

OVER DOSED:

A Comprehensive Federal Strategy for Addressing America's Prescription Drug and Heroin Epidemic

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The treatment and prevention of prescription drug and heroin abuse is one of the most important and difficult challenges facing our country. Nationwide, drug overdose deaths, fueled by prescription painkillers, now claim more lives than car accidents, with approximately 100 Americans dying from an overdose every day, nearly half from prescription opioid painkillers.

To the extent they can, given current legal, regulatory, and budgetary constraints, federal agencies and the White House have been developing solutions and dedicating resources to address the prescription drug epidemic. The attention paid has raised the profile of this issue in the news and national consciousness, but there is still much more that needs to be done.

There is no one silver bullet for a disease as complex as opioid addiction. It will require a broad range of actions that must all work in unison. The current crisis demands strategic planning that thoughtfully brings together science, medicine, public health and law enforcement in a multi-faceted solution. The foundation of a comprehensive approach must integrate policy changes that focus on prevention, treatment and enforcement.

Prevention

Prescription drug abuse is the nation's fastest-growing drug problem. The over-prescription of pain pills for acute medical events often leads to medicine

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cabinets full of unused pain medications, providing easy access to teens and others for misuse and abuse of these drugs. In 2012 health care providers wrote 259 million prescriptions for opioid painkillers, enough for every American adult to have a bottle of pills.

Unfortunately, once an individual is addicted to prescription opioids, they may be driven to use illicit substances that have similar neurological effects, most notably heroin. According to a report released last year by the Substance Abuse and Mental Health Services Administration (SAMHSA), four out of five heroin users started abusing prescription drugs first. We need to prevent opioid addiction before it takes hold. This will require a balanced approach to ensure that people who need prescription pain medication have access to it while minimizing the negative consequences associated with the misuse and abuse of this class of drugs.

Treatment

Breaking the cycle of addiction lies with the ability to appropriately care and treat those with substance use disorders. Even with levels of opioid abuse and dependence that have reached epidemic proportions, treatment in the U.S. is limited, highly stigmatized and under-resourced, resulting in an inability of many individuals to access the care that is needed.

Access to evidence-based treatment services can help those with substance

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use disorders achieve recovery and reduce the social burdens and harms associated with illicit drug use. As the U.S. health care system shifts to one that promotes the use of multidisciplinary teams to address an individual's health care needs, it is important that addiction medicine be fully integrated into the general health care setting and patients be made aware of the full continuum of evidence-based treatment and care options that are available.

Enforcement

Law enforcement plays a dual role in the opioid addiction crisis. The Drug Enforcement Administration, together with other federal, state and local law enforcement must shut down pill mills, detect and deter diversion of prescription drugs, and stem the supply of heroin into our communities. However, law enforcement leaders at every level recognize that we cannot arrest and incarcerate our way out of this crisis. One of the most important tasks law enforcement has is caring for inmates with substance use disorders and helping reduce drug related recidivism. A multi-pronged approach is necessary, and law enforcement must have the tools it needs to keep opioids off our streets and reduce recidivism.

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The treatment and prevention of prescription drug and heroin abuse is one of the most important and difficult challenges facing our country. Nationwide, drug overdose deaths, fueled by prescription painkillers, now claim more lives than car accidents, with approximately 100 Americans dying from an overdose every day, nearly half from prescription opioid painkillers. Drug overdose death rates have been rising steadily since 1992, with a 118 percent increase from 1999 to 2011 alone. While the surge has been particularly dramatic in certain regions of the country, including New England and Appalachia, communities across the country that were once free from the debilitating disease of addiction are now seeing substance abuse and overdose deaths in unprecedented numbers.



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In response to the ongoing crisis, several states, cities and towns have started to take action. The federal government has placed a renewed focus on opioid prescription drugs and is actively cracking down on heroin coming from Mexico and Central America and pill mills across the country that are contributing to the supply of prescription painkillers on our streets. To the extent they can, given current legal, regulatory, and budgetary constraints, federal agencies and the White House have been developing solutions and dedicating resources to address the prescription drug epidemic. The attention paid has raised the profile of this issue in the news and national consciousness, but there is still much more that needs to be done.

There is no one silver bullet for a disease as complex as opioid addiction. It will require a broad range of actions that must all work in unison. The current crisis demands strategic planning that thoughtfully brings together science, medicine, public health and law enforcement in a multi-faceted solution. The foundation of a comprehensive approach must integrate policy changes that focus on prevention, treatment and enforcement.

In response to a dramatic increase in opioid overdoses in the state of Massachusetts, this year Senator Edward J. Markey (D-Mass.) introduced the Recovery Enhancement for Addiction Treatment Act (TREAT Act), to expand the ability of trained medical professionals to provide life-saving medication-assisted therapies for patients suffering from heroin and prescription drug

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addiction. He also has introduced the Opioid Overdose Reduction Act, legislation that would protect individuals who administer lifesaving opioid overdose prevention drugs from legal liability. Senator Markey has called on the Food and Drug Administration (FDA) to engage researchers, addiction treatment leaders, and drug developers to develop and approve new therapies that will reduce drug use as well as reduce the harms associated with it. He has urged the leaders of federal agencies to support community naloxone distribution programs and expand access to addiction treatment and recovery services.

Senator Markey convened three separate roundtables throughout Massachusetts over a period of six months with law enforcement, health care and public health experts from across the state. In August the Senator brought federal leaders from the Office of National Drug Control Policy (ONDCP), the National Institute on Drug Abuse (NIDA), the Substance Abuse and Mental Health Services (SAMHSA) and the Drug Enforcement Agency (DEA) to Boston to meet with state and local officials and leaders to discuss the issues that are causing the current crisis of addiction and craft solutions to address the problem.

This report, separated into the three main components —prevention, treatment and enforcement —outlines a comprehensive federal strategy to address the heroin and prescription drug abuse epidemic based on the ideas and insights gained from these roundtables.

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Prescription drug abuse is the nation's fastest-growing drug problem. While many types of prescription drugs are abused, there is currently a rapidly escalating, deadly epidemic of prescription painkiller abuse. Each day, 46 people die from an overdose of prescription painkillers in the United States and more than 30 people are admitted to an emergency room because of opioid complications.¹ The unprecedented rise in overdose deaths in the US parallels a 300 percent increase since 1999 in the sale of these potent painkillers.²

According to data from the Centers for Disease Control (CDC), health care providers wrote 259 million prescriptions for opioid painkillers in 2012, enough for every American adult to have a bottle of pills.³ Although the U.S. comprises less than five percent of the world's population, Americans consume 80 percent of the global opioid painkillers and 99 percent of the global supply of hydrocodone, the active ingredient in Vicodin.⁴ In fact, Vicodin and other drugs containing the narcotic hydrocodone are now the most commonly prescribed medications in the U.S.⁵ While the prevailing approach used to be that opioid painkillers were not addictive if they were legitimately used to treat pain, we now know that is not the case. It is estimated that five-25 percent of people who use prescription pain pills over the long-term become addicted to these medications.⁶ As such, special consideration should be given when this class of painkillers is prescribed, and doctors should be prepared and trained to spot signs of addiction and intervene early.

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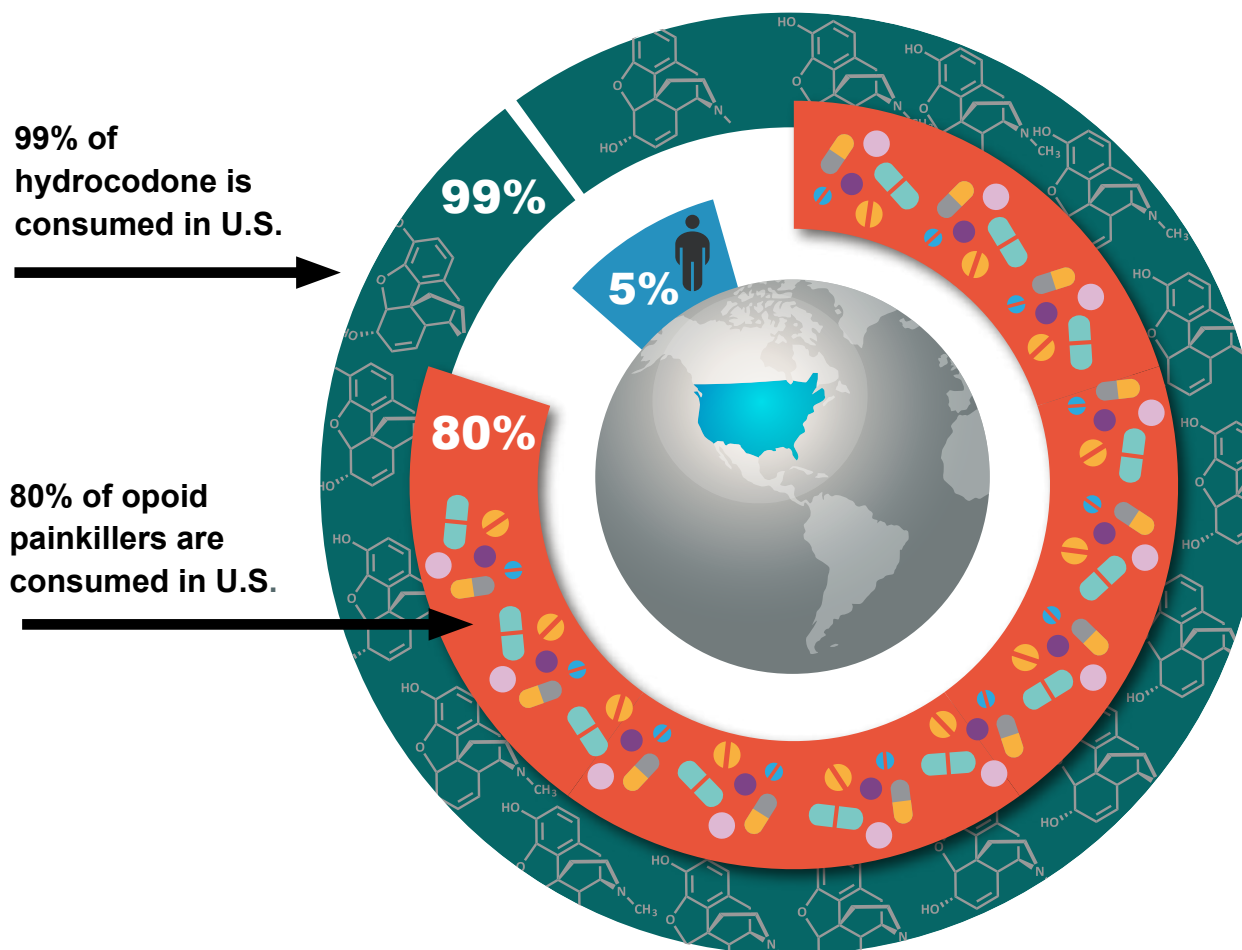
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U.S. CONSUMPTION OF OPIOID PAINKILLERS

Although the U.S. comprises less than 5 percent of the world's population, it consumes 80% of the global opioid painkillers and 99% of the global supply of hydrocodone, the active ingredient in Vicodin.

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The over-prescription of pain pills for acute medical events often leads to medicine cabinets full of unused pain medications, providing easy access to teens and others for misuse and abuse of these drugs. In fact, it is estimated that 69 percent of people who abused prescription pain killers obtained the drugs from a family member or friend.⁷ Unfortunately, in some instances once an individual is addicted to prescription opioids, they may be driven to use illicit substances that have similar neurological effects, most notably heroin. According to a report released last year by SAMHSA, four out of five heroin users started abusing prescription drugs first.⁸

From a pharmacological perspective, there are few differences between prescription opioid pain relievers and heroin. One of the similar properties of opioid drugs is their tendency, when used over long periods of time, to increase tolerance, necessitating a higher dose to achieve the same effect and breeding dependency.⁹ The need to overcome this tolerance, combined with the much cheaper street value of heroin, may drive a shift from prescription drug dependency to heroin abuse. The abuse of heroin, which is typically injected intravenously, is also linked to the transmission of human immunodeficiency virus (HIV), hepatitis (especially Hepatitis C), sexually-transmitted infections, and other blood-borne diseases. In terms of mortality from overdoses, deaths related to prescription opioids began rising in the early part of the 21st century. By 2002, death certificates listed opioid painkiller poisoning as a cause of death more commonly than heroin or cocaine.¹⁰

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The current opioid overdose crisis has been primarily driven by the health care system. Shifting attitudes among patients and health care providers regarding the liberal use of pain medication and a subsequent increase in the number of prescriptions for opioid pain pills for acute purposes, as well as the dose and quantity of each prescription, are all contributing factors. However, in addressing the multi-faceted problem of prescription opioid and heroin abuse in this country, we must consider the role played by prescription pain pills in healing and reducing human suffering. It is estimated that more than 100 million people suffer from chronic pain in this country. For some of them, opioid therapy may be appropriate.¹¹ Unfortunately, opioid painkillers are not the panacea for chronic pain, but a lack of good alternatives for pain management



results in chronic prescriptions for these medications, even when it is not appropriate or necessary. Nonetheless, in addressing this problem, it is important to achieve a balanced approach to ensure that people suffering from chronic pain can get the relief they need while minimizing the negative consequences associated with the misuse and abuse of this class of drugs.

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I. Increasing education and awareness among patients, health care providers and the general public

Education must be the foundation of any effective plan to combat the opioid epidemic. Without effective education, health care providers, patients, parents, young people, and law enforcement will be unaware of the potential to misuse, abuse or become addicted to prescription drugs, the signs and symptoms of addiction, the availability of evidence-based treatment for addiction, the ease with which lifesaving measures for overdose can be administered, and the proper way to dispose of unused or unwanted drugs.

Although great strides have been made in raising general awareness of the dangers of illegal drugs, there remains a misconception that the misuse or abuse of prescription drugs is safer than improper use of other substances because they are approved and distributed legally through the health care system. This misconception may lead youth, in particular, to believe it is safe to use prescription painkillers recreationally. The nuanced message that these drugs are safe and effective when used properly, but also harmful and addictive can be difficult to effectively convey. This is why targeted educational and prevention campaigns are so needed.

In addition to the education of the general public, refocusing the education of our health care providers, as it relates to pain and addiction, could go a long way in helping stem the tide of opioid overdoses. In particular, the medical

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community should discuss and develop evidence-based best practices regarding pain and pain relief, including the recognition of addiction and to communicate those clearly to their patients. Perspectives on pain have shifted markedly over the past fifty years. A generation ago, fears of addiction predominated. Many doctors were reluctant to prescribe pain medications — particularly narcotics — and patients were reluctant to take them, even when they were prescribed. In the 1980s and 1990s, in part in response to the development and marketing of new pain medications, and in part in response to evidence that patients whose pain was controlled healed more quickly and that chronic pain was truly debilitating, attitudes toward pain shifted. Medical professionals were taught that pain was, and most definitely should be, treated, and if a patient had legitimate pain, he or she could not become addicted to their pain pills. Patients were prescribed pain medications in unprecedented quantities and were instructed to “stay ahead of the pain,” and as a result, they were conditioned to expect a pain free life.

The pendulum has swung yet again, and today there is recognition, though not fully disseminated, that addiction and pain management are inextricably connected. Even when prescribed and taken appropriately, opioid pain pills can lead to dependency and addiction in some people. Nevertheless, pain is one of the most common reasons for patients to seek medical attention and yet very little time is dedicated to education on pain in medical schools. On average, U.S. medical schools provide approximately seven hours of education on pain,

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compared to 75 hours for veterinarians and 14 hours in Canadian medical schools.¹² As a result, many U.S. doctors are being asked to treat pain, but are not sufficiently trained in how to identify, screen, and manage pain, nor may they be familiar with the alternative clinical tools that are available to treat pain without opioid drugs.

Furthermore, when it comes to substance use disorders, many health care providers are unaware of how to recognize signs of abuse or dependency or what do to when confronted with a patient who has a substance use disorder. If a physician encounters a patient who is thought to be “doctor shopping” in an attempt to secure prescriptions drugs for abuse, a doctor may appropriately turn that patient away and refuse that patient a prescription. However, this action misses a critical opportunity for intervention for a person with a substance use disorder. A survey from 2000 found that less than 20 percent of primary care physicians considered themselves very prepared to identify alcohol or drug dependence, compared to more than 80 percent feeling comfortable diagnosing hypertension and diabetes.^{13,14} Although significant attention has been brought to the issue of education on substance use disorders in the last decade, there is still much to be done in developing and preparing all health care professionals with clinically relevant training experiences in the diagnosis, prevention and treatment of opioid dependency.

POLICY RECOMMENDATIONS:

- The Drug-Free Communities Support Program (DFC) is a federal grant program that provides funding to community-based coalitions that organize to prevent youth substance use. The program has supported nearly 2,000 coalitions and currently mobilizes nearly 9,000 community volunteers across the country. Data has shown that where DFC dollars are invested, youth substance use is lower. The 2014 President's budget contained a \$6.3 million cut to the DFC program and the Senate appropriations committee has funded the DFC program at \$92 million, level funding from FY2013. To build on effective infrastructure of the Drug-Free Communities Support Program the federal government should enhance funding to the DFC program to allow current and prior community coalition grantees with established infrastructure to apply for supplemental funds to address prevention of their community's prescription drug epidemic in a comprehensive community wide fashion.
- Congress should appropriate funds to be used by Substance Abuse and Mental Health Services Administration (SAMHSA) to award cooperative agreement funds to states and nonprofit entities for the purpose of conducting consumer education about opioid abuse, including the dangers of prescription opioids, how to prevent abuse,

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how to dispose safely of prescription medications, how to recognize the signs of misuse and addiction, and how to access treatment, including information on the full continuum of treatment options for a person with a diagnosed substance use disorder. Priority for these grants should be given to localities with a high incidence of opioid abuse.

- While public education campaigns, school-based programs, and other educational initiatives all have merit, they may or may not reach all of those who are prescribed opioids. Federal partners, including the Office of National Drug Control Policy (ONDCP), Drug Enforcement Administration (DEA), and Health and Human Services (HHS) should work with pharmacies and manufacturers to develop effective educational materials for patients that address the appropriate use of prescription drugs, the risks and signs of addiction and abuse, seeking treatment for addiction, the importance of secure storage, and the need for safe disposal of unwanted or unused pills. This material should be distributed with every prescription dispensed of an opioid. Work should also be done with pharmacies, including Walgreens, CVS, Rite Aid, Walmart, Target, and Costco to distribute the materials whenever they dispense opioids.
- Congress should amend the law to require as a condition of new

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or renewed DEA registration to prescribe controlled substances (i.e. opioid pain relievers) the completion of three hours of continuing education. The continuing education module should, at a minimum, address the best practices for pain management, responsible prescribing of pain medications, recognition of the signs of addiction, treatment of opioid addiction and resources for linking a patient to evidence based treatment. A module that covers this requirement should be developed by SAMHSA and offered online for free as an option for all providers and allied professionals.

- To help train the next generation of providers, legislation should be enacted that directs funds towards creating “Centers of Excellence” for addiction in medical schools and medical training centers. The funds would be competitively awarded to programs that have a multidisciplinary team that serves as the expert board in addiction in the state and provides technical assistance and outreach to community health centers. The program would be responsible for training medical fellows in addiction medicine who can help to improve early intervention and linkage to addiction specialty services in primary care and emergency departments. The multidisciplinary team should include both physicians and allied professionals who are specialists in addiction medicine, chronic pain care, internal medicine, pediatrics, and obstetrics and gynecology and will work to develop real clinical protocols and solutions for educating, screening, identifying, early intervention and treatment of substance use disorders.

Prevention, continued

II. Research and development of new pain treatments and tamper-proof medications

An important initiative in reducing the misuse and abuse of prescription opioids is researching and developing alternative approaches to treating pain. This includes research to identify new pharmacological compounds with reduced abuse, tolerance, and dependence risk, as well as devising alternative delivery systems and formulations for existing drugs that minimize diversion, abuse and risk of overdose. Abuse-deterrent formulations target the known or expected routes of abuse, such as crushing to snort or dissolving to inject. The science of abuse deterrence is relatively new, and both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. Nonetheless, there are FDA-approved opioid medications that are in abuse-deterrent formulations on the market, including the recently approved combination of oxycodone and naloxone, which when crushed blocks any euphoric properties of the oxycodone.

Some progress has been made in developing non-opioid based medications for severe pain that do not produce the same tolerance and dependence as opioid medications. However, the success of these treatments for chronic pain is still being assessed. Further research into the non-medication strategies for the treatment of pain, particularly chronic pain, is needed.

POLICY RECOMMENDATIONS:

- The Centers for Medicare and Medicaid Services (CMS) should prioritize coverage determinations for any Food and Drug Administration (FDA)-approved non-narcotic treatment for pain management, so that the patients can access these alternatives without concern about cost reimbursement.
- The federal government should increase funding to the National Institute on Drug Abuse (NIDA) geared toward broad research and development of alternatives to deal with pain, including both medication and non-medication based treatments. This research should be undertaken in collaboration with the Food and Drug Administration (FDA), to help these developments get to market rapidly.
- CMS should encourage and allow FDA-approved tamper proof formulations of opioid pain pills to be substituted by a pharmacist for equivalent medications when available under the prescription drug benefits of Medicare and Medicaid.
- Congress should give FDA the authority to more rapidly approve opioid drug formulations that are abuse-deterrent and ensure that any generic drugs that are seeking approval based on a prior approval of an abuse deterrent drug are also resistant to abuse.

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- Representatives William Keating (D-Mass.) and Hal Rodgers (R-Ky.) introduced a bill in February 2013 called the Stop Tampering of Prescription Pills Act that amends the law governing FDA to incentivize pharmaceutical manufacturers to produce tamper resistant drugs. The bill requires generics that are based on a drug that uses a tamper-resistant formulation to also be comparably resistant to tampering; requires FDA to deny any new drug applications for opioids that are not abuse deterrent, unless the active ingredient is not available on the market in an abuse deterrent formulation; and requires that any generics be removed from the market, if the brand drug it was approved based on has been subsequently introduced in an abuse deterrent formulation.

III. Tracking and monitoring opioid prescriptions

Prescription Drug Monitoring Programs (PDMPs) are a critical component of opioid abuse prevention. A PDMP is a statewide electronic database of prescriptions dispensed by pharmacies for controlled substances. Information collected by a PDMP usually includes the patient name and date of birth, the prescriber's name and the type of prescription, including dosage and quantity. This information can be used to help support the legitimate medical use of controlled substances, identify or prevent drug abuse or diversion, facilitate the detection of patients who may have an addiction problem, and inform and educate public health agencies and health professionals about the use, abuse and diversion of prescription drugs.

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PDMPs are organized and administered by individual states, and each state designates a regulatory, administrative or law enforcement agency to administer its PDMP. Nearly two-thirds are administered by state pharmacy boards, professional licensing agencies or health departments.¹⁵ The remainder are run by law enforcement agencies. The administering agency allows access to or distributes information from the database to individuals who are authorized under state law to receive the information for purposes of their profession.

As of December 2013, 49 states including Guam had operational PDMPs.¹⁶ While PDMPs can be effective, they vary greatly from state to state. In some states, a physician, pharmacist or law enforcement official can request information from the PDMP; in others, reports are automatically generated by the PDMP and distributed to authorized persons.¹⁷ Twenty-two states have laws requiring a prescriber to consult a PDMP before issuing a prescription, however, only five states require pharmacist to consult the PDMP before dispensing a prescription.¹⁸ In most states, information contained in the PDMP is gathered weekly, in a few states the information is entered daily or in real-time.¹⁹

One of the main hurdles to the successful deployment of PDMPs is interoperability, the ability of information gathered in a particular state's PDMP to be shared easily with another state. The ability to be interoperable is important for both law enforcement and health care providers. For example, if a doctor moves a practice from Florida to Massachusetts, it would be helpful for

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law enforcement in Massachusetts to be able to access information from the Florida PDMP, if that physician is suspected of operating a “pill mill.” Likewise, if a patient who lives in Massachusetts goes to an emergency room in New Hampshire complaining of severe pain and requesting prescription opioids, it would be advantageous for the physician in New Hampshire to determine from the Massachusetts PDMP if this patient is a frequent “doctor shopper.” Unfortunately, as of January 2014, only 28 states were engaged in interstate data sharing with at least one other state, but none of the PDMPs are interoperable with all of the states.²⁰

The Department of Justice has helped foster interoperability through the use of prescription monitoring information exchange (PMIX) architecture.²¹ The PMIX program is intended to enable the interstate exchange of PDMP information, providing information on an individual’s prescription drug history across states participating in the information exchange. To facilitate information security and data privacy, data are encrypted while passing through “hubs,” and no data are actually stored on these hubs. PMIX allows for hubs to exist at the state and national levels, and it allows for hub-to-hub information exchange.

Because PDMPs are administered by the states, federal prescribers, such as an Indian Health Services physician or federal dispensers, such as a Veterans Administration (VA) pharmacy, do not consistently utilize or fully participate in PDMPs.²² For example, the VA announced in March 2014 that it has begun

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developing and testing software to transmit prescription information to state PDMPs, but its regulations do not require VA physicians to query state PDMPs before prescribing opioid pain relievers. This is unfortunate in light of the frequent use of opioid painkillers by veterans as well as the high overdose rate among this population. Prescription drug abuse among military personnel has been on the steady rise. In 2008, 11 percent of service members reported misusing prescription drugs, up from two percent in 2002 and four percent in 2005.

The federal government has established two grant programs aimed at supporting state PDMPs: the Harold Rogers PDMP grant, administered by the Department of Justice, and the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) grant program, administered by the Department of Health and Human Services (HHS). The Harold Rogers PDMP received \$7 million in appropriations for FY2014; NASPER last received appropriations of \$2 million in FY2010. At its peak, in FY2006, federal funding for PDMPs reached \$22.5 million.²⁵

POLICY RECOMMENDATIONS:

- Congress should reauthorize NASPER and more generously fund both it and the Harold Rogers PDMP grants. As a condition of these grants the states must mandate its use by providers and pharmacists, share data between law enforcement and public health officials, engage with other states on improving functional

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interoperability and encourage the input and update of real time data. The federal government should also increase funding for more robust technical assistance to states wishing to improve functionality of their prescription monitoring programs.

- In June 2014, Senators Kelly Ayotte (R-N.H.) and Joe Donnelly (D-Ind.) introduced “The Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act (S. 2504) which, among other things provides for reauthorization of both NASPER and the Harold Rogers PDMP grants.
- Senator Tom Udall (D-N.M.) introduced the Increasing Safety of Prescription Drug Use Act of 2013 (S. 1657) and Senator Jeanne Shaheen (D-N.H.) and Representative Ed Whitfield (R-Ky.) introduced the NASPER Reauthorization Act. (S. 2529/H.R. 3528). These measures all mandate interoperability as a condition of states receiving grants for the maintenance or improvement of PDMPs and reauthorize appropriations for NASPER.

- The Department of Veterans Affairs (VA) and the Department of Defense (DOD) should



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immediately begin sharing patient information with state PDMPs and provide controlled substance prescription information electronically to the PDMPs in states in which they operate health care facilities or pharmacies.

- Congress should require DOD, VA, and the Indian Health Services to issue rules requiring their prescribers to check PDMPs for patient controlled substance prescription histories before generating prescriptions for controlled substances.
- Congress should require that IHS and any other federally-funded health care programs to provide controlled substance prescription information to state PDMPs in states where they operate health care facilities or pharmacies.

IV. Reducing mixed messages related to pain management expectations

Under the Patient Protection and Affordable Care Act (ACA), the Centers for Medicare and Medicaid Services (CMS) is required to link the results of patient satisfaction surveys to incentive payments for Medicare.²⁶ Under CMS's "value-based purchasing plan", Medicare began withholding one percent of its payments to hospitals in October 2012.²⁷ That money — \$850 million in the first year — will go into a pool to be doled out as bonuses to hospitals that score above average on several measures. One of those measures is the hospital's

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score on patient satisfaction surveys, and 3 of the 25 questions related to care on the survey request information as to how well the hospital relieved the patient's pain. The primary focus of these questions related to pain is the effective use of drugs to manage pain perception. In fact, one question asks "how often the hospital staff did everything they could" to help you with your pain.²⁸

Physicians who exercise their judgment and decide to limit or not to prescribe opioid pain pills to certain patients may pay the price in the form of a poor rating on these surveys. Consequently, some physicians may feel pressure to prescribe opioids in order to meet satisfaction metrics by which their practices are judged. Furthermore, the inclusion and wording of these questions reinforces patient expectations and demands for pain killers to totally ameliorate their pain. It becomes difficult to shift expectations about pain management and addiction through education, if physicians and patients are receiving mixed messages through these surveys and ultimately through payments.

POLICY RECOMMENDATIONS:

- CMS should immediately conduct a review to determine whether the questions in the hospital patient satisfaction surveys are influencing patient and physician behavior related to the provision of prescription opioids. Based on the result of its review, CMS should determine how these questions could be reworded, reduced or eliminated to relive any unintended contribution to the abuse of prescription opioids.

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V. Encouraging proper disposal of unused/excess prescription opioids

The failure to provide safe and easily accessible means for disposing of unused prescription opioids is unquestionably fueling the opioid abuse epidemic. SAMHSA's 2012 National Survey on Drug Use and Health found that approximately 69 percent of people who used prescription pain relievers non-medically got them from friends or relatives, while approximately five percent got them from a drug dealer or from the Internet.²⁹ The scale of the problem is vast, with more than 25 million Americans initiating the non-medical use of a prescription medication over the ten year period from 2002 through 2011.³⁰ Therefore, a comprehensive plan to address prescription drug abuse must include proper disposal of unused, unneeded, or expired medications. Providing individuals with a secure and convenient way to dispose of medications will help prevent diversion and abuse, and help to reduce the introduction of drugs into the environment.

On October 12, 2010 the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted (Pub. L. 111-273, 124 Stat. 2858). Before passage of The Disposal Act, people who wanted to dispose of unused, unwanted, or expired controlled substance pharmaceuticals had few legal options. The Controlled Substances Act (CSA) only permits ultimate users to destroy those substances themselves, by throwing them in the garbage or flushing them

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down the toilet (two methods that are neither recommended nor safe), or give them to law enforcement. These restrictions have resulted in the accumulation of controlled substances in household medicine cabinets that are available for abuse, misuse, and accidental ingestion. The Disposal Act amended the CSA to authorize ultimate users to deliver their controlled substances to another person for the purpose of disposal as long as they followed rules that would be ultimately developed and published by the DEA.

On September 8, 2014, four years after the Disposal Act was enacted, the DEA published final regulations in the Federal Register that will take effect on October 9, 2104. The proposed regulations expand the entities to which unused, unwanted, or expired controlled substances may be given for the purpose of disposal, as well as the methods by which controlled substances may be collected. For consumers, the rule proposes three voluntary options: (A) take-back events, (B) mail-back programs, and (C) collection receptacles.

A. Drug take-back events

Drug take-back events have proven successful. On April 26, 2014 the last DEA-sponsored national take-back day, 780,158 pounds (390 tons) of prescription medications were collected from members of the public at more than 6,000 locations.³¹ DEA has another take-back day scheduled for September 27, 2014, but in light of the new regulations, DEA has decided this will be the last national

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take-back day. DEA's rules, proposed in September 2014, would make additional drug take-back events relatively easy to organize and operate. Events can be conducted by a federal, state, tribal, or local law enforcement agency or by an organization or individual who partners with a law enforcement agency. In addition, a law enforcement officer must be appointed by the agency to maintain control and custody of the drugs from the time the substances are collected until the secure transfer, storage, or destruction of the controlled substance has occurred.

B. Mail-back programs

DEA's proposed mail-back program could be successful. It allows individuals who have surplus controlled substances to mail them to an authorized disposal entity in a special tamper-proof envelope. Although the program has promise, its success will depend on funding to develop the packaging envelope, distribute it widely and pay for postage, as well as recruiting "destruction sites" to which the envelopes can be mailed. Ideally, every time a prescription for a controlled substance is filled by a pharmacy or provided to a patient by a doctor, dentist or other health care professional, the patient would be handed the return envelope with instructions for how to mail any unused opioids back for disposal. The program would obviously need funding and the cooperation of pharmacies to succeed.

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C. Collection receptacles

Under DEA's proposal, law enforcement agencies, any registered manufacturer or distributor or retail pharmacy will be allowed to maintain a collection receptacle at their DEA-registered locations in certain circumstances. The proposed rules, however, are so strict that it seems unlikely that many will be installed. The collection receptacles must have a permanent outer container and a removable inner liner that must be waterproof, tamper-evident and tear-resistant. The outer container must be securely fastened to a permanent structure, such as a wall, floor or removable countertop. Finally, in order to be allowed to install a receptacle, a retail pharmacy or other entity must agree to destroy the sealed inner liner and the contents on-site in a manner prescribed by DEA, deliver the inner liners and their contents to an authorized third-party for destruction or request assistance from the DEA. Presumably, both the first and second method will cost money that will be the responsibility of the entity housing the collection receptacle. To succeed, the program will require the development of receptacles that satisfy DEA's requirements and funding for receptacles and the disposal of the inner liners and their contents.

POLICY RECOMMENDATIONS:

- DEA should encourage local law enforcement agencies to regularly schedule drug take-back events in their communities as soon as the federal rules are in effect.

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- The Department of Justice should provide grant money and technical assistance to states and local communities in developing drug take-back programs . To be eligible for the grant money, the take-back programs must cover a sufficient service area to assist consumers with unused, unwanted, or expired prescription opioids to dispose of them safely. These programs also should have educational outreach components on how to identify and seek help in treating a substance use disorder.
- DEA should immediately convene local law enforcement, retail pharmacies, pharmaceutical companies and others in both the public and private sectors to ensure that the new rules meet the urgent need for safe and effective disposal.
- DEA should work with the U.S. Postal Service, pharmacy associations and others to develop and widely distribute postage-paid tamper proof envelopes and collection receptacles for surplus controlled substances. The funding should come from existing DEA appropriations.

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Breaking the cycle of addiction lies with the ability to appropriately care and treat those with substance use disorders. Simply eliminating an individual's substance of choice or incarcerating an individual to restrict access to a substance does not eliminate the underlying disease of addiction. However, even with levels of opioid abuse and dependence that have reached epidemic proportions, treatment in the U.S. is limited, highly stigmatized and under-resourced, resulting in an inability of many individuals to access the care that is needed. According to data collected by SAMHSA, approximately 65,000 people in Massachusetts are dependent on opioids, 50,000 of whom need treatment but are not currently receiving it.³² In the United States, the National Institute on Drug Abuse (NIDA) estimates that as of 2012, 2.1 million Americans suffered from substance use disorders related to prescription opioid pain relievers in and an estimated 467,000 were addicted to heroin.³³

Like other chronic diseases, addiction can be managed successfully. Access to evidence-based treatment services can help those with substance use disorders achieve recovery and reduce the social burdens and harms associated with illicit drug use. However, the segmented and highly restrictive treatment settings for patients with opioid dependence reinforce the stigma many people associate with treatment for substance abuse and help perpetuate the misconception that opioid dependence is a willful choice and not a long-term chronic medical disorder. As the U.S. health care system shifts to one that promotes the use

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of multidisciplinary teams to address an individual's health care needs, it is important that addiction medicine be fully integrated into the general health care setting and patients be made aware of the full continuum of evidence-based treatment and care options that are available.

Improving access to opioid dependence treatment

Opioid addiction is a chronic disease that, untreated, places a large burden on the health care system. Roughly 475,000 emergency room visits each year are attributable to the misuse and abuse of opioid painkillers.³⁴ Effective therapy for opioid addiction, combined with social and behavioral supports, can decrease overdose deaths, be cost-effective, reduce transmissions of HIV and viral hepatitis, and reduce other social harms such as crime.

Many persons with substance use disorders do not seek services from addiction specialists, but may access primary care for a broad array of services. Especially in areas of high need, community health centers are one of the primary locations where patients with substance use disorders gain access to medical care. However, as indicated in assessments by the National Association of Community Health Centers (NACHC) in 2010 and 2011, sufficient screening for addiction and linkage to ongoing treatment in community health center settings has been challenging. For example, only 15 percent of Federally Qualified Health Centers (FQHCs) provide medically-assisted therapy for opioid abuse.³⁵

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Medication Assisted Therapy (MAT), also known as pharmacotherapy, is the use of FDA- approved medications, in combination with counseling and behavioral therapies, to provide a whole patient approach to the treatment of opioid addiction. Research shows that when treating substance use disorders, a combination of medication and behavioral therapies is most successful. A recent report issued by the New England Comparative Effectiveness Public Advisory Council (CEPAC), a core program of the Institute for Clinical and Economic Review (ICER), also found that the use of MAT is cost effective, concluding, conservatively, that every dollar spent on maintenance treatment in New England would result in \$1.80 in savings.³⁶ According to the Director of the National Institutes of Drug Abuse, these medications can improve lives and reduce the risk of overdose, yet they are markedly underutilized.

Since 2007, the Massachusetts Department of Public Health (DPH) has partnered with the Boston Medical Center to integrate office-base opioid treatment into community health centers. Specifically, DPH has funded 14 community health centers, including eleven FQHCs to employ registered nurse care managers and medical assistants to assist primary care physicians in providing buprenorphine using a “Best Practice” model that combines the use of medication with behavioral health counseling and random drug screening and monitoring. Boston Medical Center also receives funds to provide technical assistance to the programs at these community health centers. To date, more than 7,200 clients have been served through these programs. Federal supports for

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such strategies could expand this successful model throughout the country, improving the capacity of the health care and addiction treatment systems and allowing more patients, especially those who are underserved and high-risk, including pregnant women, to receive treatment in their neighborhood with their primary care or OB/GYN physician. Furthermore, by emphasizing the treatment of substance use disorders using a team based approach that focuses on treatment adherence, coordinated access to recovery, systematic health, counseling and case management would provide a more holistic approach to health care for individuals with substance use disorders that mirrors the modern high quality primary care provided for other chronic health conditions. Ultimately, decisions regarding the course of treatment for an individual's unique health care needs should be made in consultation with a patient's clinician and after discussion the full range of treatment options and comprehensive services that are available.

I. Increasing evidence based treatment in areas of need

Federally qualified health centers (FQHCs) receive enhanced reimbursement from Medicare and Medicaid, as well as other benefits, including certain grant funding. In order to qualify to be designated a FQHC, a health center must serve an underserved area or population, offer a sliding fee scale, provide comprehensive services, have an ongoing quality assurance program, and have a governing board of directors. Community health centers can also be

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designated as FQHC-look alike. These centers also provide primary health care services to low-income, underserved, and special populations, are eligible for certain federal grants and may receive special Medicare and Medicaid reimbursement.

Unfortunately, the Health Resources and Services Administration (HRSA), the federal agency responsible for administering the FQHC programs, does not track coverage for specific substance abuse services (separate from general mental health services) at these centers, which can be a limiting factor in determining the communities that are still in need of improved access to addiction services.

POLICY RECOMMENDATIONS:

- To improve data collection and better support and expand access to treatment, HRSA should immediately begin determining which FQHCs and FQHC look-alike facilities are offering substance abuse services, whether these services are offered directly at the health center or if they are managed through an ancillary community provider, whether these services include the option of medication assisted therapies, and what the geographical coverage is for these services in every state.

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- Going forward, to be qualified for the FQHC program, any newly designated FQHC or FQHC look-alike must be able to offer screening for opioid dependency and if unable to provide direct services within the health center, have a program in place to formally link patients to evidence-based treatment with a qualified medical professional.
- To increase treatment capacity and improve the ability of FQHCs to provide outpatient treatment for opioid dependency according to best practices, HRSA should provide specific grant funding to help health centers implement innovative programs that provide comprehensive addiction care services of MAT combined with behavioral therapy. This grant program should focus on improving timely entry, access to and retention into quality treatment for addiction particularly for geographical regions where there is unmet need for such services. Furthermore, as a part of this program funds should be provided to larger medical institutions that can serve as regional hubs of technical assistance to the community health centers.
- In order to support the provision of high quality patient care, HRSA should require FQHCs to report measures of how many individuals are screened for opioid addiction and are provided clinical services for treatment. Furthermore, HRSA should set targets for what these measurements should be.

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II. Increasing capacity and willingness of health providers to serve more patients with addiction

Unfortunately, of the approximately 2.5 million Americans who abused or were dependent on prescription opioids or heroin in 2012, fewer than one million received medication-assisted therapy for their condition.³⁹ That's because access to effective medicines to help treat opioid addiction in outpatient and primary care settings remains limited in part due to current federal restrictions. In order to address the epidemic of opioid overdoses, we need to expand the ability of trained medical professionals to provide effective and evidence based treatments, including medication-assisted therapies.

There are only three FDA-approved medications for opioid dependency: methadone, buprenorphine and naltrexone. Methadone has been used in the treatment of opioid dependency for almost 50 years; however, federal law restricts the dispensing of methadone to federal- and state-approved opioid maintenance programs also known as methadone clinics. As a result, buprenorphine is the most commonly used of the pharmacological interventions by office-based physicians and has been used in the treatment of opioid dependency for over ten years. Buprenorphine, works by “sticking” to the opioid receptors in the brain, suppressing withdrawal symptoms and cravings for opioids and does not cause euphoria in the opioid-dependent patient due to a “ceiling effect” that limits its efficacy at high doses. Currently, federal

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law prohibits physicians from treating more than 100 patients at a given time. Naltrexone, first approved for alcohol dependency, also works to block opioids from acting on the brain. It has been approved as a once a month intramuscular injection, but is only recommended to be used once patient has undergone full detoxification. There are no federal limitations on the clinical use of naltrexone for treatment. All medication assisted therapies are most successful when combined with behavioral therapy and counseling. Given the severity of this public health emergency, a renewed focus should be placed on developing alternative treatments that can to treat substance use disorders.

The Drug Abuse Treatment Act (DATA) of 2000 established the basis to provide buprenorphine-assisted treatment in regular outpatient clinic settings. For many patients, this is a less stigmatizing environment than a stand-alone treatment clinic. It does not require daily visits for dispensing, and so it can be easier for some patients to stay in treatment while better maintaining their work and family responsibilities. Under current law, in order for physicians to be authorized to prescribe certain opioid addiction medicines, they must meet specific conditions and apply for a special waiver. Even with such a waiver, physicians are severely limited in the number of patients they can treat (no more than 100 at a given time), contributing to long waitlists and the inability of patients to get treatment for their addiction when they need it. Additionally, allied professionals, such as nurse practitioners and physician's assistants, even if they are allowed by state licensing to prescribe controlled substances for pain, are currently

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ineligible to prescribe buprenorphine for addiction treatment, which can severely limit access to this treatment in rural areas where allied professionals are the main source of primary care. Furthermore, restrictions in the area of addiction medicine that are disproportionate to regulations in all other fields of medicine can serve to reinforce stigma and prevent the provision of high quality, responsive treatment.

POLICY RECOMMENDATIONS:

- **Broaden the scope of federal law to allow certain qualified physicians to treat more patients with medication assisted therapies and expand the ability of allied professionals to assist in treatment where qualified by state law.**
 - Senator Markey along with several Senate colleagues, introduced legislation in July 2014 called The Recovery Enhancement for Addiction Treatment Act (TREAT Act, S. 2645). This bill would allow nurse practitioners and physician assistants to treat patients with opioid addiction therapies provided they are trained in opioid addiction treatment, are supervised by a physician who is approved to prescribe for the treatment of opioid dependency, and are allowed by state law to prescribe controlled substances. The legislation also allows physicians to treat an unlimited number of patients, provided they are certified as addiction treatment specialists or are appropriately trained and practicing in a clinical setting that has defined oversight, performance metrics, or quality review.

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Congress should create a grant program that can be administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) to assist with the dissemination of evidence based models for treating opioid dependence and to help assist providers in understanding the full menu and continuum of treatment options for opioid dependency as well as the appropriate criteria to use when determining the best course of treatment for a patient.

There are currently only three approved treatments for opioid addiction. FDA should prioritize and actively engage with the National Institute on Drug Abuse and the private sector to rapidly develop clinical tools that can be used in the treatment of addiction and in reducing the harms associated with addiction. FDA should also prioritize developing clear standards for approval of treatments that can reduce the harms associated with drug use.

III. Reducing health insurance coverage barriers to treatment and intervention in all treatment settings

The 2008 Parity and Addiction Equity Act does not require private plans or Medicaid managed care to cover addiction services, but if they do, it requires that financial requirements (such as co-pays, deductibles) and treatment limitations (such as visit limits) applicable to substance use disorder benefits be no more restrictive than the predominant requirements or limitations applied to other medical/surgical benefits. The Patient Protection and Affordable Care Act

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(ACA) of 2010 went a step further, mandating behavioral health and substance abuse services as part of the essential health services for qualified health plans, meaning that plans sold on the health care exchanges must include coverage. However, neither of these federal laws applies to TRICARE, traditional Medicaid (fee-for service) or Medicare.⁴⁰

Despite these federal parity laws, private insurers can implement benefits management, pre-approval and re-approval approaches that may interfere with patients gaining immediate access to treatment. For example, reports have captured instances in which a patient was denied coverage determined appropriate by their provider because it was not considered to meet “criteria for medical necessity” or in some cases patients will be required to try and fail a treatment option, before being covered for the preferred treatment.⁴¹ Additionally in instances where a patient is on long-term medication assisted treatment, a provider may be required to “re-authorize” continued treatment every six months, a burden that is not required for medication management of other chronic diseases, like diabetes. Because substance use disorder is a chronic disease that often involves multiple relapses, insurance barriers to covering evidence-based treatment, can be a significant barrier to gaining treatment where and when a patient needs it.

A new law enacted in Massachusetts requires all insurance companies to provide a minimum of 14 days of inpatient treatment coverage and also removes

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prior authorization for early intervention services for substance use disorder treatment, outpatient services including medication assisted therapies, and other inpatient and outpatient intensive services. Further reducing payment burdens associated with long-term treatment of addiction will help clinicians and patients make the best treatment choices without being influenced by insurance coverage.

POLICY RECOMMENDATIONS:

- TRICARE provides civilian health benefits for military personnel, military retirees, and their dependents, but is currently exempt from the parity laws for substance abuse treatment. Congress should expand the parity laws so that patients being treated in the TRICARE system are eligible for robust inpatient and outpatient treatment, including medically assisted therapies, for addiction. A review of this expansion and how treatment is being expanded should be performed by the Defense Health Agency.
- The Centers for Medicare and Medicaid Services (CMS) should convene an expert panel for the medical treatment of opioid addiction to determine whether the current reimbursement rates for inpatient and outpatient treatment are sufficient. The results from this expert panel should be formally provided to Congress.

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- CMS should, with the assistance of an expert panel, determine best practices for pharmacy benefits management of medications used in the treatment of substance use disorders, including the need for standardized and non-burdensome authorizations. Insurance companies should be encouraged to adopt these uniform management practices that will help a patient and their clinician design a treatment plan that meets patient's unique and individualized needs — regardless of coverage.
- State Medicaid plans should be required to give all individuals with diagnosed opioid dependency the choice and opportunity to receive care in the setting of the patient's choice. All plans should have a rational package of comprehensive treatment care options, including access to pharmacotherapy, drug testing, counseling or other behavioral interventions, and physician visits.
- Currently there exists a federal prohibition on certain inpatient mental health facilities to get Medicaid reimbursement for services if the facility has more than 16 residential beds (known as Institutions of Mental Disease (IMD)). The policy dates back to 1965 and was put in place to discourage the warehousing of individuals with severe mental illness. Because of this prohibition certain residential facilities with more than 16 beds that specialize in treatment of

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addiction would also be excluded from Medicaid reimbursement. The Centers for Medicaid and Medicare services should implement a pilot program that allows certain facilities that specialize in providing a full continuum of evidence based addiction treatment services to access federal matching funds for such services.

IV. Improving care for vulnerable populations-pregnant women and youth

Opioid use in pregnancy is not uncommon, and the use of illicit opioids during pregnancy is associated with an increased risk of adverse outcomes for the child. Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise. Neonatal abstinence syndrome (NAS) is the term used to refer to the withdrawal syndrome of infants. It is an expected condition that follows prenatal exposure to opioid agonists. A study on the national incidence of NAS indicated that between 2000 and 2009 the number of newborns with NAS increased nearly threefold.⁴² With the increased widespread use of opioids, it is expected that the trend of increased NAS will continue. Babies going through opioid withdrawal



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typically have lengthy hospital stays to manage symptoms that include seizures, dehydration, breathing problems, tremors, difficulty feeding and irritability. According to the American College of Obstetricians and Gynecologists, the current standard of care for pregnant women with opioid dependency includes treatment with methadone.⁴³

Special considerations are needed for women who are opioid dependent to ensure appropriate pain management, manage addiction throughout pregnancy, prevent postpartum relapse and a risk of overdose, and provide adequate contraception to prevent unintended pregnancies. Similarly, special considerations are needed in the treatment of infants with NAS and youth, under the age of 18, with substance use disorders. There remain many unanswered questions regarding best practices on evaluation, identification, treatment and management of infants with NAS and children with opioid dependency. A coordinated research effort is needed to better inform best practices to address vulnerable populations, including pregnant women, infants and youth.

POLICY RECOMMENDATIONS:

- The Secretary of Health and Human Services should convene an expert panel of providers, including those with expertise in addiction medicine and in the care pregnant women, infants and children to develop best practice guidelines for the diagnosis and treatment of NAS.

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- The Secretary of Health and Human Services should also identify barriers to the identification and treatment of pregnant mothers with opioid dependency and areas where additional research is needed on addressing the care needs of pregnant women and girls with substance use disorders.
- The Centers for Disease Control and Prevention should provide technical assistance to the States to improve the availability and quality of data collection and surveillance regarding neonatal abstinence syndrome and opioid dependency in youth.
 - Senator Mitch McConnell (R-Ky.) and Representative Katherine Clark (D-Mass.) have filed independent legislative efforts (the Protecting our Infants Act and CRIB Act, respectively) that specifically require the development of best practices for the diagnosis and treatment of NAS. Both bills also recognize the need for better surveillance data on NAS collected by the states. Improved surveillance on the magnitude of the problem will help state and federal resources specific to NAS be directed to regions where the need is greatest.
 - Neither of the bills specifically addresses the growing incidence of opioid dependence among youth (under the age of 18). Developing best practice guidelines for the screening, intervention and treatment of adolescent populations with opioid dependency, taking into consideration the special mental, physical, and social needs of children is critical.

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V. Reducing deaths associated with opioid overdoses

Overdoses from opioids have increased dramatically in the United States. Deaths from drug overdoses have tripled among men and increased fivefold among women between 1999 and 2010.⁴⁵ Approximately 38,000 people die each year from drug overdoses, or more than 100 per day.⁴⁶ Nationwide, drug overdoses now claim more lives than motor vehicle accidents.⁴⁷ Furthermore, opioid overdoses, once almost always due to heroin use, are now increasingly due to abuse of prescription painkillers.⁴⁸

A key driver of the overdose epidemic is the presence of an underlying substance use disorder. Consequently, one of the key strategies in reducing opioid overdose deaths is expanding access to addiction treatment services, particularly MAT, which have proven to be safe and effective in helping patients recover and reducing the risk of overdose. Another FDA approved prescription drug that can be used in a rescue situation to prevent death from overdose is called naloxone. As a pure opioid antagonist, naloxone counters the effects of opioids including the respiratory depression, sedation and hypotension that can lead to death following opioid misuse or abuse. Naloxone is regularly carried by medical first responders, such as EMT, and is listed on the World Health Organization's List of Essential Medicines.

However, because opioid overdose often occurs when the victim is with friends or family members, these people may be the best situated to act in a timely

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manner to save the life of a victim by administering naloxone. Despite the ease of administration of this drug, many state practice laws discourage or prohibit the prescription of drugs to anyone other than the intended recipient. Furthermore, some prescribers are wary of prescribing naloxone because of liability concerns and bystanders may be afraid to administer it for fear of civil or criminal repercussions. Recently, the FDA approved an automatic injector of this opioid overdose antidote that is specifically tested and intended for use by caregivers, family members or coworkers.

Several states, including Massachusetts, have established programs that train and equip potential non-medical bystanders, such as friends and family members, to recognize and reverse overdose events using first aid techniques and emergency supplies of naloxone. In Massachusetts alone, the program has reversed more than 2,300 overdoses and reduced overdose death in the approximate 15 communities where the programs are located. Several states including Massachusetts have also passed laws that make it easier for medical professionals to prescribe and dispense naloxone and for lay administrators to use it without fear of legal repercussions.⁵⁰

POLICY RECOMMENDATIONS:

- To prevent the fear of liability of getting in the way of saving lives and expanding naloxone distribution, federal law should provide immunity from civil liability for health care professionals who

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prescribe naloxone, for individuals who work for or volunteer at state or local programs that distribute this treatment, and to anyone who administers the treatment to a person who has overdosed.

- Senator Markey has introduced legislation, the Opioid Overdose Reduction Act (S. 2092) that extends civil liability protections to those who distribute and administer naloxone in an overdose situation. Additionally, by insisting that immunity from liability is tied to education about overdose prevention and treatment, the Opioid Overdose Reduction Act ensures that first responders, community volunteers, and loved ones know how to identify someone who has overdosed, how to safely administer naloxone, and how to secure follow-up care and treatment.
- To support community and state based efforts to increase the availability of naloxone, the federal government should provide funding for the dissemination of overdose prevention and management education, including naloxone distribution to potential bystanders.
- Senator Jack Reed (D-R.I.), in conjunction with Senators Markey, Dick Durbin (D-Ill.), Sheldon Whitehouse (D-R.I.) and Patrick Leahy (D-Vt.), has introduced the Senate companion (The Overdose

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Prevention Act) to House legislation (the S.O.S. Act) introduced by Representative Donna Edwards (D-Md.) to expand federal monetary support for state, community and local run naloxone education and distribution programs. Program-based resources include trainings on how to recognize the signs of an overdose, seek emergency medical help, and administer naloxone and other first aid. The Senate Overdose Prevention Act also provides federal funding for the purchase and distribution of naloxone by community and government stakeholders to people at risk of experiencing or witnessing an overdose. In addition, the Overdose Prevention Act implements measures that would enhance public awareness of overdose risk and enhance overdose surveillance and federal research capabilities.

- As existing naloxone programs scale up and new communities adopt measures to expand distribution of naloxone, the FDA should closely monitor supply and demand for this drug and be prepared to address any indications of a drug shortage as needed within the limits of their authority.
- SAMHSA, in coordination with other relevant federal agencies, should create and disseminate training and toolkit materials on overdose prevention tailored to specific settings and populations, including chronic pain management, addiction treatment facilities and emergency departments. In developing such materials, the

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agencies should discuss the value in developing best practice guidelines for the prescription of naloxone in conjunction with opioid painkillers.

- To improve data collection associated with overdoses, the CDC should issue guidelines to states on the surveillance data that should be routinely and systematically collected on overdoses, including those overdoses that did not result in death. Information collected should include the drug formulation used at the time of the overdose, the dosage level, the age and sex of the individual, whether the individual was in an opioid treatment program and the nature of the program, and discharge plans for patients that were saved from death by overdose with naloxone or any other opioid overdose reversal drug.

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Law enforcement plays a dual role in the opioid addiction crisis. On one hand, the Drug Enforcement Administration (DEA), together with other federal, state and local law enforcement must shut down pill mills, detect and deter diversion of prescription drugs, and stem the supply of heroin into our communities. On the other hand, law enforcement leaders at every level recognize that we cannot arrest and incarcerate our way out of this crisis, even while we contend with thousands of inmates already in jails and prisons who need treatment for their substance use disorder.

A multi-pronged approach is necessary. First, law enforcement must have the tools it needs to keep opioids off our streets. Prescription Drug Monitoring Programs (PDMPs) allow law enforcement to investigate and prosecute operators of pill mills. (See [page 10](#) for a description of PDMPs). Diversion — the development of illegal markets for legitimate drugs — can also be addressed through PDMPs. According to the National Drug Threat Assessment, the most commonly diverted controlled prescription drugs are opioid pain relievers, including codeine, fentanyl, oxycodone, hydrocodone and methadone.⁵¹ It is important to note that virtually all of the illegal methadone sold on the street is diverted from methadone prescribed for pain relief, not methadone prescribed for treatment of addiction.⁵² In addition, it appears that law enforcement rarely encounters illicit methadone and that the number of methadone seizures nationwide is declining.⁵³ Buprenorphine seizures, too, have been decreasing⁵⁴,

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and these diverted drugs are most likely from addiction treatment.⁵⁵ Moreover, using diverted buprenorphine is more common where treatment programs are scarce. In one study, persons using diverted buprenorphine were seven times more likely to report being unable to access a treatment program.⁵⁶ This suggests that increasing access to treatment may reduce diversion of this drug. Nonetheless, continued monitoring of buprenorphine diversion is necessary to maintain integrity of treatment programs and determine what steps, if any, are needed to further reduce diversion.

The second role for law enforcement is equally important. An astonishing 85 percent of prisoners in the United States either have a prior or present substance use disorder or committed a crime that was related to their substance use.⁵⁷ Thus, one of the most important tasks law enforcement has is caring for this population. Persons who enter the criminal justice system with substance use disorder must be provided with effective treatment to help reduce rates of recidivism. Traditionally, treatment has occurred either through drug courts or through prison treatment programs. Both approaches need to be expanded — both with respect to the number of persons they reach and with respect to their treatment modalities, so that all evidence-based practices that have proven effective are utilized, including pharmacotherapy. In addition, particularly with respect to incarcerated inmates, re-entry programs must be strengthened so that when inmates return to their communities, they have a better chance of succeeding. That requires that programs be in place before an inmate is discharged and that funding for those programs is available.

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I. Strengthening drug courts

By the end of 2013, there were more than 2,900 drug courts operating throughout the United States, with more than half targeting adult offenders.⁵⁸ Drug courts have been effective across several measurable metrics, but many have been resistant to utilizing the full range of evidence-based practices available to them. Specifically, drug courts generally have not utilized medication-assisted therapy (MAT) as one of the most cost-effective and efficient evidence based methods of treatment for substance use disorders.

*[A]lmost half of substance abuse treatment professionals don't "believe" in the use of medications (American Association for Treatment of Opioid Dependence, 2012) despite the evidence to the contrary, and for several decades, drug court judges have faced strong resistance from some treatment professionals, probation officers, and other team members in use of medications to augment traditional substance abuse treatment.'*⁵⁹

Indeed, many drug courts specifically preclude the use of any medication in the treatment of addiction. Yet, as treatment experts recognize:

"Medication-Assisted Treatment (MAT)...has demonstrated excellent outcomes among offenders, including drug court participants...These medications are helpful to reduce cravings, to block the reinforcing effects of alcohol and opioids, and to assist in the withdrawal management

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process...Drug court participants should be allowed the opportunity to benefit from medications proved effective the same as any individual who is not supervised by the criminal justice system.”⁶⁰

POLICY RECOMMENDATIONS:

- In order to ensure that drug courts are as effective as they can possibly be and that offenders have access to all evidence-based treatments that are appropriate for their individual recovery, the Department of Justice (DOJ) should condition funding under the Drug Court Discretionary Grant Program or any other program that provides drug court funding on the provision of all evidence-based treatment options, including medication-assisted treatment programs (MAT). DOJ should monitor implementation to insure drug court participants have meaningful access to medication-assisted treatment once program changes are implemented.
- Overcoming traditional drug court resistance to MAT may prove challenging. DOJ should require all drug courts that receive federal funding to have all defendants who are addicted to opioids, including heroin or prescription drugs, evaluated by a medical professional (physician, nurse practitioner or physician assistant) to determine whether MAT is an appropriate treatment option, and if so, to offer it to the defendant.

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- Congress and DOJ should increase federal grant assistance to drug courts to compensate for the increased cost of MAT. Drug courts receiving federal assistance should be required to report to DOJ on the relative effectiveness of different treatments for opioid addiction, including medication -assisted treatment programs.

II. Improving drug treatment in state and federal jails and prisons

An estimated 10-15 percent of the total state and federal prison population, approximately 200,000 people, are estimated to currently or historically have struggled with opioid dependence or abuse.⁶¹ Although most correctional professionals recognize the need to provide substance abuse treatment in custody, the provision of MAT in prisons and jails and effective connection to medication-assisted therapies upon re-entry is rare. A recent survey of fifty states, the District of Columbia and the Federal Bureau of Prisons' medical directors found that 28 states (55 percent) offer methadone in some situations, although typically only to pregnant women and for the management of chronic pain. Seven (14 percent) offer buprenorphine to some inmates; 23 (45 percent) refer to methadone programs upon release, and 15 (25 percent) refer to buprenorphine providers upon release.⁶³ These numbers make plain that prison officials are ignoring the documented benefits of MAT and the demonstrated social and economic benefits of expanding medication-assisted therapies to inmates and providing MAT upon re-entry into communities.

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The Federal Bureau of Prisons (BOP) should be the model for substance abuse treatment, but both the quality and quantity of addiction services in BOP facilities need to be improved. BOP Clinical Guidelines allow methadone to be used only to ease symptoms of withdrawal, and state bluntly with respect to buprenorphine, “this medication is not routinely used” in the BOP. Indeed, if a person comes into federal custody on buprenorphine or methadone, they typically would not be able to continue on either form of these therapies. This policy persists despite evidence that some inmates have died as a result of withdrawal from MAT while in custody⁶⁴ and some believe the policy violates the Americans with Disabilities Act⁶⁵ by not recognizing substance abuse as a chronic disease that needs maintenance.

In addition, although more than half of opioid-addicted prisoners relapse within a month of their discharge and face disproportionately high risks of infectious diseases, such as HIV and Hepatitis C, only 23 states offer referrals to treatment programs that offer evidence based treatment with medication for prisoners upon release.⁶⁶

POLICY RECOMMENDATIONS:

- Congress should increase funding to the Bureau of Prisons (BOP) to provide appropriate and comprehensive drug treatment programs, including MAT, for persons in federal custody. BOP should study the use of MAT in its facilities to determine whether, among other things,

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MAT helps reduce recidivism and to determine whether outcomes for prisoners using MAT differ from those who do not.

- To ensure state, tribal and local jails and prisons provide comprehensive drug treatment, DOJ should condition grant funding to state, tribal, and local prison and jail substance abuse programs, such as Residential Substance Abuse Treatment (RSAT) for State Prisoners Program (42 U.S.C. § 3796ff), on the provision of comprehensive drug treatment, including MAT. DOJ should also mandate the study of MAT in comparison to other treatment programs.
- DOJ should study the effectiveness of pilot projects in Massachusetts, New York, Maryland, Pennsylvania, and California that provide injectable naltrexone to inmates prior to release from custody or in drug court. If warranted based on the results of the effectiveness of these pilots, additional funds should be provided to expand the use of injectable naltrexone and other medication assisted therapies.
- Congress should provide additional funding for federal, state, tribal and local re-entry programs that provide seamless transitions from custody to treatment in the community, including treatment programs that provide MAT. Before inmates are discharged, prison officials should identify and refer inmates to appropriate community programs.

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- Senator Leahy together with Representative James Sensenbrenner (R-Wisc.) have introduced the Second Chance Reauthorization Act of 2013 (S.1690/R.R. 3465) which provides for expanded re-entry programs for state and federal offenders, including continued treatment for substance use disorder in the community.

III. Ensuring medical coverage upon re-entry

When people return to the community after incarceration, their health care needs are great, but their ability to access coverage is typically poor. Research demonstrates that in the first few weeks after release from custody, individuals are particularly vulnerable.⁶⁷ Lack of health insurance is compounded by rates of mental illness, substance use disorders, infectious disease and disorders, and chronic health conditions that are substantially higher than rates in the general population.

Critically, when an individual returns to the community after incarceration, disruptions in the continuity of medical care have been shown to increase rates of re-incarceration and lead to poorer and more costly health outcomes.⁶⁸ For people with a substance use disorder, re-entry often means a return to drug use. With health insurance, inmates discharged to the community can access treatment programs that may offer proven therapies for addiction. They would also be able to access health care and services to address other medical conditions, including mental illness that may exacerbate their substance use disorder.

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Some inmates enter custody with Medicaid coverage, but routinely, states terminate their inmates' Medicaid coverage. The result is that upon discharge, individuals need to reapply for Medicaid in order to access services — a process that may take as long as 45 to 90 days.⁶⁹ It doesn't have to be this way. Indeed, CMS has encouraged states to suspend rather than terminate Medicaid coverage for persons in custody.⁷⁰ Unfortunately, only 12 states have taken that advice.⁷¹ The result is an insurance coverage gap for persons re-entering the community that likely results in increased morbidity, mortality, drug use and recidivism. As Massachusetts Middlesex County Sheriff Peter J. Koutoujian observed: "When you talk about controlling costs, providing better health care, and reducing recidivism, this is a winner on every level."⁷²

Implementation of the Affordable Care Act (ACA), particularly in states that opt to expand Medicaid, will result in many more inmates being eligible for Medicaid. That, coupled with high federal reimbursement rates for states that expand Medicaid to cover newly eligible adults (100 percent through 2016, 95 percent through 2019, and 90 percent thereafter), make suspension an even more attractive option for states.⁷³

POLICY RECOMMENDATIONS:

- Congress should prohibit states from terminating an inmate's Medicaid coverage. Instead, states should be required to suspend

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coverage and deem the time the inmate is incarcerated as stayed for purposes of annual reauthorization.

- CMS should encourage local, state and tribal jails and prisons to enroll eligible inmates in Medicaid and then suspend their coverage.
- CMS should encourage states to allow community substance use disorder treatment providers to provide services, including MAT, in prisons and jails, particularly just prior to discharge. Those providers can then continue ongoing care once the inmate is released. CMS should consider allowing selected states, on a pilot basis, to bill Medicaid for those pre-release services.

APPENDIX A

Federal Policy Recommendations Section-by-Section

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PREVENTION

I. Increasing education and awareness among patients, health care providers and the general public

- To build on effective infrastructure of the Drug-Free Communities Support Program the federal government should enhance funding to the DFC program to allow current and prior community coalition grantees with established infrastructure to apply for supplemental funds to address prevention of their community's prescription drug epidemic in a comprehensive community wide fashion.
- Congress should appropriate funds to be used by SAMHSA to award cooperative agreement funds to states and nonprofit entities for the purpose of conducting consumer education about opioid abuse, including the dangers of prescription opioids, how to prevent abuse, how to dispose safely of prescription medications, how to recognize the signs of misuse and addiction, and how to access treatment, including information on the full continuum of treatment options for a person with a diagnosed substance use disorder. Priority for these grants should be given to localities with a high incidence of opioid abuse.
- Federal partners, including the Office of National Drug Control Policy (ONDCP), Drug Enforcement Administration (DEA), and Health and Human Services (HHS) should work with pharmacies and manufacturers to develop effective educational materials for patients that address the appropriate use of prescription drugs, the risks and signs of addiction and abuse, seeking treatment for addiction, the importance of secure storage, and the need for safe disposal of unwanted or unused pills.
- Congress should amend the law to require as a condition of new or renewed DEA registration to prescribe controlled substances (i.e. opioid pain relievers) the completion of three hours of continuing education.

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- To help train the next generation of providers, legislation should be enacted that directs funds towards creating “Centers of Excellence” for addiction in medical schools and medical training centers.

II. Research and development of new pain treatments and tamper-proof medications

- The Centers for Medicare and Medicaid Services (CMS) should prioritize coverage determinations for any FDA-approved non-narcotic treatment for pain management, so that the patients can access these alternatives without concern about cost reimbursement.
- The federal government should increase funding to the National Institute on Drug Abuse (NIDA) geared toward broad research and development of alternatives to deal with pain, including both medication and non-medication based treatments.
- CMS should encourage and allow FDA-approved tamper proof formulations of opioid pain pills to be substituted by a pharmacist for equivalent medications when available under the prescription drug benefits of Medicare and Medicaid.
- Congress should give FDA the authority to more rapidly approve opioid drug formulations that are abuse-deterrent and ensure that any generic drugs that are seeking approval based on a prior approval of an abuse deterrent drug are also resistant to abuse.

III. Tracking and monitoring opioid prescriptions

- Congress should reauthorize NASPER and more generously fund both it and the Harold Rogers PDMP grants.
- The Department of Veterans Affairs (VA) and the Department of Defense (DOD) should immediately begin sharing patient information with state PDMPs and provide controlled substance prescription information electronically to the PDMPs in states in which they operate health care facilities or pharmacies.
- Congress should require DOD, VA, and the Indian Health Services to issue rules requiring their prescribers to check PDMPs for patient controlled substance prescription histories before generating prescriptions for controlled substances.

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- Congress should require that IHS and any other federally-funded health care programs to provide controlled substance prescription information to state PDMPs in states where they operate health care facilities or pharmacies.

IV. Reducing mixed messages related to pain management expectations

- CMS should immediately conduct a review to determine whether the questions in the hospital patient satisfaction surveys are influencing patient and physician behavior related to the provision of prescription opioids.

V. Encouraging proper disposal of unused/excess prescription opioids

- DEA should encourage local law enforcement agencies to regularly schedule drug take-back events in their communities as soon as the federal rules are in effect.
- The Department of Justice should provide grant money and technical assistance to states and local communities in developing drug take-back programs.
- DEA should immediately convene local law enforcement, retail pharmacies, pharmaceutical companies and others in both the public and private sectors to ensure that the new rules meet the urgent need for safe and effective disposal.
- DEA should work with the U.S. Postal Service, pharmacy associations and others to develop and widely distribute postage-paid tamper proof envelopes and collection receptacles for surplus controlled substances.

TREATMENT

I. Increasing evidence based treatment in areas of need

- To improve data collection and better support and expand access to treatment, Health resources and Services Administration (HRSA) should immediately begin determining which Federally Qualified Health Centers (FQHCs) and FQHC look-alike facilities are offering substance abuse services, whether these services are offered directly at the health center or if they are managed through an ancillary community provider, whether

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these services include the option of medication assisted therapies, and what the geographical coverage is for these services in every state.

- Going forward, to be qualified for the FQHC program, any newly designated FQHC or FQHC look-alike must be able to offer screening for opioid dependency and if unable to provide direct services within the health center, have a program in place to formally link patients to evidence-based treatment with a qualified medical professional.
- To increase treatment capacity and improve the ability of FQHCs to provide outpatient treatment for opioid dependency according to best practices, HRSA should provide specific grant funding to help health centers implement innovative programs that provide comprehensive addiction care services of MAT combined with behavioral therapy.
- In order to support the provision of high quality patient care, HRSA should require FQHCs to report measures of how many individuals are screened for opioid addiction and are provided clinical services for treatment.

II. Increasing capacity and willingness of health providers to serve more patients with addiction

- Broaden the scope of federal law to allow certain qualified physicians to treat more patients with medication assisted therapies and expand the ability of allied professionals to assist in treatment where qualified by state law.
- Congress should create a grant program that can be administered by SAMHSA to assist with the dissemination of evidence based models for treating opioid dependence and to help assist providers in understanding the full menu and continuum of treatment options for opioid dependency as well as the appropriate criteria to use when determining the best course of treatment for a patient.
- There are currently only three approved treatments for opioid addiction. FDA should prioritize and actively engage with the National Institute on Drug Abuse and the private sector to rapidly develop clinical tools that can be used in the treatment of addiction and in reducing the harms associated with addiction.

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III. Reducing health insurance coverage barriers to treatment and intervention in all treatment settings

- Congress should expand the parity laws so that patients being treated in the TRICARE system are eligible for robust inpatient and outpatient treatment, including medically assisted therapies, for addiction.
- The Centers for Medicare and Medicaid Services (CMS) should convene an expert panel for the medical treatment of opioid addiction to determine whether the current reimbursement rates for inpatient and outpatient treatment are sufficient.
- CMS should, with the assistance of an expert panel, determine best practices for pharmacy benefits management of medications used in the treatment of substance use disorders, including the need for standardized and non-burdensome authorizations.
- State Medicaid plans should be required to give all individuals with diagnosed opioid dependency the choice and opportunity to receive care in the setting of the patient's choice.
- The Centers for Medicaid and Medicare services should implement a pilot program that allows certain facilities that specialize in providing a full continuum of evidence based addiction treatment services to access federal matching funds for such services.

IV. Improving care for vulnerable populations-pregnant women and youth

- The Secretary of Health and Human Services should convene an expert panel of providers, including those with expertise in addiction medicine and in the care pregnant women, infants and children to develop best practice guidelines for the diagnosis and treatment of neonatal abstinence syndrome (NAS).
- The Secretary of Health and Human Services should also identify barriers to the identification and treatment of pregnant mothers with opioid dependency and areas where additional research is needed on addressing the care needs of pregnant women and girls with substance use disorders.

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- The Centers for Disease Control and Prevention should provide technical assistance to the States to improve the availability and quality of data collection and surveillance regarding neonatal abstinence syndrome and opioid dependency in youth.

V. Reducing deaths associated with opioid overdoses

- To prevent the fear of liability of getting in the way of saving lives and expanding naloxone distribution, federal law should provide immunity from civil liability for health care professionals who prescribe naloxone, for individuals who work for or volunteer at state or local programs that distribute this treatment, and to anyone who administers the treatment to a person who has overdosed.
- To support community and state based efforts to increase the availability of naloxone, the federal government should provide funding for the dissemination of overdose prevention and management education, including naloxone distribution to potential bystanders
- As existing naloxone programs scale up and new communities adopt measures to expand distribution of naloxone, the FDA should closely monitor supply and demand for this drug and be prepared to address any indications of a drug shortage as needed within the limits of their authority.
- SAMHSA, in coordination with other relevant federal agencies, should create and disseminate training and toolkit materials on overdose prevention tailored to specific settings and populations, including chronic pain management, addiction treatment facilities and emergency departments. In developing such materials, the agencies should discuss the value in developing best practice guidelines for the prescription of naloxone in conjunction with opioid painkillers.
- To improve data collection associated with overdoses, the CDC should issue guidelines to states on the surveillance data that should be routinely and systematically collected on overdoses, including those overdoses that did not result in death.

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ENFORCEMENT

I. Strengthening drug courts

- In order to ensure that drug courts are as effective as they can possibly be and that offenders have access to all evidence-based treatments that are appropriate for their individual recovery, the Department of Justice should condition funding under the Drug Court Discretionary Grant Program or any other program that provides drug court funding on the provision of all evidence-based treatment options, including medication-assisted treatment programs (MAT).
- The Department of Justice should require all drug courts that receive federal funding to have all defendants who are addicted to opioids, including heroin or prescription drugs, evaluated by a medical professional (physician, nurse practitioner or physician assistant) to determine whether MAT is an appropriate treatment option, and if so, to offer it to the defendant.
- Congress and DOJ should increase federal grant assistance to drug courts to compensate for the increased cost of MAT. Drug courts receiving federal assistance should be required to report to DOJ on the relative effectiveness of different treatments for opioid addiction, including medication -assisted treatment programs.

II. Improving drug treatment in state and federal jails and prisons

- Congress should increase funding to the Bureau of Prisons to provide appropriate and comprehensive drug treatment programs, including MAT, for persons in federal custody.
- To ensure state, tribal and local jails and prisons provide comprehensive drug treatment, DOJ should condition grant funding to state, tribal, and local prison and jail substance abuse programs, such as Residential Substance Abuse Treatment (RSAT) for State Prisoners Program (42 U.S.C. § 3796ff), on the provision of comprehensive drug treatment, including MAT. DOJ should also mandate the study of MAT in comparison to other treatment programs.

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- DOJ should study the effectiveness of pilot projects in Massachusetts, New York, Maryland, Pennsylvania, and California that provide injectable naltrexone to inmates prior to release from custody or in drug court.
- Congress should provide additional funding for federal, state, tribal and local re-entry programs that provide seamless transitions from custody to treatment in the community, including treatment programs that provide MAT.

III. Ensuring medical coverage upon re-entry

- Congress should prohibit states from terminating an inmate's Medicaid coverage. Instead, states should be required to suspend coverage and deem the time the inmate is incarcerated as stayed for purposes of annual reauthorization.
- CMS should encourage local, state and tribal jails and prisons to enroll eligible inmates in Medicaid and then suspend their coverage.
- CMS should encourage states to allow community substance use disorder treatment providers to provide services, including MAT, in prisons and jails, particularly just prior to discharge.

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Footnotes

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- 1 CDC VitalSigns: Opioid Painkiller Prescribing-Where you Live Makes a Difference, July 2014
- 2 CDC. Vital Signs: Overdoses of Prescription Opioid Pain Relievers-United States, 1999-2008. MMWR 2011; 60: 1-6
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- 9 Dr. Nora Volkow, Director, National Institute on Drug Abuse Testimony before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, April 29, 2014
- 10 Paulozzi et al. Increasing deaths from opioid analgesics in the United States Pharmacoepidemiology and Drug Safety, 2006; 15 pp. 618–627
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- 13 The National Center on Substance Abuse at Columbia University. Missed opportunity: national survey of primary care physicians and patients on substance abuse. National Center on Substance Abuse at Columbia University; New York: 2000
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- 23 Id.
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- 25 Congressional Research Service, Prescription Drug Monitoring Programs. March 24, 2014. See: <http://fas.org/sgp/crs/misc/R42593.pdf>.
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- 41 Heroin addicts face barriers to treatment, Associated Press. April 7, 2014 See: <http://www.foxnews.com/health/2014/04/07/heroin-addicts-face-barriers-to-treatment/>
- 42 <http://jama.jamanetwork.com/article.aspx?articleid=1151530>
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- 45 CDC Morbidity and Mortality Weekly Report July 5, 2013 Vital Signs: Overdoses of Prescription Opioid Pain Relievers and Other Drugs Among Women — United States, 1999–2010
- 46 CDC Press Release: Opioids drive continued increase in drug overdose deaths. February 20, 2013. Total drug overdose numbers: 38,329 in 2010; 60 percent of these related to prescription drugs including opioid pain medications.
- 47 CDC: Drug Overdose in the United States: Fact Sheet. See: <http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html> or Centers for Disease Control and Prevention. Wide-ranging OnLine Data for Epidemiologic Research (WONDER) [online]. (2012) Available from URL: <http://wonder.cdc.gov/mortsql.html>.
- 48 *Unintentional Drug Poisoning in the United States*, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, July 2010.
- 49 <http://www.nejm.org/doi/full/10.1056/NEJMp1402780>
- 50 The Network for Public Health Law. Legal interventions to reduce overdose mortality: naloxone access and overdose good Samaritan laws. Updated November 2013
- 51 U.S. Department of Justice, Drug Enforcement Administration. National Drug Threat Assessment 2013
- 52 Partnership for Drug-Free Kids, *Don't Blame Clinics for Methadone ODs*, SAMSHA Says. April 10, 2007. Available at <http://www.drugfree.org/join-together/dont-blame-clinics-for-methadone-ods-samhsa-says/>
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- 55 JBS International, Inc. Center for Health Services & Outcomes Research, Bonnie B. Wilford, Diversion and Abuse of Buprenorphine: A Brief Assessment of Emerging Indicators. Results of the Vermont Case Study. November 30, 2006 at 5. See also Yokell, Michael A, Zaller, Nickolas D., Green, Traci C., and Rich, Josiah D., *Buprenorphine and Buprenorphine/Naloxone Diversion, Misuse, and Illicit Use: An International Review*. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3154701/>. It's important to note that Suboxone has a better safety profile than either methadone or narcotic pain medications. It has a "ceiling effect" that limits the

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additional effect people get beyond a certain dose, and is co-formulated with Narcan, helping prevent abuse. Visits to emergency rooms for drug poisoning or overdose have been increasing dramatically, with 34 percent of visits due to prescriptions drugs, yet Suboxone comprises only 0.6 percent of those visits. http://buprenorphine.samhsa.gov/FOR_FINAL_summaryreport_colorized.pdf

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when the incarcerated individual is admitted as an inpatient in a hospital, nursing facility, juvenile psychiatric facility, or intermediate care facility for at least 24 hours. Because community-based inpatient care can represent a sizeable portion of the cost of care provided to individuals in prisons and jails, there is the potential for considerable cost savings to a state that is able to effectively use Medicaid funding to finance some of these services. For example, North Carolina has reported that it saved \$10 million in the first year of billing Medicaid for eligible inpatient services, while California saved about \$31 million by doing so in FY 2013. See *Medicaid and Financing Health Care for Individuals Involved with the Criminal Justice System*, Justice Center, The Council of State Governments, July 2013.