAMHSA, 2015) four out of five report that they started with opioid pain relievers. (JONES, HEROIN USE AND HEROIN USE RISK BEHAVIORS AMONG NONMEDICAL USERS OF PRESCRIPTION OPIOID PAIN RELIEVERS - UNITED STATES, 2002-2004 AND 2008-2010, 2013)

Opioid Pain Medications and Heroin are Chemically Similar and just as Addictive



States with the **highest heroin fatality rates.**

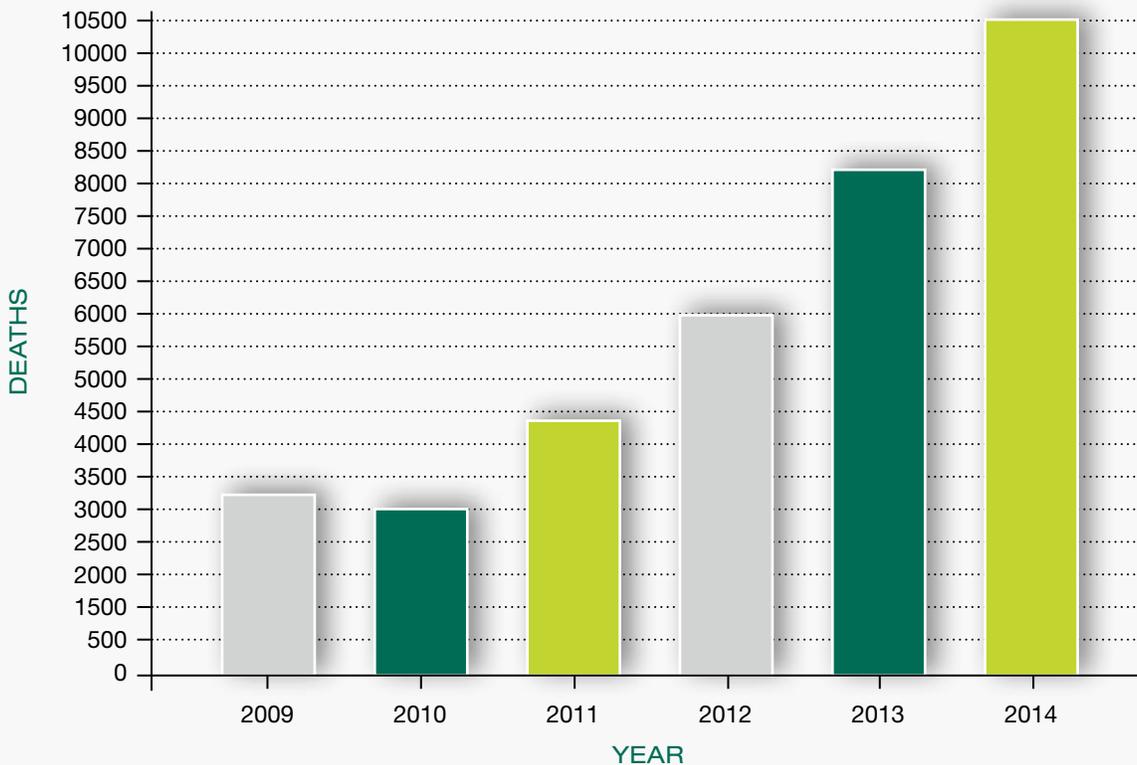
In fact, nonmedical users of opioid pain medications were 19 times more likely to use heroin than people reporting no misuse of opioids. *(MUHURI, GFROERER, & DAVIES, 2013)*

More research is needed to fully understand what prompts a person misusing opioid pain medications to transition to heroin. However, it is widely believed the transition to heroin happens as users turn to dealers for their daily supply of opioids, heroin is offered as a cost saving measure.

Nonmedical users of opioid pain medications were **19 times more likely** to use heroin

OVERALL RANK	STATE	AGE-ADJUSTED HEROIN DEATH RATE PER 100,000
1	Ohio	11.1
2	West Virginia	9.8
3	Connecticut	8.9
4	New Hampshire	8.1
5	Massachusetts	7.2
6	New Mexico	7.2
7	Rhode Island	6.8
8	Delaware	6.3
9	Vermont	5.8
10	Missouri	5.8

FIGURE 1: Heroin Deaths by Year,
United States, 2009-2014



DEADLY EMERGENCE OF FENTANYL



Fentanyl, a synthetic opioid, is 50 times more potent than heroin and 100 times more potent than morphine. (CDC, 2016) It is commonly prescribed to manage pain for advanced stage cancer patients.

However, fentanyl, when added to heroin, can create a lethal combination and is often added by drug dealers without the end user's knowledge. The Drug Enforcement Administration (DEA) has documented the import of illegally manufactured fentanyl into parts of the U.S. (U.S. DEPARTMENT OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION, 2015) DEA National Forensic Laboratory Information System (NFLIS) found

fentanyl reports increased 300 percent from the second half of 2013 to the first half of 2014. The DEA issued a health advisory in March 2015 after documenting a surge of fentanyl drug seizures and deaths. (U.S. DRUG ENFORCEMENT ADMINISTRATION, 2015)

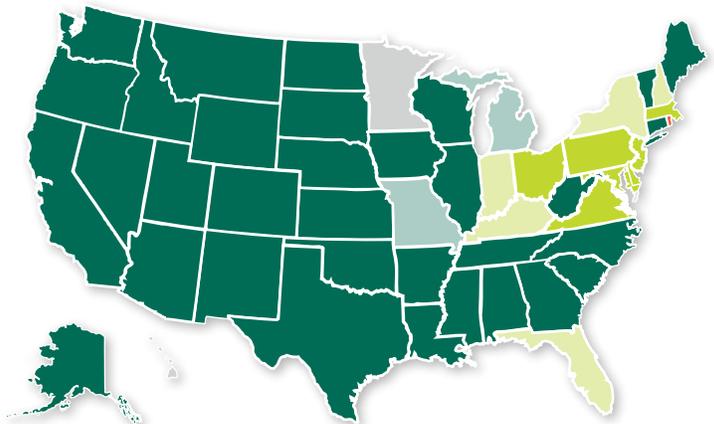
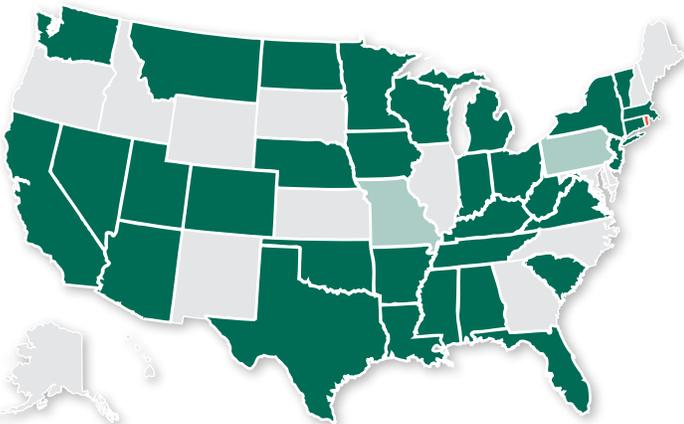
The maps below show the extent to which fentanyl reports have grown since 2009, when 35 states reported analyzing fentanyl. That same year, no state had more than 49 fentanyl reports. By 2014, 46 states reported fentanyl, with six states having 100 or more reports. (U.S. DEPARTMENT OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION, 2015)



In only a 72-hour period in Chicago, 74 people died from an overdose of fentanyl laced heroin in October 2015.
(GORNER, NICKEAS, & SOBOL, 2015)

FIGURE 2:
2009 Fentanyl Reports in NFLIS by State,
January - June 2009

FIGURE 3:
2014 Fentanyl Reports in NFLIS by State,
January - June 2014





In 21 states, more than **25 percent** of overdose death certificates did not specify the drugs involved in the death.



Improved data collection is vital to fully understand the scope of the epidemic.

A March 2015 DEA National Threat Assessment Summary noted the true number of fentanyl-related deaths is most likely higher because “many coroners’ offices and state crime laboratories do not test for fentanyl or its analogs unless given a specific reason to do so.” (*U. S. DRUG ENFORCEMENT ADMINISTRATION, 2015*) Better mortality data is needed to accurately track the involvement of fentanyl and other drugs in opioid-related deaths. A 2013 study documented variation in how states certify manner of death, including toxicology, and found that death certificates often do not specify the drugs involved in overdose deaths. For example, in 21 states, more than 25 percent of overdose death certificates did not specify the drugs involved in the death. (*WARNER, PAULOZZI, NOLTE, DAVIS, & NELSON, 2013*)

A CDC Health Advisory Network (HAN) alert recommends that medical examiners and coroners screen for fentanyl in suspected opioid overdose cases, especially in areas reporting increases in fentanyl seizures or unusually high spikes in heroin or unspecified drug overdose fatalities. (*CENTERS FOR DISEASE CONTROL AND PREVENTION, 2015*) The HAN alert further recommends that coroners and medical examiners use Substance Abuse Mental Health Safety Administration (*SAMHSA*) consensus recommendations to report opioid-related deaths. (*GOLDBERGER, MAXWELL, CAMPBELL, & WILDFORD, 2013*) **The National Safety Council urges states to adopt these recommendations.** Improved data collection is vital to fully understand the scope of the epidemic.

Certificate of Death

CERTIFICATE NUMBER: _____

LEGAL NAME (Include AKA's if any) (First, Middle, Last)

4b. UNDER 1 YEAR
Months _____ Days _____

4c. UNDER 1 DAY
Hours _____ Minutes _____

2. SEX _____

5. DATE OF BIRTH (Month/Day/Year)

3. SOCIAL SECURITY NUMBER _____

7b. COUNTY _____

6. BIRTHPLACE (City and State or Foreign Country)

STATE PROGRESS



Multiple actions will be needed to end this drug epidemic and reduce the loss of life. It is only with concentrated state focus and efforts to reduce opioid overprescribing and to improve the ability to identify and offer help to those at risk. By ensuring that effective and coordinated substance abuse treatment is readily available to those with opioid use disorder, we can end the loss of life in the current drug crisis.

The National Safety Council examined state progress on six key indicators:

1. Mandatory Prescriber Education
2. Opioid Prescribing Guidelines
3. Eliminating Pill Mills
4. Prescription Drug Monitoring Programs (PDMPs)
5. Increased Access to Naloxone
6. Availability of Opioid Use Disorder (OUD) Treatment



1.	Requires Mandatory Prescriber Education	17 states meet this indicator: CA, CT, DE, IA, KY, MA, NV, NH, NM, NC, OR, RI, SC, TN, VT, WI, WV
2.	Adopted Opioid Prescribing Guidelines	22 states meet this indicator: AL, AZ, AR, CA, CO, HI, IN, KY, MA, MN, NH, NM, NC, OH, OK, PA, RI, TN, UT, VT, WA, WV
3.	Eliminating Pill Mills	12 states meet this indicator: AL, FL, GA, IN, KY, LA, MS, OH, TN, TX, WI, WV
4.	Allows Physician and Pharmacy delegates to PDMPs	40 states meet this indicator: AL, AR, AZ, CA, CO, CT, DE, DC, ID, IL, IN, IA, KS, KY, LA, MD, MA, MN, MT, NH, NJ, NM, NY, NC, ND, OH, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
5.	Allows Naloxone to be prescribed with a standing order	35 states meet this indicator: AK, AL, AR, CA, CO, DE, FL, GA, IL, IN, KY, LA, MD, ME, MN, MS, NC, ND, NV, NH, NJ, NM, NY, OH, OK, PA, RI, SD, TN, TX, UT, VA, VT, WA, WI
6.	Availability of Opioid Use Disorder (OUD) Treatment	3 states meet this indicator: ME, NM, VT

STATE PROGRESS



STATE	REQUIRES MANDATORY PRESCRIBER EDUCATION	ADOPTS OPIOID PRESCRIBING GUIDELINES	ELIMINATES PILL MILLS	ALLOWS PHYSICIAN DELEGATES TO ACCESS PDMPs	ALLOWS NALOXONE STANDING ORDER	MEETS NEED FOR OUD TREATMENT
Alabama		✓	✓	✓	✓	
Alaska					✓	
Arizona		✓		✓		
Arkansas		✓		✓	✓	
California	✓	✓		✓	✓	
Colorado		✓		✓	✓	
Connecticut	✓			✓		
Delaware	✓			✓	✓	
District of Columbia				✓		
Florida			✓		✓	
Georgia			✓		✓	
Hawaii		✓				
Idaho				✓		
Illinois				✓	✓	
Indiana		✓	✓	✓	✓	
Iowa	✓			✓		
Kansas				✓		
Kentucky	✓	✓	✓	✓	✓	
Louisiana			✓	✓	✓	
Maine					✓	✓
Maryland				✓	✓	
Massachusetts	✓	✓		✓		
Michigan						
Minnesota		✓		✓	✓	
Mississippi			✓		✓	
Missouri						

State ranking were based on best available data at time of publication.

STATE PROGRESS



STATE	REQUIRES MANDATORY PRESCRIBER EDUCATION	ADOPTS OPIOID PRESCRIBING GUIDELINES	ELIMINATES PILL MILLS	ALLOWS PHYSICIAN DELEGATES TO ACCESS PDMPs	ALLOWS NALOXONE STANDING ORDER	MEETS NEED FOR OUD TREATMENT
Montana				✓		
Nebraska						
Nevada	✓				✓	
New Hampshire	✓	✓		✓	✓	
New Jersey				✓	✓	
New Mexico	✓	✓		✓	✓	✓
New York				✓	✓	
North Carolina	✓	✓		✓	✓	
North Dakota				✓	✓	
Ohio		✓	✓	✓	✓	
Oklahoma		✓			✓	
Oregon	✓			✓		
Pennsylvania		✓		✓	✓	
Rhode Island	✓	✓		✓	✓	
South Carolina	✓			✓		
South Dakota				✓	✓	
Tennessee	✓	✓	✓	✓	✓	
Texas			✓	✓	✓	
Utah		✓		✓	✓	
Vermont	✓	✓		✓	✓	✓
Virginia				✓	✓	
Washington		✓		✓	✓	
West Virginia	✓	✓	✓	✓		
Wisconsin	✓		✓	✓	✓	
Wyoming				✓		

State ranking were based on best available data at time of publication.

MANDATORY PRESCRIBER EDUCATION

The medical community is an important and vital partner in addressing the opioid epidemic. An Institute of Medicine report recommends that all healthcare providers keep their knowledge of pain management current through continuing medical education (CME). (*NATIONAL RESEARCH COUNCIL, 2011*) Licensure, certification and recertification examinations should include assessments of providers' pain education. Unfortunately, research has shown that practicing physicians received fewer than 12 hours of pain management education in medical school. (*MEZEI & MURINSON, 2011*) Another study found that 60 percent of physicians surveyed did not "receive training on identifying prescription drug abuse and addiction" in medical school. (*THE NATIONAL CENTER ON ADDICTION AND SUBSTANCE ABUSE, 2005*)

Addressing this knowledge gap is necessary to reduce dangerous prescribing practices and improve treatment of pain. **NSC recommends that states require CMEs on pain management for prescribers of controlled substances.** Seventeen states currently require education for physicians and other professionals who prescribe controlled substances to treat pain. (*FEDERATION OF STATE MEDICAL BOARDS, 2015*) For example, Kentucky doctors are required to take 4.5 hours of activity related to KASPER (Kentucky All Schedule Prescription Electronic Reporting), pain management or addiction disorders. In New Mexico, prescribers who are registered with the DEA must complete a 5 hour CME class about pain and addiction. Following implementation of New Mexico's CME requirement, the amount of opioids per prescription declined and prescribers issued fewer high-dose prescriptions. (*KATZMAN, ET AL., 2014*)

NSC Calls for Federal Educational Standards on Pain Management

Based on the successes seen by states like New Mexico in changing prescribing patterns as a result of the requirement for CME classes, **the National Safety Council recommends that the DEA require CME for all prescribers who apply for a new or renewed registration under the Controlled Substances Act of 1970.²**

The proposed CME should include the following topics:

- ✓ Relative efficacy and risks of medications used to treat acute and chronic pain
- ✓ Responsible prescribing, including the use of tools such as state Prescription Drug Monitoring Programs
- ✓ Linkage to treatment for those with addiction

Not all prescribers are required to register with the DEA—only those who will prescribe controlled substances such as opioid pain medications. Therefore, DEA controlled substance registration and renewal provides a targeted opportunity to address this knowledge gap.



State requires medical education

for prescribers on pain management

17 states meet this indicator:

California,
Connecticut,
Delaware,
Iowa,
Kentucky,
Massachusetts,
Nevada,
New Hampshire,
New Mexico,
North Carolina,
Oregon,
Rhode Island,
South Carolina,
Tennessee,
Vermont,
West Virginia
and Wisconsin

(*FEDERATION OF STATE MEDICAL BOARDS, 2015*)

² The Controlled Substances Act of 1970 established that some medications require additional screening and oversight by the Drug Enforcement Agency (DEA) when prescribed, including most opioid pain medications.

OPIOID PRESCRIBING GUIDELINES

Opioid prescribing guidelines helps medical providers make informed choices about pain treatment. Guidelines consist of recommendations for pain treatment based on the current knowledge of the risks and benefits of opioid use, as well as the risks and benefits of alternative non-opioid treatments. A number of medical professional organizations, state licensing agencies, state medical boards and, most recently, the CDC have published opioid prescribing guidelines. When states have developed guidelines, both regulatory and voluntary approaches have been used to develop and implement a guideline. States have developed opioid prescribing guidelines for a variety of clinical settings, including chronic pain, emergency medicine and workers compensation.

Washington, Kentucky, Ohio, Vermont and Indiana are among the states that have taken a regulatory approach by changing controlled substance regulations and establishing interagency and prescriber workgroups to develop a prescribing guideline.

Utah, in 2009, convened a steering committee and workgroups to develop their guideline, *Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain*. Arizona and North Carolina used a similar process, convening workgroups comprised of prescribers and medical associations to develop a guideline for hospital emergency departments regarding the prescribing of opioid pain relievers for patients with non-cancer pain.

Types of Opioid Guidelines

Chronic Pain

Chronic pain guidelines comprise recommendations on the use of opioids in treating pain lasting longer than three months or past the time of normal tissue healing. Twenty-two states have developed prescribing guidelines for chronic pain.

In March 2016, CDC issued an *Opioid Prescribing Guideline for Chronic Pain*. This guideline is intended to inform pain treatment decisions of primary care providers treating chronic, non-cancer pain.

The CDC guideline includes:

- ✓ Lower dosage recommendations. Higher opioid doses are associated with higher risk of overdose and death—even relatively low doses (20-50 morphine milligram equivalents (MME) per day) increase risk
- ✓ Risk assessment criteria for all patients. Previous guidelines focused safety precautions on “high risk patients,” however, opioids pose risk to all patients, and currently available tools cannot rule out risk for abuse or other serious harm
- ✓ More specific recommendations compared to previous guidelines on monitoring and discontinuing opioids when risks and harms outweigh benefits



State or state medical board has issued an opioid prescribing guideline

22 states meet this indicator:

Alabama,
Arizona,
Arkansas,
California,
Colorado,
Hawaii,
Indiana,
Kentucky,
Massachusetts,
Minnesota,
New Hampshire,
New Mexico,
North Carolina,
Ohio,
Oklahoma,
Pennsylvania,
Rhode Island,
Tennessee,
Utah, Vermont,
Washington and
West Virginia

(NATIONAL SAFETY COUNCIL, 2016)

OPIOID PRESCRIBING GUIDELINES (CONTINUED)

Emergency Medicine

Nine states have adopted guidelines developed by the American College of Emergency Physicians (ACEP) to inform the use of opioids in hospital emergency departments. **Key elements of the ACEP guideline include:**

- ✓ Use of short-acting, instead of long-acting, opioids
- ✓ Prescriptions for no more than a seven-day supply. States like Ohio have specified that no more than a three-day supply of opioid pain medications should be prescribed for acute pain in emergency room settings

Workers' Compensation

Three states have developed a guideline for the use of opioid pain medications in the treatment of occupational injuries covered by state workers' compensation programs. Following the 2007 implementation of the opioid dosing guideline, Washington workers' compensation system examined detailed billing data to learn about changes in opioid prescribing to workers receiving disability compensation. The introduction in Washington of an opioid dosing guideline appears to be associated with a decline in the mean dose for long-acting opioids, percent of claimants receiving opioid doses ≥ 120 mg morphine equivalent dose per day, and number of opioid-related deaths among injured workers. (FRANKLIN, MAI, TURNER, SULLIVAN, WICKIZER, & FULTON-KEHOE, 2012)

Guideline development is critical as opioids, even when prescribed at low doses, carry significant risks. States like Washington which have implemented a prescribing guideline, reduced opioid prescribing and reduced opioid overdose fatalities. As a result, **the National Safety Council recommends that all states adopt an opioid prescribing guideline.** At a minimum, the guideline should address:

- ✓ When initiation of opioid treatment is appropriate
- ✓ Guidance on maximum dose and duration of opioid treatment
- ✓ Information on how to monitor treatment to ensure patient safety



Washington State Case Study

Washington has seen success in reducing overdose deaths and opioid prescribing rates through the implementation of a prescribing guideline.

In 2007, voluntary guidelines were introduced in Washington to guide physicians on responsible opioid prescribing for non-cancer pain. Following introduction of the guideline, prescribers reported increases in awareness of safer opioid prescribing practices, and the State realized subsequent decreases in overdose deaths. In 2010, Washington required all licensing boards to establish rules and adopt one evidence-based prescribing guideline. The State developed a number of tools and resources to support responsible opioid prescribing practices. In addition, it increased training and support for prescribers to recognize substance abuse and make referrals to treatment. These efforts have resulted in a 29 percent reduction in drug overdose death rate since 2008.

ELIMINATING PILL MILLS

“Pill mills” are a doctor’s office, clinic or health care facility that routinely prescribes controlled substances outside the scope of standard medical practice and often in violation of state laws. Frequently advertised as “pain management” clinics, pill mills can operate within medical practices that treat a variety of legitimate medical issues. Typical characteristics of pill mills include non-individualized care, lack of referrals to specialists or use of diagnostic tests and repetitive combinations of medications that do not vary from patient to patient.

NSC recommends continued state policy development that stops the establishment and/or operation of pill mills that function outside guidelines for licensed, qualified physicians and whose primary treatment is prescribing opioids. State policy should include requirements for acceptable standards of medical care including:

- ✓ Following prescribing guidelines in accordance with standards established by state licensing authorities and prevailing best practice standards
- ✓ Defining ownership requirements to ensure that clinic owners can be held accountable by state licensing authorities
- ✓ Restricting the dispensing of controlled substances
- ✓ Requiring use of state prescription drug monitoring programs by pain clinics
- ✓ Requiring an appropriate medical evaluation including adequate patient history and physical examination
- ✓ Conducting an appropriate risk assessment at each visit

Ten states have adopted pain clinic requirements to target activities consistent with these practices. Two additional states—Alabama and Indiana—have enacted regulations for prescribers related to specific prescribing activities rather than regulations limited to pain clinics. This trend may allow for a greater variety of enforcement options and address pill mills operating within other medical specialties or practice settings. *(NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS, 2014)*



The State has a law or laws that regulate pain clinics or pain management services

12 states meet this indicator:

Alabama,
Florida,
Georgia,
Indiana,
Kentucky,
Louisiana,
Mississippi,
Ohio,
Tennessee,
Texas,
West Virginia and
Wisconsin

(NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS, 2014)





Florida State Case Study

By 2009, Florida was known as the epicenter of the nation's pill mill activity. DEA's Automation of Reports and Consolidated Orders System (ARCOS) reported that 98 of the top 100 oxycodone dispensing physicians in the nation were located in Florida. *(FLORIDA OFFICE OF THE ATTORNEY GENERAL)* Starting in 2010, in an effort to address this growing public health threat, Florida began requiring pain clinic registrations and inspections and enacted a number of laws to curb high-volume prescribing. **These included:**

- Bans on physician dispensing
- Establishment of a PDMP
- Tougher penalties for illegal prescribing

As a result of these new requirements, opioid prescribing rates decreased and overdose deaths declined by 23 percent between 2010 and 2012.

(JOHNSON, PAULOZZI, PORUCZNIK, MACK, & HERTER, 2014) After the 2010 law, Florida experienced a significant decrease in the amount of opioids prescribed - equal to 500,000 fewer 5-mg hydrocodone tablets.

(RUTKOW, CHANG, DAUBRESSE, WEBSTER, STUART, & ALEXANDER, 2015) Another study found the death rate from prescription painkiller overdoses in Florida was 7 percent lower than expected. In 2011, the rate was 20 percent lower and in 2012, 34.5 percent lower. *(KENNEDY-HENDRICKS, RICHEY, MCGINTY, STUART, BARRY, & WEBSTER, 2016)*

Today, none of the top 100 opioid dispensing physicians reside in Florida.



PRESCRIPTION DRUG MONITORING PROGRAMS

Patients who obtain opioid painkillers from four or more doctors or pharmacies are at an increased risk of overdose. Therefore, state Prescription Drug Monitoring Programs (PDMPs) can be a valuable tool to help prescribers make informed clinical decisions and avoid costly or fatal errors. PDMPs serve as an early warning system, alerting prescribers and state officials about high-risk patients seeking prescriptions from multiple doctors and risky prescribing practices and allowing them to intervene when necessary to protect patients and the community.

Unfortunately, PDMPs are underutilized by prescribers. A 2015 study of primary care prescribers found that while a majority reported having obtained data from their PDMP at some point in time, prescribers consulted PDMP data in fewer than one-quarter of instances when they prescribed opioids to patients. (RUTKOW, TURNER, LUCAS, HWANG, & ALEXANDER, 2015) In states with voluntary PDMP use, prescribers verified patient history only 14 percent of the time before prescribing an opioid. (SHATTERPROOF, 2016)

In a Johns Hopkins survey, family practice physicians reported they did not use the PDMP because it was time-consuming process and data was not reported in an easy to use format. Other issues identified include physician perception that data was needed only for a few patients. (RUTKOW, TURNER, LUCAS, HWANG, & ALEXANDER, 2015)

State action remains necessary to ensure widespread adoption and utilization of PDMPs by prescribers and pharmacists. Fourteen states require prescribers to access the PDMP prior to prescribing a schedule II, III or IV controlled substances. The number is based on how it is defined. (PDMP CENTER OF EXCELLENCE BRANDEIS UNIVERSITY, 2016) In Kentucky, New York and Tennessee—three of the first states to mandate prescriber use of the PDMP—increased PDMP utilization has resulted in reductions in opioid prescriptions and in patients visiting multiple providers—75 and 36 percent reductions respectively in doctor shopping in New York and Tennessee.

However, the rapid implementation of these mandates has not been without challenges. A Brandeis Center of Excellence report recommends that states establish stakeholder groups to build consensus and offer feedback to better integration of PDMP data in clinical decisions. (PDMP CENTER OF EXCELLENCE BRANDEIS UNIVERSITY, 2016) CDC has provided funding to states to develop universal registration and use, making PDMPs easier to use and the data more timely. (CENTERS FOR DISEASE CONTROL AND PREVENTION, 2016)



State PDMP allows prescriber and dispenser delegates

40 states meet this indicator:

Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Montana, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin and Wyoming

(NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS, 2014)



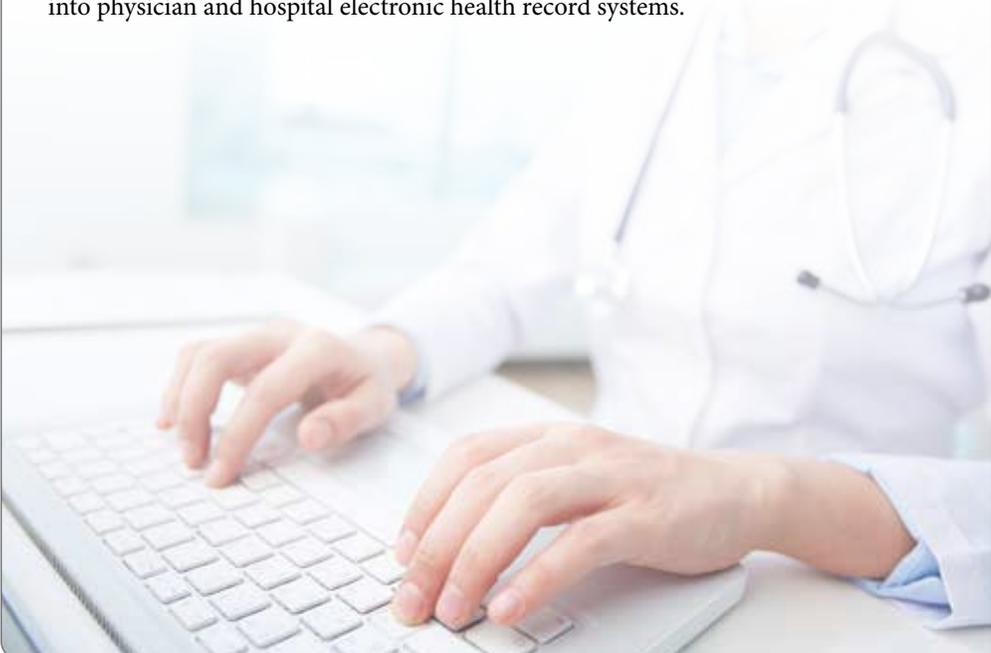
PRESCRIPTION DRUG MONITORING PROGRAMS

(CONTINUED)

Forty states allow physicians and dispensers to appoint delegates or staff from their practice to access PDMP data, making it easier to integrate into clinical workflow. Institutional accounts are another PDMP innovation that makes it easier for clinicians, hospitals or universities to manage and supervise a delegate's PDMP utilization. To increase the effective use of PDMPs, **NSC recommends that State PDMPs allow prescriber and physician delegates and the creation of institutional accounts.**

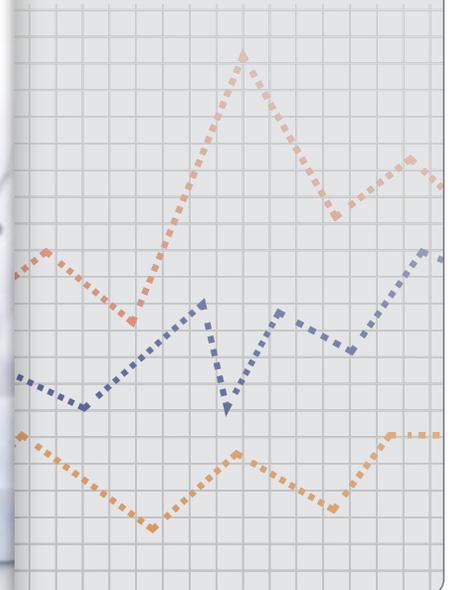
Another hurdle to PDMP utilization is complicated multi-step application and verification processes. **NSC recommends that states simplify the PDMP registration process, integrating and automating when possible with other licensing processes.** Prescribers and pharmacists need easy-to-use reports with real-time information. Oklahoma's PDMP was the first to offer real-time data reports to pharmacists and physicians to assist them in making timely clinical decisions whether to issue a prescription or dispense medication to a patient. Since then, 27 state PDMPs now collect prescription information from pharmacies within 24 hours of dispensing controlled substances. The remaining state PDMPs collect this data within 72 hours or weekly. **NSC recommends that all states collect prescription data within 24 hours.**

NSC also recommends that States improve reporting response times and upgrade PDMP technology to facilitate data transfer into clinical workflows. The Kentucky PDMP processes the majority of PDMP queries within 15 seconds or less, and a number of states are currently working on pilot programs to integrate PDMP data into physician and hospital electronic health record systems.



**Making
Changes**

**PRESCRIBERS
and
PHARMACISTS
NEED
EASY-TO-USE
REPORTS
with
REAL-TIME
INFORMATION**



INCREASED ACCESS TO NALOXONE

Opioid overdoses are reversible with the timely administration of naloxone. Naloxone, available by prescription, can be administered as an injection or nasal spray. It is not a controlled substance and has no abuse potential.

Physicians can provide a prescription for naloxone to a person at risk of overdose, similar to prescribing an EpiPen for people with severe allergies. However, unlike some types of allergic reactions, an opioid overdose renders the victim unable to self-administer this medication. Making naloxone available to family members and friends of those suffering from addiction, as well as first responders, will save lives.

Some states have increased access to and use of naloxone by amending medical practice laws and regulations to allow a licensed healthcare professional to prescribe naloxone for use by a third-party such as a family member. For example, Massachusetts allows community programs to provide naloxone to trained individuals with a standing order from the health department.

Community overdose education and prevention programs distribute naloxone overdose prevention kits and provide training. Education includes how to recognize the signs of an overdose, when and how to administer naloxone and the importance of rescue breathing until 9-1-1 first responders arrive.

Use of naloxone has increased greatly. From 1996 through June 2014, laypersons reported using naloxone in 26,463 overdose reversals. In 2013 alone, nearly 40,000 laypersons with 93 organizations reported 8,032 overdose reversals—lives that may not have been saved without laws allowing increased naloxone access.

(WHEELER, JONES, GILBERT, & DAVIDSON, 2015)



State allows
a standing order
for naloxone

35 states meet
this indicator:

Alabama, Alaska,
Arkansas, California,
Colorado, Delaware,
Florida, Georgia,
Illinois, Indiana,
Kentucky, Louisiana,
Maine, Maryland,
Minnesota,
Mississippi,
Nevada,
New Hampshire,
New Jersey,
New Mexico,
New York,
North Carolina,
North Dakota,
Ohio, Oklahoma,
Pennsylvania,
Rhode Island,
South Dakota,
Tennessee, Texas,
Utah, Vermont,
Virginia,
Washington and
Wisconsin

(NETWORK FOR PUBLIC HEALTH LAW, 2016)

INCREASED ACCESS TO NALOXONE (CONTINUED)

Thirty-five states permit naloxone to be prescribed with a standing order.³ (NETWORK FOR PUBLIC HEALTH LAW, 2016) More recently, Connecticut, Idaho, North Dakota and New Mexico started allowing naloxone to be dispensed by pharmacists. About a dozen states permit pharmacists to establish collaborative practice agreements with a physician to dispense naloxone. Other states allow the pharmacy board to establish standards that permit naloxone to be dispensed.

However, while this progress is encouraging, more work is needed to ensure that naloxone remains affordable. **Therefore, NSC recommends that states, insurers, and other relevant payers work to ensure that naloxone is covered by all insurance plans, including public plans.**

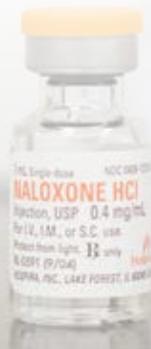
Good Samaritan Provisions

Opioid overdose often happen when the victim is with friends or family members. Witnesses or bystanders to an overdose may be in the best position to save a life by administering naloxone. However, some overdose bystanders sometimes fail to summon medical assistance for fear of police involvement.

(TOBIN, DAVEY, & LATKIN, 2005)

“Good Samaritan” laws provide protection from negative consequences associated with calling for help. Opioid overdose bystanders can become “Good Samaritans” by calling emergency responders without fear of arrest or other negative legal consequences.

Thirty-four states and the District of Columbia have enacted Good Samaritan provisions. **NSC recommends that all states enact Good Samaritan laws to remove any barriers to seeking help for a drug overdose.**



Sal's Story

Patty DiRenzo, of Blackwood, NJ lost her son Sal to a fatal overdose. His death could have been prevented if the people with whom he was using drugs had called 9-1-1 for help. They didn't, most likely afraid of legal consequences. Instead of saving a life by seeking help, Sal was left alone to die, without the medical help he needed. Patty lost her son, and her grandson lost his father, because someone was afraid to call 9-1-1.

Patty believes with proper treatment Sal could have beaten his addiction, but this opportunity was lost forever with his passing. The majority of overdose victims do not die until one to three hours after they have initially taken a drug, and most of these deaths occur in the presence of others. This leaves a significant amount of time for witnesses to intervene and call for medical help, but the fear of arrest and prosecution prevents many from making that call. Good Samaritan laws remove these legal barriers, so that calling 9-1-1 is never a crime.

Patty believes “Saving a life is far more important than punishing those who seek help.”

³ A standing order allows a drug to be dispensed by a pharmacy or other programs to any person who meets specific criteria and without the prescriber or patient ever meeting.

AVAILABILITY OF OPIOID USE DISORDER TREATMENT

Opioid use disorder (OUD), occurs when the recurrent use of opioid pain relievers or heroin cause significant clinical problems including health issues, disability, and the failure to meet major responsibilities at work, school or home. OUD is a brain disease and a serious chronic health condition like heart disease or diabetes. And like these conditions, medication and support to make lifestyle changes may be required to effectively treat an OUD. **As a chronic disease, if left untreated, OUD will worsen, often resulting in death.** In 2014, more than 2.4 million people had an opioid use disorder related to use of opioid pain relievers or heroin. (SAMHSA, 2015)

Medication assisted treatment (MAT) with buprenorphine or methadone is the most effective treatment for OUD. (WORLD HEALTH ORGANIZATION, 2009) A third medication, Naltrexone, can also be used to treat OUD. However, it is less effective in sustaining long-term recovery. (COUSINS, RADFAR, CRÈVECOEUR-MACPHAIL, ANG, DARFLER, & RAWSON, 2016)

Methadone is provided in a clinic setting at opioid treatment programs (OTP). OTPs are federally regulated clinics that dispense methadone, usually as a liquid, daily to patients. Barriers to methadone include waiting lists for treatment, relatively few locations in most states, insurance coverage limits and requirements for daily clinic visits. In 2012, nearly all state OTPs operated at greater than 80 percent capacity, and OTPs in 12 states reported 100 percent capacity. (JONES, CAMPOPIANO, BALDWIN, & MCCANCE-KATZ, 2015)

With most state OTPs operating at capacity, buprenorphine which can be prescribed in office-based settings, offers the most viable way to expand access for MAT. Buprenorphine is prescribed by SAMHSA certified physicians who receive specialized training. Patient caseloads for buprenorphine prescribers are capped at 30 individuals in the first year. (SAMHSA, 2016) After the first year, physicians can expand their caseload to 100 patients, but many physicians do not apply for this extension. If all physicians provide buprenorphine at the maximum level, 1,093,150 people can receive treatment in the US, which is less than the number needed. (JONES, CAMPOPIANO, BALDWIN, & MCCANCE-KATZ, 2015)



State has sufficient buprenorphine treatment

capacity to treat residents with opioid dependence

3 states meet this indicator:

Maine,
New Mexico
and Vermont

(JONES, CAMPOPIANO, BALDWIN & MCCANCE-KATZ, 2015)



AVAILABILITY OF OPIOID USE DISORDER TREATMENT

(CONTINUED)

Treatment capacity in the United States lags behind the need for opioid treatment. An analysis of national and state treatment capacity found that rates of opioid abuse or dependence (891.8 per 1,000,000 people) far exceeded the maximum buprenorphine treatment capacity (420.3) and numbers of people receiving methadone (119.9) at an OTP. Most states had opioid dependence rates higher than their buprenorphine treatment capacity. Only three states—Maine, New Mexico and Vermont had maximum buprenorphine treatment capacity sufficient to meet the treatment need in their state. (JONES, CAMPOPIANO, BALDWIN, & MCCANCE-KATZ, 2015)

States must close the treatment gap. **NSC recommends that physician patient caseload limits be raised for buprenorphine wavered physicians and that advanced practice nurses are allowed to obtain DATA-2000 waivers to prescribe buprenorphine. NSC also recommends that federal and state-funded substance abuse services offer MAT, the most effective methods of opioid dependence treatment.** Care should be coordinated and MAT provided in conjunction with counseling and recovery support services. Vermont and Massachusetts have developed innovative care models to expand buprenorphine treatment capacity in their states, and this treatment should also be affordable. **NSC recommends that States require public and private health insurers to cover medication assisted treatment.** All three options for medication-assisted treatment should be available to all patients as unique patient characteristics may mean one form of medication assisted treatment is more effective. Also caps on the length and duration of MAT should be eliminated.

**Reality
Check**

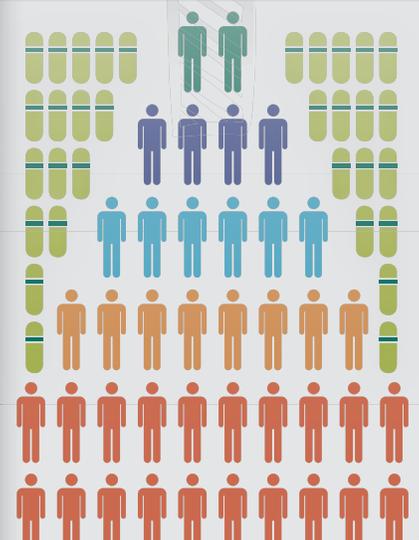
**RATES OF
OPIOID ABUSE/
DEPENDENCY**

FAR EXCEED

the maximum
buprenorphine/
methadone

**TREATMENT
CAPACITY**

in nearly
all states





Vermont: Effective and Coordinated Opioid Treatment

Through a unique partnership between the Vermont Department of Health's Division of Alcohol and Drug Abuse Programs and the Department of Vermont Health Access's Blueprint for Health, the Care Alliance was formed. The Care Alliance for Opioid Addiction is a statewide partnership of clinicians and treatment centers that provide MAT to Vermonters addicted to opioids.

How it Works

The Care Alliance uses a Hub & Spoke model to ensure that each person's care is effective, coordinated and supported. People can access care by requesting services at a regional opioid treatment center (Hub), or their primary care provider (Spoke), or by dialing 2-1-1, a statewide, free, confidential information and help service. Five regional opioid treatment centers in 8 locations in Vermont serve as treatment hubs. Regional opioid treatment centers treat patients with complex needs with medication assisted treatment, either methadone or buprenorphine. In the Spokes, community physicians lead a team

of nurses and clinicians to treat patients with medication assisted therapy, using buprenorphine. Patient care is coordinated and supported and supervised by a physician. Nurses and counselors connect patients with community-based support services. Support services may include mental health and substance abuse treatment, pain management, life skills and family support, job development and recovery support.

Highlights of Vermont's Opioid Treatment System to Date:

- In 2015, more than 4,800 people received MAT in Vermont, up from 2,867 in January 2013
- The 90-day retention rate among Vermont Medicaid-eligible individuals served by the Hub and Spoke system is 77 percent and greater than the national average of 70 percent and is increasing
- Vermonters who stay in treatment in Hubs longer than 90 days show improved overall functioning at discharge than those who left treatment earlier

RECOMMENDATIONS



NSC believes that if the following recommendations are implemented by state leaders, we can begin to reverse this epidemic and save lives.

1. Establish State requirements for medical education on effective pain management
2. Require CME for prescribers who apply for a new or renewed registration under the Controlled Substances Act of 1970. CME should be pertinent to the classes of controlled substances prescribed by the provider. The proposed CME should include the following topics:
 - ✓ Relative efficacy and risks of medications used to treat acute and chronic pain
 - ✓ Responsible prescribing, including the use of tools such as state Prescription Drug Monitoring Programs (PDMPs)
 - ✓ Linkage to treatment for those with addiction
3. Adopt state opioid prescribing guideline. At a minimum, the guideline should address:
 - ✓ When initiation of opioid treatment is appropriate, provide guidance on maximum dose and duration of opioid treatment
 - ✓ Monitor treatment to ensure patient safety
4. Develop or strengthen state policy that stops the establishment and/or operation of pill mills that function outside prescribing standards for licensed, qualified physicians and whose primary treatment is prescribing opioids. State policy should include requirements for acceptable standards of medical care including:
 - ✓ Following prescribing guideline in accordance with standards established by state licensing authorities and prevailing best practice standards
 - ✓ Defining ownership requirements to ensure that clinic owners can be held accountable by state licensing authorities
 - ✓ Restricting the distribution of controlled substances
 - ✓ Requiring use of state prescription drug monitoring programs by pain clinics
 - ✓ Requiring an appropriate medical evaluation including adequate patient history and physical examination
 - ✓ Conducting an appropriate risk assessment at each visit
5. Make PDMPs easy to use:
 - ✓ Require the collection of prescription data within 24 hours
 - ✓ Simplify the PDMP registration process, integrating and automating when possible with other medical professional licensing processes
 - ✓ Improve reporting response times and facilitate data transfer into clinical workflows
6. Improve reporting of drugs involved in drug overdose fatalities:
 - ✓ Encourage medical examiners and coroners to screen for fentanyl for suspected opioid overdose cases
 - ✓ Require coroners and medical examiners use SAMHSA consensus recommendations to report opioid-related deaths
7. Expand access to naloxone and remove barriers to its purchase and use
 - ✓ Enact laws allowing standing orders for naloxone
 - ✓ Require insurers, and other relevant payers to ensure that naloxone is covered by insurance plans, including public plans
 - ✓ Enact laws to enact “Good Samaritan” laws to remove any barriers to seeking help for a drug overdose
8. Increase patient caseload caps for buprenorphine wavered physicians
9. Allow advanced practice nurses to obtain waiver to prescribe buprenorphine. Expand use of medication assisted treatment, ensure it is offered and available at state-funded treatment providers
10. Require public and private health insurers to cover medication assisted treatment
11. Remove caps on the duration of medication-assisted treatment

ABOUT THE NATIONAL SAFETY COUNCIL

Founded in 1913 and chartered by Congress, the National Safety Council, **nsc.org**, is a nonprofit organization whose mission is to save lives by preventing injuries and deaths at work, in homes and communities, and on the roads through leadership, research, education and advocacy. NSC advances this mission by partnering with businesses, government agencies, elected officials and the public in areas where we can make the most impact—distracted driving, teen driving, workplace safety, prescription drug overdoses and Safe Communities.

Visit **nsc.org** to learn more.





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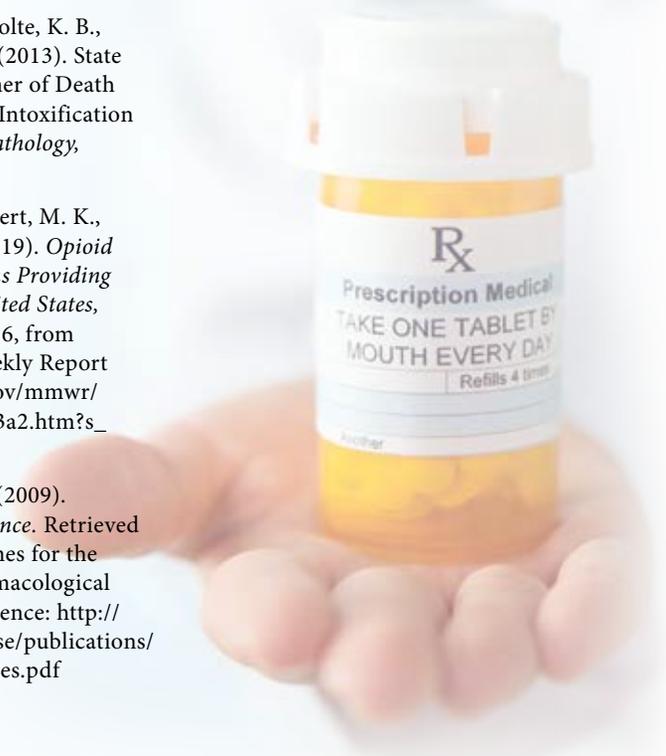
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nsc.org/rxreport

State and National Totals of Filled Prescriptions - All Opioid Analgesics

State	2013 Rx Total	2014 Rx Total	2015 Rx Total	Rx per Capita 2015	Rate of change 2014-15	Rate of change 2013-15
Alabama	6,814,305	6,393,791	5,840,754	1.2	-8.6%	-16.7%
Alaska	468,266	457,730	420,617	0.6	-8.1%	-11.3%
Arizona	5,050,348	5,038,497	4,813,236	0.7	-4.5%	-4.9%
Arkansas	3,477,289	3,523,762	3,312,715	1.1	-6.0%	-5.0%
California	21,047,372	20,561,933	18,666,608	0.5	-9.2%	-12.8%
Colorado	3,678,624	3,637,189	3,471,691	0.6	-4.6%	-6.0%
Connecticut	2,512,161	2,476,310	2,297,397	0.6	-7.2%	-9.3%
Delaware	823,522	814,682	768,974	0.8	-5.6%	-7.1%
District of Columbia	530,757	520,817	462,789	0.7	-11.1%	-14.7%
Florida	13,636,391	13,413,544	12,708,441	0.6	-5.3%	-7.3%
Georgia	8,643,869	8,305,929	7,880,524	0.8	-5.1%	-9.7%
Hawaii	717,220	694,579	645,508	0.5	-7.1%	-11.1%
Idaho	1,361,009	1,348,590	1,263,510	0.8	-6.3%	-7.7%
Illinois	8,800,796	8,518,837	8,003,978	0.6	-6.0%	-10.0%
Indiana	6,924,241	6,307,577	5,837,382	0.9	-7.5%	-18.6%
Iowa	2,274,401	2,246,454	2,121,545	0.7	-5.6%	-7.2%
Kansas	2,751,590	2,677,203	2,504,956	0.9	-6.4%	-9.8%
Kentucky	4,997,389	4,900,964	4,471,521	1.0	-8.8%	-11.8%
Louisiana	5,497,900	5,248,487	4,818,945	1.0	-8.2%	-14.1%
Maine	1,105,502	1,060,604	985,562	0.7	-7.1%	-12.2%
Maryland	4,229,380	4,181,855	3,941,165	0.7	-5.8%	-7.3%
Massachusetts	4,584,487	4,431,390	4,066,743	0.6	-8.2%	-12.7%
Michigan	10,482,299	10,315,827	9,528,806	1.0	-7.6%	-10.0%
Minnesota	3,330,832	3,250,152	2,975,420	0.5	-8.5%	-11.9%
Mississippi	3,514,236	3,407,069	3,212,366	1.1	-5.7%	-9.4%
Missouri	5,755,659	5,602,998	5,217,577	0.9	-6.9%	-10.3%
Montana	798,887	776,545	722,011	0.7	-7.0%	-10.6%
Nebraska	1,497,183	1,470,605	1,378,816	0.7	-6.2%	-8.6%
Nevada	2,436,691	2,467,414	2,393,881	0.8	-3.0%	-1.8%
New Hampshire	970,834	937,024	886,243	0.7	-5.4%	-9.5%
New Jersey	5,160,965	5,082,090	4,917,404	0.5	-3.2%	-5.0%
New Mexico	1,422,434	1,436,906	1,409,482	0.7	-1.9%	-0.9%
New York	10,957,729	10,450,786	10,164,060	0.5	-2.7%	-7.8%
North Carolina	9,482,526	9,232,258	8,717,746	0.9	-5.6%	-8.8%
North Dakota	505,227	495,555	466,131	0.6	-5.9%	-8.4%
Ohio	11,261,528	10,794,842	9,955,858	0.9	-7.8%	-13.1%
Oklahoma	4,666,575	4,242,737	3,972,838	1.0	-6.4%	-17.5%
Oregon	3,456,129	3,389,575	3,145,023	0.8	-7.2%	-9.9%
Pennsylvania	11,330,259	11,031,159	10,394,466	0.8	-5.8%	-9.0%
Rhode Island	871,892	823,219	732,367	0.7	-11.0%	-19.1%
South Carolina	4,866,458	4,797,342	4,490,916	0.9	-6.4%	-8.4%
South Dakota	570,917	585,432	581,534	0.7	-0.7%	1.8%
Tennessee	8,525,017	8,239,110	7,800,947	1.2	-5.3%	-9.3%
Texas	18,569,734	17,959,748	15,903,061	0.6	-11.5%	-16.8%
Utah	2,364,661	2,308,830	2,186,792	0.7	-5.3%	-8.1%
Vermont	418,161	415,687	388,108	0.6	-6.6%	-7.7%
Virginia	6,346,359	6,047,580	5,608,460	0.7	-7.3%	-13.2%
Washington	5,163,236	5,121,469	4,881,633	0.7	-4.7%	-5.8%
West Virginia	2,420,990	2,389,802	2,076,883	1.1	-13.1%	-16.6%
Wisconsin	4,326,863	4,224,458	3,984,693	0.7	-5.7%	-8.6%
Wyoming	413,701	405,626	382,837	0.7	-5.6%	-8.1%
All States	251,814,805	244,462,567	227,780,915	0.7	-6.8%	-10.6%

Source: Xponent, IMS Health, Plymouth Meeting, PA Copyright 2016



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BRAD D. SCHIMEL
ATTORNEY GENERAL



DOSE OF REALITY
PREVENT PRESCRIPTION PAINKILLER ABUSE IN WISCONSIN.

AG SCHIMEL SHARES A “DOSE OF REALITY”

Public information, awareness campaign targets prescription painkiller abuse

September 17, 2015

Contact: Anne E. Schwartz (608) 266-6686

Wisconsin Attorney General Brad Schimel served up a DOSE OF REALITY today to alert Wisconsinites to the dangers of misusing opioid pain medications – an abuse that now exceeds deaths involving heroin and cocaine combined. DOSE OF REALITY – Prevent Prescription Painkiller Abuse in Wisconsin, is a statewide marketing campaign designed to raise awareness of this issue and to encourage the community to take action.

“There is so much information to share – and misinformation to clear up - surrounding this issue, which I discovered as I traveled the state over the past year talking about the heroin and prescription painkiller abuse epidemic,” Schimel said. “This is a message of hope and prevention. We can win this battle and make our state safer and healthier.”

“Overdoses of opioid painkillers such as oxycodone, hydrocodone, and methadone, accounted for 45% of the 843 drug overdose deaths in Wisconsin in 2013,” said Kitty Rhoades, Secretary of the Department of Health Services. “This is truly a public health crisis, and one that can be eliminated through sharing information about the risks involved in misusing these medications.”

This campaign is not designed to vilify prescription painkillers nor those who prescribe them, but to raise awareness that when used or stored improperly, they can be dangerous or even deadly. Prescription painkillers can be beneficial when properly prescribed by a licensed medical or dental professional, properly used as directed, stored securely and disposed of properly. DOJ will be working over the next 30 days to promote the DOJ Drug Take Back Day on October 17, 2015. The DOSE OF REALITY website, doseofrealitywi.gov has an interactive map so people can find a drug take back location near them.

- more -

Dose of Reality Release
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Additionally, the website offers information, resources and a unique online ordering portal that will make the DOSE OF REALITY campaign assets available at no charge to DOJ's partners to access, customize and use in their own communities and audiences as they see fit. Many of these materials are available today, and more will be added to the portal in the next several weeks.

DOJ will be airing TV and radio spots, using social media, and advertising in other venues to accomplish the following goals:

- Inform and educate Wisconsinites about the improper use of prescription painkillers
- Warn about the dangers of inadequate storage and disposal of prescription painkillers
- Inform each audience as to the role they play in education and abuse prevention, from medical providers and parents to high school students and young adults
- Encourage positive action

AG Schimel said in his video introduction to the DOSE OF REALITY campaign on the website, "We must address the problem of prescription painkiller abuse before it buries us – literally."

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