National Heroin Task Force Final Report and Recommendations

America's opioid epidemic demands a comprehensive, collective response. As directed by Congress, the Department of Justice (DOJ) and the White House Office of National Drug Control Policy (ONDCP) convened the National Heroin Task Force in March 2015 to develop strategies to confront the heroin problem and curtail the escalating overdose epidemic and death rates. The Task Force developed this report outlining the steps the Administration is taking to address the opioid problem through a multifaceted approach of robust criminal enforcement, prevention efforts, and increased access to substance use disorder treatment and recovery services. These efforts must be enhanced and broadened, marshalling all of society - from local communities, the medical community, and public health organizations to Federal, state, local, and tribal law enforcement agencies - to successfully address this crisis. Everyone has a role to play and the recommendations contained in this report will complement and support the work already underway across the Federal government including the Obama Administration's October 2015 announcement regarding public and private efforts to address prescription opioid misuse and heroin use and the Department of Health and Human Services (HHS) Opioid Initiative launched in March 2015, to name just a few.¹

The Task Force was co-chaired by DOJ and the ONDCP. The diligent work of public health, public safety, and legal professionals representing more than 25 Federal agencies is incorporated in this report.²

In short, we find that:

- there are solutions and there is hope for mitigating this public health crisis, that is devastating families in communities across our Nation;
- effective solutions require law enforcement and public health officials to work closely together;
- substance use disorders are brain diseases that can be successfully treated;
- preventing inappropriate use of prescription opioids, initial use of heroin, and injection drug use must be prioritized;
- education and intervention at all levels are essential, including activities to prevent drug-related harms, especially overdose prevention tools;
- appropriate treatment options must be readily available, affordable, and easily accessible, and
- millions of Americans are in recovery from heroin and other opioid use disorders; their progress should be highlighted to encourage others to enter treatment.

We respectfully submit this report.

David J. Hickton United States Attorney

Western District of Pennsylvania

Mary Lou Leary

Deputy Director, Office of State, Local and Tribal Affairs Office of National Drug Control Policy

¹ See Appendix II and III to this report.

² We gratefully acknowledge the leadership provided by the committee chairpersons: Dr. Melinda Campopiano, Jason Cunningham, Frances Harding, and the Honorable Rod Rosenstein and the participation by members of the National Heroin Task Force. See Appendix I to this report.

Contents

Mission Statement	4
Executive Summary	4
The Crisis	5
Finding 1: Public safety and public health strategies in response to opioids must be integrated a complementary	
1.1 Recommendation: Prevent opioid misuse and abuse by ensuring safe and appropriate prescribi	ng6
a. Require practitioners (such as physicians, dentists, and others authorized to prescribe) wh request DEA registration to prescribe controlled substances to be trained on responsible of prescribing practices as a precondition of registration	pioid
b. States should consider adopting or recommending uniform prescribing guidelines	7
c. Patients should be informed and empowered so they can actively participate in their pain management and make informed decisions	7
d. Consistently and proactively enforce safe prescribing practices	8
1.2 Recommendation: Integrate data management, reporting, and analysis	9
a. Support interstate interoperability and use of Prescription Drug Monitoring Programs	9
b. Disrupt supply and focus prevention, treatment, and intervention resources through coordinate real-time sharing of accurate data	
1.3 Recommendation: Reduce the excessive supply of opioids through strategic enforcement mechanisms with assistance from community partnerships	11
a. Prioritize prosecution of medical professionals who improperly prescribe opioids	11
b. Prioritize prosecutions of heroin distributors, especially when the drug causes death, and enhance investigation and prosecution techniques for targeting the drug supply chain	12
c. Encourage and promote safe drug disposal	12
1.4 Recommendation: Enlist pharmaceutical companies to address the harms associated with prescription opioids	13
1.5 Recommendation: Look to examples of promising robust public health-public safety partnersh inform development of effective strategies.	_
1.6 Recommendation: Prevent overdose deaths through the effective use of naloxone, real-time communication, and Good Samaritan laws	15
a. Ensure access to naloxone	15
b. Provide immediate and comprehensive care to those administered naloxone	16
c. Consider state limited liability laws to shield those who administer naloxone and Good Samaritan laws for witnesses seeking medical help	16
d. Develop public safety and public health real-time rapid response strategies for overdose e	
Finding 2: Policies regarding opioid and heroin use must be grounded in scientific understand that substance use disorders are a chronic brain disease that can be prevented and treated, lead to recovery	ding
2.1 Recommendation: Provide linkages to services at the first sign of an opioid use disorder	
a. Apply a continuum of care approach to the problem of opioid use disorder	
b. Implement Screening, Assessment, and Linkage to Treatment	
2.2 Recommendation: Make effective treatment for opioid use disorder, including medication assitteeatment, readily available and as accessible as other chronic disease treatments	isted
a. Make evidence-based medication assisted treatment readily available	
b. Incorporate treatment for opioid use disorder, including medication assisted treatment, int	to the
2.3 Recommendation: Support the availability of long-term treatment and recovery services	20

Finding 3: Visible community-based recovery supports must be available, affordab	•
3.1 Recommendation: Implement coordinated community responses to promote prevelevel	
3.2 Recommendation: Improve opioid training and expertise of public and private hea	•
a. Ensure greater availability of substance use disorder and recovery support spetthroughout the country	
b. Improve training and expertise of all health care professionals on treatment of substance use disorder	
3.3 Recommendation: Take steps to mitigate public health and public safety conseque drug use at the local level	-
Conclusion	23
Appendix I	24
Appendix II	25
Appendix III	32

Mission Statement

The National Heroin Task Force was charged³ with developing a comprehensive response to the nation's opioid crisis.⁴ Comprising a broad array of experts in public safety and public health, the Task Force developed a set of recommendations that incorporates essential components of prevention, education, treatment, recovery, investigation, and prosecution. This report is intended to provide a framework for national, regional, state, tribal, and local efforts to both restrict heroin supply and reduce heroin use and its consequences.

Executive Summary

The United States is in the grip of a national crisis - an unprecedented surge in the illicit use of prescription opioid medications and heroin.⁵ In 2014, 1.9 million people had a prescription opioid use disorder and nearly 600,000 had a heroin use disorder.⁶ The national data on overdose deaths are startling: in 2014, there were more than 27,000 overdose deaths involving prescription opioid medications and/or heroin.⁷ That is equivalent to an average of one death every 20 minutes.

The opioid epidemic affects a broad cross-section of the United States population without regard to age, gender, race, ethnicity, or economic status. Living in a rural, suburban, or urban jurisdiction does not insulate an individual from the ravages of the opioid epidemic. Traditional law enforcement methods are a critical component of any counter-illicit drug strategy, but they will not resolve this crisis alone. The opioid crisis is also fundamentally a public health problem. While law enforcement agencies will continue to prosecute drug traffickers, "pill mill" operators, and those responsible for the increased supply of opioid drugs for non-medical purposes, for long-term success, Federal, state, local, and tribal partners must forge strong public health and public safety partnerships to stop the flow of opioids into communities, prevent initiation of non-medical opioid use, and support access to treatment and recovery services. We must all work together – law enforcement, public health, youth, parents, faith-based organizations, government agencies, health and medical professionals, educational institutions, social service providers, and the private sector – to meet this challenge.

The National Heroin Task Force plenary panel met four times between April and September 2015 and, consistent with its mission, focused exclusively on addressing the domestic dimensions of the opioid epidemic and proposing domestic solutions to the crisis. Four subcommittees were formed to address the most critical areas of concern: 1) Education and Community Awareness; 2) Treatment and Recovery; 3) Coordinated Community Responses; and 4) Law Enforcement Responses. The subcommittees met on numerous occasions between April

³ Senate Report 113-181, accompanying S. 2437. Pub. L. 113-235, "The Federal Government must have a comprehensive approach to the growing heroin crisis. While a strong law enforcement effort is critical to the response, heroin is not simply an enforcement problem. As discussed at the subcommittee's hearing on the Department of Justice's fiscal year 2015 budget request on April 3, 2014, the Committee directs the DOJ to lead the response by convening a multi-agency task force to address the growing heroin problem in the United States. The task force should convene experts from the law enforcement, medical, public health, and educational fields to develop a coordinated response to help our citizens and communities."

⁴ Opioids include heroin and the *entire family* of natural, synthetic, and semi-synthetic opioid substances that have similar effects on the opioid receptors.

⁵ Opioid prescription medications can also be referred to as opioid medications, prescription opioids, prescription pain relievers, prescription pain analgesics, and Schedule II, III, and IV prescriptions that contain an opioid. Medications that fall within this class include hydrocodone (e.g., Vicodin), oxycodone (e.g., OxyContin, Percocet), morphine (e.g., Kadian, Avinza), codeine, and related drugs.

⁶ SAMSHA, Substance Use Disorders, retrieved from http://www.samhsa.gov/disorders/substance-use.

⁷ Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2014 on CDC WONDER Online Database, released December 9, 2015.

⁸ A pill mill is a term generally used to describe a doctor's office, clinic, or pharmacy that is unlawfully prescribing or dispensing controlled substances outside of current medical standards.

⁹ For example, because there is a growing concern about prescription opioid misuse among high school and college youth, especially those engaged in athletics, several organizations have committed to educating these athletes and sports medicine professionals. The organizations include the National Collegiate Athletic Association, National Association of High School Coaches, American College of Sports Medicine, National Athletic Trainer's Association, and National Interscholastic Athletic Administrators Association. *See* FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use, retrieved from https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector.

and September 2015, consulted with recognized experts, and developed findings and recommendations regarding consensus priorities.

The recommendations contained in this report are premised upon three principles: 1) public safety and public health authorities must integrate and harmonize their response to the misuse of prescription opioid medications and use of heroin; 2) policies regarding heroin use and misuse of prescription opioid medications must be grounded in a scientific understanding that substance use disorder is a chronic brain disease that can be prevented and treated; and 3) treatment and recovery services and support must be accessible and affordable.

The Crisis

Heroin-involved overdose deaths are increasing at dramatic rates throughout the United States, among men and women, and most age groups and races/ethnicities. Heroin use and dependence strongly correlate with heroin-related overdose deaths, which increased by 406% between 2006 and 2014. In 2014, more than 10,500 people died from an overdose involving heroin.

Today's heroin is dramatically different from the heroin of the 1980s. It is much higher in purity and much lower in price, ¹⁴ creating easier access to a more potent drug that is often used in combination with other drugs. ¹⁵ In 1981, the average retail-level purity of heroin was 10%, but by 1999 the purity level increased to an average of 40%. Over the past 10 years the price per gram has decreased greatly and continues to remain stable and relatively low, while purity levels have declined slightly to 30%. ¹⁶ A recent analysis in the United States found that for every \$100 decrease in the price per gram of heroin there was a 2.9% increase in the number of heroin overdose hospitalizations. ¹⁷ The recent surge in opioid-involved deaths may be related to a rise in heroin adulterated with fentanyl, a semisynthetic opioid. ¹⁸

Today's heroin epidemic can be attributed in part to inappropriate prescribing of opioids ¹⁹ over the last 20 years, which resulted from a variety of factors including marketing of newly-developed prescription opioid medications ²⁰ and limited provider education on appropriate opioid prescribing. ²¹ The widespread prescribing of opioids has contributed to the public impression that these medications do not carry a high risk of addiction. Evidence shows that some people who abuse opioid medications migrate to heroin because heroin is more accessible and less costly than prescription opioids. ²² In fact, nearly 80% of recent heroin initiates reported that they began their opioid use through the nonmedical use of prescription opioid medications. ²³ This means that prescription opioid misuse is a strong risk factor for heroin use.

¹⁴ 2013 National Level STRIDE Price and Purity Data, DEA-DCW-DIR-068-15, (Sept. 2015).

¹⁰ Op Cit., Centers for Disease Control and Prevention, WONDER Online Database.

¹¹ Jones et. al., Vital Signs: Demographic and Substance Use Trends Among Heroin Users – United States, 2002-2013, Morbidly and Mortality Weekly Report (July 2015) 64(26); 719-725.

¹² Op Cit., Centers for Disease Control and Prevention. WONDER Online Database.

¹³ Ibid.

¹⁵ Jones et. al., Vital Signs: Demographic and Substance Use Trends Among Heroin Users – United States, 2002-2013, Morbidly and Mortality Weekly Report (July 2015) 64(26); 719-725.

¹⁶ Institute for Defense Analyses, *The Price and Purity of Illicit Drugs: 1981-2007*. Paper P-4369 (October 2008). Re-estimates through 2012 in 2012 dollars were done with the application of the same methodology, unpublished (May 2013); data available in ONDCP. 2015. *National Drug Control Strategy: Data Supplement* 2015, Washington, DC.

¹⁷ Unick et al. The relationship between US heroin market dynamics and heroin-related overdose, 1992-2008. Addiction. 2014;109(11)1889-98.

¹⁸ Rudd RA et al. Increases in drug and opioid overdose deaths – United Sates, 2000-2014. MMWR 2015;64:1-5.

¹⁹ Derived from the opium poppy (or synthetic versions of it) and used for pain relief.

²⁰ Van Zee, A. 2009. The promotion and marketing of OxyContin: Commercial Triumph, Public Health Tragedy. American Journal of Public Health 99(2):221-227. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/. http://www.n

²² Cicero, T. et. al., *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, JAMA Psychiatry (July 2014) 71(7):821-826, retrieved from http://archpsyc.jamanetwork.com/article.aspx?articleid=1874575.

Muhuri, P. et. al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*,

²³ Muhuri, P. et. al., Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States, CBHSQ Data Review (August 2013), retrieved from

 $[\]underline{http://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm.}$

According to the International Narcotics Control Board, the United States is by far the leading consumer of prescription opioid medications, followed by Canada where slightly more than half as many opioids were consumed as in the United States between 2009 and 2011. ²⁴ In 2012, 259 million prescriptions for opioids were filled in the United States, enough for every American adult to have his or her own bottle of pills. ²⁵ In 2014, there were 20,808 overdose deaths involving prescription opioid medications, more than 3 times as many deaths as in 1999. ²⁶

The dramatic increase in prescription opioid abuse and deaths involving opioid medications is intertwined with the recent increases in deaths involving heroin. ²⁷ Given these alarming trends, Federal, state, tribal, and local partners must take rapid, effective action to combat the opioid crisis.

Finding 1: Public safety and public health strategies in response to opioids must be integrated and complementary

1.1 Recommendation: Prevent opioid misuse and abuse by ensuring safe and appropriate prescribing

a. Require practitioners (such as physicians, dentists, and others authorized to prescribe) who request DEA registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registration

Inappropriate prescribing of opioid medications is a key driver of the increase in opioid-related morbidity and mortality. Health care providers receive limited education about the appropriate role of prescription opioids in pain management and how to prescribe them appropriately. It is estimated that fewer than 10% of medical schools offer instruction in addiction treatment, and according to one study, 80% of attending physicians rate their medical school education on chronic pain treatment as inadequate. Healthcare educators can benefit from the implementation of curricula in medical, dental, pharmacy, and nursing schools and continuing medical education on pain management, safe opioid prescribing, and the identification and management of substance use disorders.

In 2015, the National Institutes of Health funded 11 health professional schools as designated Centers of Excellence in Pain Education (CoEPEs). The CoEPEs will act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing, pharmacy, and other schools to enhance and improve how health care professionals are taught about pain and its treatment.³¹ Currently, live and online prescriber continuing education courses are available through a number of sources, including the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Action Opioid Analgesics,³² and Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institute on Drug Abuse (NIDA).³³

²⁴ International Narcotics Control Board. 2013. Narcotic Drugs: Estimated World Requirements for 2013. Statistics for 2011. (Table XIV.1.a.). United Nations, New York.

²⁵ Paulozzi, LJ; Mack, KA; and Hockenberry, JM. <u>Vital Signs: Variation Among States in Prescribing Opioid Pain Relievers and Benzodiazepines – United States, 2012.</u> Mortality and Morbidity Weekly Report 63(26):563-568 (July 4, 2014).

²⁶ Op Cit., Centers for Disease Control and Prevention. WONDER Online Database.

²⁷ Muhuri, P. et. al., Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States, CBHSQ Data Review (August 2013), retrieved from

http://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm. ²⁸ Paulozzi L, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid analgesics—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487- 1492. ²⁸ Paulozzi L, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses

²⁶ Paulozzi L, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid analgesics—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487-1492.

²⁹ Centers for Disease Control and Prevention. *Opioid Painkiller Prescribing* (July 2014) retrieved from http://www.cdc.gov/vitalsigns/opioid-prescribing/.

³⁰ Mezei, L. and Murinson, B. 2011. Pain education in North American medical schools. *The Journal of Pain*, 12(12):1199-1208.

³¹ National Institutes of Health. 2015. Centers of Excellence in Pain Education retrieved from http://painconsortium.nih.gov/NIH Pain Programs/CoEPES.html.

³² Extended-Release and Long-Acting (ER/LA) Risk Evaluation and Mitigation Strategy (REMS) Continuing Education Programs; available at www.er-la-opioidrems.com.

³³ SAMHSA's Efforts to Fight Prescription Drug Misuse and Abuse, retrieved from http://www.samhsa.gov/prescription-drug-misuse-abuse/samhsas-efforts; NIDA: Opioid and Pain Management CMEs/CEs, retrieved from https://www.drugabuse.gov/opioid-pain-management-cmesces.

Given the scope of the opioid epidemic and the limited education of health professionals on pain management and substance use disorder treatment, required training of prescribers and the development and maintenance of up-to-date clinical practice guidelines may help ensure that patients have access to appropriate opioid treatment while also reducing the inappropriate use of prescription opioids. To date, only ten states (Connecticut, ³⁴ Delaware, ³⁵ Iowa, ³⁶ Kentucky, ³⁷ Massachusetts, ³⁸ New Mexico, ³⁹ Tennessee, ⁴⁰ Utah, ⁴¹ West Virginia, ⁴² and Maryland ⁴³) have passed legislation requiring such education for providers.

In October 2015, the President directed federal departments and agencies to provide training to Federal healthcare professionals. Training for federal prescribers should include effective prescribing of opioid medications for all employees who prescribe controlled substances as part of their federal employment responsibilities. The training must address effective prescribing, pain management, potential misuse of opioids, proper methods of disposing of controlled substances, and identification of individuals who may have substance use disorders and referral of these patients to proper treatment programs. Training must also be consistent with guidelines on pain medication prescribing forthcoming from the Centers for Disease Control and Prevention (CDC).44

b. States should consider adopting or recommending uniform prescribing guidelines

States have broad authority to regulate the prescribing and dispensing of prescription drugs and should review these practices in light of the growing prescription opioid and heroin overdose epidemic. Several states have already enacted or recommended prescribing guidelines and model CDC guidelines are available. 45 For example, Washington State implemented opioid prescribing rules as part of a multi-pronged approach to the epidemic. That multi-pronged approach was associated with a more than 25% decline in prescription opioid overdose deaths between 2008 and 2012.46

The CDC is developing a new guideline for Prescribing Opioids for Chronic Pain⁴⁷ that will primarily focus on the use of opioids in treating chronic pain (i.e., pain lasting longer than three months or past the time of normal tissue healing) exclusive of patients in active cancer treatment, palliative care, or end-of-life care. In developing the guidelines, CDC scientists followed a rigorous scientific process using experts in the field and the most recent scientific evidence. Improving the way opioids are prescribed through clinical practice guidelines can ensure patients with chronic pain have access to safer, more effective chronic pain treatment. This guideline can be adopted by states who seek to enact uniform prescribing guidelines.

c. Patients should be informed and empowered so they can actively participate in their pain management and make informed decisions

Prescription opioid medications can play an important role in the treatment of some types of pain, but they must be managed in a safe and appropriate manner. Appropriate management of pain should include active involvement of patients through discussions with their prescribers

³⁴ CONN. GEN. STAT. § 20-10b (2015).

³⁵ 24 DE Reg. § 3.1.1.

³⁶ IOWA ADMIN. CODE r. 653-11.4 (2011).

³⁷ 201 Ky. Admin. Reg. 9:250; 9:310 (2013).

³⁸ MGL 94C, Section 18(e).

³⁹ N.M. ADMIN. CODE § 16-10-14 (2012).

⁴⁰ TENN. CODE ANN. § 63-1-402 (2013).

⁴¹ UTAH CODE Ann. § 58-37-6.5 (2013).

⁴² W. VA. CODE § 30-1-7A (2015).

⁴³ Maryland Board of Physicians, Department of Health and Mental Hygiene, available at: http://www.mbp.state.md.us/pages/overdose.html.

Presidential Memorandum -- Addressing Prescription Drug Abuse and Heroin Use (October 21, 2015), retrieved from https://www.whitehouse.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescriptiondrug-abuse-and-heroinon 12/4/15.

45 See Pennsylvania Guidelines on the use of Opioids to Treat Chronic Noncancer Pain, retrieved from

http://www.pamedsoc.org/DocumentVault/VaultPDFs/PatientcarePDFs/opioid-guidelines-PDF.html; Washington State's Interagency Guideline on Prescribing Opioids for Pain, retrieved from http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf; State Opioid Prescribing Policy: Florida, retrieved from http://fapmmed.net/State Opioid Prescribing Policy.pdf.

Franklin, G. et al., A Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned, Am. J. Pub. Health (March 2015) retrieved from http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2014.302367.

New CDC Opioid Prescribing Guidelines: Improving the Way Opioids are Prescribed for Safer Chronic Pain Treatment. http://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf.

about the risks and benefits of all treatment options, including prescription opioids. Health care providers should consider non-opioid pharmacological and non-pharmacological pain treatment modalities, or combinations of modalities, and explain the risks and benefits of these options to every patient. If a patient's treatment includes the use of prescription opioids, the physician and patient should work together to develop a treatment plan, including the expectations and goals of treatment and how and when to discontinue the medication if necessary.

Public and patient education programs can increase awareness of and knowledge about appropriate pain treatment and opioid abuse. Coordinated multi-media public awareness and education campaigns have the potential to increase knowledge and understanding about the harms associated with prescription opioid pain medications, who is most at risk, and what alternatives to opioid pain relievers exist. The campaigns also should include the importance of taking prescription opioid pain medication as prescribed, safe storage and disposal of medications, the dangers of selling or sharing prescription drugs, recognition of and response to an opioid overdose, and the benefits of medication assisted treatment (MAT) of opioid use disorders.⁴⁸

d. Consistently and proactively enforce safe prescribing practices

Preventing the inappropriate prescribing and dispensing of controlled substances is both a Federal and state responsibility and requires close coordination between public health and public safety agencies. As noted above, many prescribers can benefit from additional and improved training. When inappropriate prescribing practices are more systematic and suggest more troubling practices and potential violations of law, state licensing boards should investigate allegations of violations, and impose sanctions through regulatory board reviews and hearings. This includes sanctions against practitioners who prescribe controlled substances outside of established practice standards in a manner that puts the patient's safety in jeopardy. States should not wait to aggressively pursue health care practitioners who prescribe or dispense controlled substances in this manner. They should use the authority vested in their individual boards to investigate prescription opioid overdose deaths and practitioners with high risk prescribing patterns. State medical boards may need to obtain access to state Prescription Drug Monitoring Program (PDMP) data (within the bounds of state law and regulations, e.g., bona fide investigation or subpoena) as well as mortality data to make use of this information. In some cases such access may require legislative changes.

While the Federal government does not intervene in the practice of medicine, the Drug Enforcement Administration (DEA) is required through Federal statutes and regulations to ensure that pharmaceutical controlled substances are not diverted for illegitimate use. The Controlled Substances Act (CSA) requires the registration of individuals and entities involved in the prescribing, dispensing, or distribution of controlled substances, including manufacturers, distributors, prescribing practitioners, and pharmacies. Violations of the CSA can result in criminal, civil, or administrative sanctions against the registrant or co-conspirator. Today, the DEA regulates 1.5 million registrants and through Tactical Diversion Squads has steadily increased the frequency of compliance inspections for manufacturers (including bulk manufacturers), distributors, pharmacies, importers, exporters, and narcotic treatment programs. The objective in this increased oversight is to enable DEA to take a more proactive approach to educating registrants and ensuring that registrants understand and comply with the CSA.

When registrants fail to comply with the CSA, administrative sanctions can include the modification or revocation of a controlled substance registration. Federal violations of the CSA hinge upon whether a controlled substance prescription is valid. A practitioner who writes a controlled substance prescription that is not issued for a legitimate medical purpose and that does not fall within the standard of accepted medical practice is in violation of the CSA. Proper prescription of opioids is incumbent upon the prescriber, but the pharmacist who fills the prescription must also ensure that prescriptions are valid before dispensing a controlled substance under Federal law and, in most cases, state law.

Early coordinated intervention across jurisdictions can limit the harm inflicted by unscrupulous prescribers and prevent the diversion of large quantities of prescription opioid medications. DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness

_

⁴⁹ 21 U.S.C § 824.

⁴⁹ 21 U.S.C § 824.

⁵⁰ See 21C.F.R. 1306.04.

Conferences (PDACs) throughout the country; to date, 34 separate PDACs have been held in 16 different states. These conferences are designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conference addresses pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners.

1.2 Recommendation: Integrate data management, reporting, and analysis

a. Support interstate interoperability and use of Prescription Drug Monitoring Programs

PDMPs can play a vital role in reducing and preventing prescription drug abuse and drug overdose. PDMPs are state-run databases that collect data on dispensed controlled substance prescriptions from pharmacies and in some cases doctors that dispense from their offices. PDMP data is made available to authorized users, including prescribers, dispensers, and law enforcement. As of October 2015, 49 states,⁵¹ the District of Columbia, and Guam have passed legislation authorizing PDMPs, and 49 states and Guam have operational PDMPs.

PDMPs provide both prescribers and dispensers with critical information that can be used to improve patient care. A 2002 study by the General Accounting Office (GAO)⁵² found that PDMPs help reduce the time required for drug diversion investigations, while a review⁵³ of research conducted on PDMPs between 2001 and 2011 found that they reduce doctor shopping, change prescribing behavior, and reduce prescription drug abuse.⁵⁴

One small study found that physicians in the emergency department (ED) who queried a PDMP changed their prescribing behavior for management of ED patients in more than 40% of the cases where they reviewed PDMP data. When these changes were made 61% of the time clinicians decided not to prescribe or prescribed less medicine than planned. In 39% of cases, checking the PDMP data resulted in prescribing more medication than planned because the provider felt reassured that the patient was not misusing medication.

PDMP operation and functionality vary greatly across states. Variations exist in the type of information collected, who is allowed to access the data and under what circumstances, and the requirements for use and reporting. State PDMPs are taking steps to engage in information sharing with other PDMPs across state lines. While some states do not yet have the legal or technological capability to allow interstate sharing of information, it is widely recognized that interstate interoperability is necessary to close gaps in monitoring across state boundaries.

PDMPs must be fully utilized in order to reduce the prevalence of prescription drug abuse and diversion. In many states with operational PDMPs, participation by prescribers and dispensers is voluntary, with utilization rates well below 50%. One way to ensure broader use is to require practitioner enrollment and use of the PDMP. Currently, 25 states and one territory mandate use by at least some opioid prescriber/dispensers. The requirements for when to access PDMP prior to prescribing opioids vary by state. Some states require a check for every Schedule II pain reliever prescription, whereas others may only impose such requirements on methadone treatment programs. ⁵⁷

9

⁵¹ Missouri is the only state that has not passed legislation authorizing the establishment of a PDMP.

⁵² U.S. General Accounting Office. 2002. Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion. GAO-02-634. Washington, D.C.

⁵³ Worley, J. 2012. Prescription Drug Monitoring Programs, a response to doctor shopping: purpose, effectiveness, and directions for future research. *Issues in Mental Health Nursing*, 33(5):319-28.
⁵⁴ In contrast, a study of PDMPs in operation from 1999-2005 found no impact of their use on opioid overdose or

In contrast, a study of PDMPs in operation from 1999-2005 found no impact of their use on opioid overdose or overdose mortality or consumption of opioid drugs. Paulozzi, LJ., et. al., Prescription drug monitoring programs and death rates from drug overdose, *Pain Medicine* (2011) 12(5) 747-754, retrieved from http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2011.01062.x/abstract.
 Baehren, DF, et al., A statewide prescription monitoring program affects emergency department prescribing

⁵⁵ Baehren, DF, et al., A statewide prescription monitoring program affects emergency department prescribing behaviors, *Ann Emerg Med* (2010) Jul:56(1):19-23, retrieved from http://www.ncbi.nlm.nih.gov/pubmed/20045578. http://www.ncbi.nlm.nih.gov/pubmed/B20045578.

http://www.ncbi.nlm.nih.gov/pubmed/B20045578.

56 PDMP Center of Excellence at Brandeis. 2014. Mandating PDMP Participation by Medical Providers: Current Status and Experience in Selected States. Brandeis University.

⁵⁷ For a review of state laws and policies, see http://www.namsdl.org/library/2155A1A5-BAEF-E751-709EAA09D57E8FDD/.

It is possible to share PDMP data across state lines with users of other databases and with law enforcement (this varies by state), as well as to integrate it directly into electronic health records systems to improve clinical access. States should strive for improved PDMP data quality, including timely data submission and enhanced data analysis to support proactive alerts and report cards to providers, licensure boards, and law enforcement where appropriate. They should also seek continual modernization of technology systems to improve services and access to information. In particular, PDMPs should engage law enforcement, public health, and regulatory agencies to promote streamlined access and enhanced accountability.⁵⁸

PDMP funding levels also vary substantially across states. They may be funded through a variety of sources, including the state general fund, state and Federal grants, and licensing and registration fees. Ensuring a base level of funding for state PDMP efforts would improve their effectiveness. The FY 2016 Omnibus Appropriations Act includes \$13 million for the program. This is \$2 million above the FY 2015 enacted level.

b. Disrupt supply and focus prevention, treatment, and intervention resources through coordinated, real-time sharing of accurate data

To coordinate rapid and targeted responses to overdose events, Federal, state, local, and tribal public safety and public health partners must share information. A number of agencies have information about infectious disease, heroin and nonmedical opioid use, and overdose. Disease surveillance systems for the hepatitis C virus (HCV), human immunodeficiency virus (HIV), and other blood borne pathogens can identify infected persons who represent sentinel events in a community; surveillance information is also useful for guiding the development and implementation of testing programs and other disease prevention efforts. Collecting data about drug use and overdoses from these agencies and sharing it with law enforcement as appropriate can help officials identify overdose trends and trace them to their sources. Mapping these data can help focus enforcement and prosecution efforts on suspects, who are causing the most harm, and target treatment and prevention efforts on the most vulnerable areas and users.

Many Federal, state, local, and tribal, agencies have access to centralized information sharing centers, known as fusion centers. The ONDCP-funded High Intensity Drug Trafficking Area (HIDTA) task forces focus primarily on local and domestic drug traffickers, while DOJ's funded Organized Crime Drug Enforcement Task Forces (OCDETF) focus on the multi-regional, national, and transnational criminal organizations who are most responsible for the overall supply of illegal drugs and diverted pharmaceuticals in the United States, including heroin and other opioids smuggled from abroad. These task forces could also facilitate information-sharing about overdose events to spur investigations because they focus on multi-jurisdictional drug investigations; incorporate Federal, state, local, and tribal law enforcement; include de-confliction protocols in their law enforcement initiatives to ensure maximum coordination among law enforcement entities; and have access to sophisticated, law enforcement intelligence-sharing strategies and multi-jurisdictional databases.

When coordinated, Federal, state, local, and tribal sources of intelligence can enhance the efforts of law enforcement and public health professionals to develop a comprehensive assessment of the drug environment and devise effective responses. For example, the New Jersey Regional Operations and Intelligence Center (NJ ROIC) monitors drug activity in New Jersey and the surrounding region through its Drug Monitoring Initiative (DMI). The purpose of the DMI is to establish a multi-jurisdictional, multi-state drug incident information-sharing collaboration, through the robust collection and analysis of data and information about drug seizures, overdoses, related criminal behavior, and healthcare-related services. This innovative approach gathers and analyzes investigative and administrative data from sources such as law enforcement agencies, coroners, forensic labs, hospitals, and other entities and helps law enforcement agencies and public health experts understand trends, patterns, implications, and threats from illicit drug activity that can inform their response strategies.

A second promising program is the Overdose Fatality Review team program established in Maryland. Through regular meetings, local public safety, public health and treatment

⁵⁹ Through the administration of the Harold Rogers PDMP grant program, the Bureau of Justice Assistance (BJA) works to enhance the capabilities of PDMPs, including by supporting interstate data sharing and law enforcement access.

⁵⁸ Freeman, P., et al. Optimizing Prescription Drug Monitoring Programs to Support Law Enforcement Activities. University of Kentucky College of Pharmacy, NCJ 249186, https://www.ncjrs.gov/pdffiles1/nij/grants/249186.pdf. DDAD

representatives review medical examiner data on overdose deaths as well as other information to identify overdose risk factors and missed opportunities for prevention/intervention, and to make recommendations to prevent future deaths.

Similar to FY2015, in the FY2016 Consolidated Appropriations Act, Congress appropriated funds for Federal and State law enforcement, including \$7 million to DOJ's Office of Community Oriented Policing Services (COPS) Anti-Heroin Task Force (AHTF) Program, to support drug enforcement. In FY2015, resources funded under the six awards include portable drug detection devices, automated license plate readers, lab equipment, expanded data collection, and information systems to manage data on service/hotline calls, seized currency, etc. for mapping and other crime analysis.

1.3 Recommendation: Reduce the excessive supply of opioids through strategic enforcement mechanisms with assistance from community partnerships

a. Prioritize prosecution of medical professionals who improperly prescribe opioids

Medical professionals who prescribe opioid drugs outside of standard medical practices and engage in criminal behavior should be held legally accountable. Unscrupulous prescribers and dispensers, including some Internet pharmacies, propel the distribution of substantial amounts of illegal prescription opioid medications. Some rogue online pharmacies have also been exposed for failing to verify prescriptions and for illegally distributing heroin cutting agents, including fentanyl. Illegal dispensing contributes to the diversion of pharmaceutical opioid medications to illegal drug markets and fuels addiction and abuse.

Recommended prosecution strategies feature several hallmarks. First, they target prescribers who engage in conduct that is criminal in nature, without legitimate medical purpose, and not merely through negligence or an exercise of bad judgment, often incorporating data-driven targeting of the most egregious and prolific offenders. Excessive prescribing patterns and practices are often detectable through statistical analyses but also manifest themselves in ways that are readily apparent to law enforcement and the public. Rogue pain clinics, for example, often have long lines of patients who travel very long distances, including from other cities and states. ^{60, 61}

Coordination with state medical practice regulators and DEA Diversion Offices also is recommended. Because pill mill investigations may be document-intensive and time-consuming, immediate enforcement action may be necessary to prevent imminent additional harm to patients. Suspension or revocation of medical licenses and DEA registration can disrupt criminal operations and abate immediate risk. While successful prosecution can result in the permanent or long-term removal of criminal prescribers, prompt utilization of existing state regulatory authorities can usually be accomplished more quickly. Additionally, regulatory officials may serve as helpful witnesses in any eventual criminal prosecution, by explaining the nature of coordinated administrative enforcement efforts taken against the medical professional in question and the reason why immediate action was necessary.

Criminal prosecutions should be employed for specific and general deterrence. Prosecuting individual criminal pill mill operators may have a measurable and positive impact on a region and may have a deterrent effect upon other actors who may be considering or currently

_

⁶⁰ United States v. Oliver Herndon, CR 12-87 and 12-135 (Western District of Pennsylvania) United States v. Martinez, 588 F.3d at 307 (saw over 100 patients per day); Jong Hi Bek, 493 F.3d at 795 (line of people waiting to get into his office in the morning runs around the block); United States v. Hammond, 781 F.2d at 1537 (90% of physician's patients lived outside the county; witnesses described scenes of patients arriving by the car-load from various counties both in-state and out-of-state); See also Rigg, KK et. al., Prescription Drug Abuse & Diversion: Role of the Pain Clinic, J Drug Issues (2010) 40(3):681-702, retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3030470/.

⁶¹ But see Ringwalt, C. et al. (2015). The Use of a Prescription Drug Monitoring Program to Develop Algorithms to Identify Providers with Unusual Prescribing Practices for Controlled Substances. Journal of Primary Prevention, http://www.researchgate.net/publication/279754168 The Use of a Prescription Drug Monitoring Program to Develop Algorithms to Identify Providers With Unusual Prescribing Practices for Controlled Substances. Researchers who examined the North Carolina Controlled Substances Reporting System to identify unusual practices by prescribers and dispensers found that some information — specifically co-prescribed benzodiazepines, and opioids greater than 100 morphine milligram equivalents — is more useful than distance traveled by patient and other previously suggested variables. Such data analyses improve screening for problem prescribing, and with fewer false positives.

engaging in criminal conduct. The impact of prosecutions should be publicized broadly by the prosecuting office to inform the public and deter potential violators.

Finally, shutting down a rogue pain clinic or similar operation may provide an opportunity for law enforcement agencies to partner with treatment providers to devise ways of referring former patients who suffer from opioid use disorder to treatment. For example, law enforcement agents could work with public health authorities to disseminate information on treatment options for customers who show up at the closed doors of a rogue clinic. Law enforcement should meet with state, local, and tribal treatment professionals to discuss how they might generally avoid dire consequences (such as an increase in overdoses) in the aftermath of an illicit pain clinic closure.

b. Prioritize prosecutions of heroin distributors, especially when the drug causes death, and enhance investigation and prosecution techniques for targeting the drug supply chain

Prosecuting drug distributors who provide heroin that causes overdoses serves multiple objectives. First, the distributor's product may be particularly potent or otherwise dangerous, and quickly identifying the source and stopping the flow will save lives. Second, prominent prosecutions of distributors who harm users are intended to serve as a deterrent by alerting other prospective drug dealers about the high potential penalties. Finally, such cases help spread information about the severe harm caused by heroin.

Traditionally, a heroin overdose death is treated as a medical problem rather than a homicide in which a dangerous criminal remains at large. Understandably there is a tension between an interest in saving lives and not prosecuting individuals who seek help and pursuing criminal investigations to remove these dangerous drugs from the street. These pursuits, however, are not mutually exclusive. While communities should work to implement Good Samaritan laws to encourage witnesses to an overdose to call 911 (see Recommendation 1.6), first responders who respond to the scene of an overdose should be trained to process the scene and seize evidence when appropriate and permitted by law. They should also employ investigative techniques to remove harmful drugs from the streets and to target more significant drug traffickers along the supply chain.

Federal prosecutors should prioritize prosecutions of heroin traffickers when the distribution of that drug results in death or serious bodily injury from use of that product. Under 21 U.S.C. § 841(b)(1)(C), there are enhanced penalties for these aggravated drug trafficking cases. In prosecuting these cases the law has been interpreted to require "but for" causation that requires the government to prove that the drug sold by the defendant was independently sufficient to cause the death of the victim. This interpretation creates a hurdle prosecuting cases under 21 U.S.C. § 841 where the victim is found to have multiple drugs in his/her system. Under the current standard, a conviction would not be likely when any other drug may be a contributing factor in the death of the victim, even when a heroin stamp is known to be particularly potent or dangerous. A legislative solution to this problem should be considered.

It will always be the role of law enforcement to rigorously target the illegal and unauthorized supply chain of heroin. DOJ is committed to identifying, disrupting, and dismantling the most serious drug trafficking organizations responsible for the nation's drug supply. As an example, to achieve this end the United States Attorneys' offices working with the OCDETF program have created an initiative to reduce the trafficking by organized groups and others who move heroin and prescription opioids from Michigan and Ohio into Kentucky, Tennessee, West Virginia, and western Pennsylvania. Regional strategic initiatives can serve as a means of combining investigation efforts across federal districts and local communities to enhance prosecutions of serious drug traffickers.

c. Encourage and promote safe drug disposal

Approximately 51% of people who used opioid medications non-medically in the past month obtained them from friends and relatives for free the last time they used them; 11% bought

⁶² See Burrage v. United States, 134 S.Ct. 881(2014).

⁶³ U.S. Attorneys and Federal Law Enforcement Leaders Conduct Summit to Target Heroin and Opioid Trafficking and Overdose Epidemic (August 26, 2015), retrieved from https://www.fbi.gov/detroit/press-releases/2015/u.s.-attorneys-and-federal-law-enforcement-leaders-conduct-summit-to-target-heroin-and-opioid-trafficking-and-overdose-epidemic.

them from a friend or relative; and 4% took them from a friend or relative without asking.⁶⁴ Since 2010, DEA has coordinated with local stakeholders on national Take-Back Days to collect unused, unwanted, or expired prescription medications that are controlled substances in Schedules II-V. In 2014, DEA announced new rules for implementing the Secure and Responsible Drug Disposal Act of 2010.⁶⁵ These rules expand the options available for collecting controlled substances for the purpose of disposal. Options include drug mail-back programs and collection receptacles at registered locations, which may include law enforcement agencies, hospitals and clinics with an on-site pharmacy, and retail pharmacies. The goal of the new rules is to expand the options for safe and environmentally sound disposal. Prior to each National Take-Back Day, communities can view eligible collection sites at http://deadiversion.usdoj.gov/drug_disposal/.

Community coalitions can help to prevent the diversion of unused prescription opioids from homes by conducting and publicizing frequent safe disposal programs. These disposal efforts help reduce access to opioids for those without a legitimate medical need. Safe disposal sites may include police stations, certain hospitals, and pharmacies. Coalitions between community groups and law enforcement, including the DEA, may join together to support takeback events. In some communities across the country for example, people can dispose of excess prescription and other medication at the police department 24 hours a day, seven days a week, no questions asked. 66 In rural and underserved communities, mobile pick-up programs could be established. Pharmacies can host take-back sites without law enforcement involvement and can expand their capacity to fund the collection of unused products. DOJ and ONDCP supported development of a community toolkit on disposal which community coalitions can use to create disposal programs.⁶⁷

At an individual level, consumers can mail back envelopes, or follow widely-available recommendations for safe disposal alternatives. FDA provides instructions for disposal in household trash, after the medications are removed from their original packaging, placed in a sealable plastic bag and mixed with water and/or undesirable substances, such as coffee grounds or cat litter.⁶⁸ In October 2015, HHS launched a website focused on increasing education about opioid misuse and providing resources for communities. HHS.gov/Opioids is a one-stop Federal resource offering tools and information, including links to a guide for communities seeking solutions for safe drug disposal.

1.4 Recommendation: Enlist pharmaceutical companies to address the harms associated with prescription opioids

Since the 1990s, the prescription of opioids has increased sharply. Pharmaceutical manufacturers have generated unprecedented production and sales of prescription opioids and have engaged in extensive marketing campaigns.⁶⁹ While prescription opioids can play a valuable role in pain treatment for appropriately selected and monitored patients, historically, certain opioids have been marketed in a manner that underestimates their addictive potential and the associated individual and societal costs.⁷⁰ Patients and prescribers need accessible, strong, accurate warnings and comprehensive literature that explains the relative risks and benefits and is easy to understand.

In 2012, Alameda County, California enacted an ordinance to implement a safe disposal program, known as the prescription drug disposal "stewardship" program that would be financed by pharmaceutical manufacturers. This ordinance has been upheld in the courts. This model may be useful for other locales interested in funding disposal programs. Alameda County, California, King County, Washington, and a multitude of other counties are now working toward implementing stewardship drug disposal programs.

66 See for example: http://takomaparkmd.gov/government/police/services-and-programs/.

67 Partnership for Drug Free Kids. 2015. Safe Drug Disposal. A Guide for Communities Seeking Solutions. Office of Community Oriented Policing Services. Available at http://medicineabuseproject.org/assets/documents/safe_drug_disposal_guide_8_508.pdf. Downloaded 11-16-2015.

http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingO ver-the-CounterMedicines/ucm107163.pdf.

13

⁶⁴ Center for Behavioral Health Statistics and Quality. 2015. 2014 National Survey on Drug Use and Health: Detailed tables. Substance Abuse and Mental Health Services Administration, Rockville, MD.

https://www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.

Van Zee, A. 2009. The promotion and marketing of OxyContin: Commercial Triumph, Public Health Tragedy. American Journal of Public Health 99(2):221-227. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/ Ibid.

Pharmaceutical companies are subject to Federal and state laws and regulations that prohibit improper promotion of opioids, payments from manufacturers to prescribers based on patterns or volume of prescribing, and medical fraud. Law enforcement personnel should be vigilant in investigating possible violations and in pursuing civil and criminal penalties where appropriate. Attorneys General and community stakeholders should evaluate possible misbranding and fraud violations by opioid manufacturers. When intentional misbranding and fraudulent representations by manufacturers have been proven, civil and criminal penalties have been imposed.⁷¹

Through the Distributor Initiative Program, which was developed in 2005, DEA also educates registrants on maintaining controls against diversion, and monitoring for and reporting suspicious orders. DEA educates distributors about their obligations under the CSA and provides registrants with current trends and "red flags" that might indicate that an order is suspicious, such as the type of drug(s) ordered, orders of unusual size, orders that deviate from a normal pattern, frequency of orders, breadth and type of products ordered, and the location of the customer. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes. Wholesale distributors are required to design and operate a system that will detect suspicious orders and report those suspicious orders to DEA, although a more robust regulatory scheme to enhance accountability and reporting requirements may be needed to hold distributors civilly and criminally liable for failing to report.

1.5 Recommendation: Look to examples of promising robust public health-public safety partnerships to inform development of effective strategies.

Close cooperation between public safety and public health agencies is important to effectively respond to the heroin crisis. One example of such cooperation is the White House ONDCP Heroin Response Strategy. In August 2015, ONDCP awarded \$2.5 million to fund a Heroin Response Strategy among 15 states in five regional HIDTAs - New England, Appalachia, Philadelphia/Camden, New York/New Jersey, and Washington/Baltimore - to help coordinate public health and public safety partnerships.

Under the program, each of the HIDTAs will designate two regional coordinators for the five HIDTA initiatives - one to focus on public health and one to focus on public safety. The public health coordinator will analyze regional reporting on overdoses and issue alerts regarding dangerous batches of heroin, such as those laced with fentanyl, and other heroin-related threats. The alerts will allow health responders to target the distribution of naloxone or expansion of resources to reduce overdoses in the affected area(s). The public safety coordinator will ensure law enforcement authorities have the case support and intelligence needed to disrupt heroin trafficking. Each of the 15 states will also have a public safety coordinator and a public health coordinator. This unprecedented partnership should be evaluated and if proven successful, expanded and replicated in other regions.

DEA's new 360 Strategy is another example of promising partnerships and a holistic approach to combating the heroin epidemic. The strategy leverages existing Federal, state and local partnerships on three different fronts: law enforcement, diversion control, and community relations. The strategy focuses on DEA's enforcement activities directed at organizations and gangs that contribute to the heroin and prescription opioid epidemic in communities across the country. However, the 360 Strategy recognizes that enforcement alone is not enough to effectuate sustained community change. The 360 Strategy also focuses on preventing drug diversion by providing education and training to the pharmacy and medical communities and by pursuing practitioners who operate outside of medically accepted standards. Finally, it incorporates work with public health officials and local law enforcement, educators, and youth groups to rebuild communities after enforcement operations, to strengthen them and make them less susceptible to the destructive impacts of opioid abuse.

The Native American Drug and Gang Initiative (NADGI), comprising nine Wisconsin tribes, members of Great Lakes Indian Fish and Wildlife Commission, and a taskforce commander from the Wisconsin Department of Justice, Department of Criminal Investigations, is a multi-jurisdictional approach focused on combating and reducing drug and gang activity in

14

⁷¹ News Release United States Attorney's Office for the Western District of Virginia. (May 10, 2007). *The Purdue Frederick Company, Inc. And Top Executives Plead Guilty to Misbranding OxyContin; Will Pay Over* \$600 Million.

Indian Country. 72 NADGI works on investigations with the Federal Bureau of Investigation (FBI), Department of the Interior Bureau of Indian Affairs (BIA), and DEA to reduce gang, violent, and drug crime in Indian Country through deterrence, reassurance, attrition, communication, and coordination among agencies. NADGI also facilitates community education and outreach in tribal communities.

For the last three years, DOJ's Bureau of Justice Assistance, through the Harold Rogers Prescription Drug Monitoring grant program, has provided grant funding to support local and state strategies to reduce opioid abuse and overdose deaths. These grants enhance the capacity of agencies to analyze and leverage data from diverse sources, including PDMPs, to monitor drug abuse trends, identify sources of diversion, and improve decision-making.

1.6 Recommendation: Prevent overdose deaths through the effective use of naloxone, realtime communication, and Good Samaritan laws

Ensure access to naloxone

Naloxone, an opioid antagonist, is a prescription medicine that reverses the effects of both prescription opioids and heroin by counteracting the potentially fatal depression of the central nervous system and respiratory system associated with an opioid overdose. When administered promptly and appropriately to an overdose victim, naloxone quickly restores breathing and saves lives. 13 It can be administered by injection with a syringe or an auto-injector, or through nasal spray. If administered to someone who is not experiencing an opioid overdose, naloxone has no effect and causes no harm.⁷⁴

Reducing the time between the onset of opioid overdose symptoms and effective intervention is critical. Law enforcement officers often respond to the scene of a drug overdose before emergency medical professionals arrive. Therefore, law enforcement and other first responders need equipment and training to recognize and reverse an opioid overdose by giving naloxone.⁷⁵ In addition, the National Association of School Nurses recently called for training all middle school and high school nurses as well.76

Naloxone distribution and education should be considered in any community response to opioid abuse and overdose. States, municipalities, and tribal communities can develop naloxone distribution strategies, including naloxone access and training and public awareness campaigns. These strategies can include training and education on how to recognize an overdose, engage in rescue breathing, administer naloxone, and contact emergency medical services.

The cost of naloxone has been identified as a potential barrier to the broader expansion of naloxone access and innovative funding strategies are needed. Funding strategies could include states working together with stakeholders to ensure naloxone discounts for bulk purchase. For example, the National Association of Counties, National League of Cities, and United States Conference of Mayors, in conjunction with U.S. Communities Purchasing Alliance and Premier, Inc. announced that they will secure industry-leading discounts for tens of thousands of public agencies on naloxone and medications for treatment through their purchasing program that pools the purchasing power of state and local governments. The cost of naloxone could be reduced through new competition as the number of manufacturers of the product increases.

 $\underline{http://www.nasn.org/AboutNASN/MediaRoom/NewsReleaseView/tabid/765/ArticleId/855/National-Association-of-table and table an$ School-Nurses-Issue-Policy-Statements-on-Substance-Use-Prevention-and-Interv.aspx.

⁷³ Walley, AY et. al., Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis, BMJ (2013) 346, retrieved from http://www.bmj.com/content/346/bmj.f174.

Walley, AY et. al., Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis, BMJ (2013) 346, retrieved from http://www.bmj.com/content/346/bmj.f174.

Maxwell, S; et al. 2006. Prescribing Naloxone to actively injecting heroin users: a program to reduce heroin overdose deaths. Journal of Addictive Diseases 25(3):89-96.

The Fraternal Order of Police will provide 330,000 members with an Opioid Overdose Resuscitation card to help

respond to overdoses and also educate their members. The International Association of Chiefs of Police will also host several educational sessions on the role of law enforcement in overdose prevention. See FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use, retrieved from https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announcespublic-and-private-sector.

76 National Association of School Nurses Issue Policy Statements on Substance Use Prevention and Intervention,

⁽June 29, 2015) retrieved from

Individuals with a history of prescription opioid or heroin abuse who are being released from the criminal justice system are at particularly high-risk for overdose.⁷⁷ To mitigate this risk, a number of correctional facilities have begun to offer training on naloxone administration in criminal justice settings. For example, in February 2015, the New York State Department of Health AIDS Institute, New York State Department of Corrections and Community Supervision, and the Harm Reduction Coalition launched a novel opioid overdose prevention and training program, preparing inmates for reentry into the community. The program targets soon to be released inmates and provides them education on the risks of opioid use and training on the administration of naloxone.⁷⁸

A majority of states have passed laws enabling third party prescriptions where patients and caregivers may obtain naloxone by prescription to use in the event of an overdose. Some states also have obtained authorization by collaborating with physicians and pharmacies at the state and local levels to issue "standing orders" or collaborative practice agreements to allow for broad dispensing of naloxone so individual prescribers do not have to prescribe naloxone directly to individual patients.^{79, 80}

b. Provide immediate and comprehensive care to those administered naloxone

Opioid use disorders, like other substance use disorders, are chronic, relapsing conditions. Therefore, individuals who are experiencing an acute overdose event should be referred to followon services, including treatment, by health care providers to prevent future overdoses. One example is in Rhode Island where the state has undertaken an effort to provide peer recovery coaches in Emergency Departments to assist individuals who survive overdoses.

Consider state limited liability laws to shield those who administer naloxone and Good Samaritan laws for witnesses seeking medical help

As of September 2015, 43 states and the District of Columbia have passed naloxone access laws that shield individuals including citizens, prescribers, first responders, and law enforcement officers who possess or administer naloxone from criminal and civil liability when they act in good faith to provide medical services to someone exhibiting signs of an overdose. 82 These laws can serve as an example to other states.

Additionally, drug users frequently witness their peers' drug overdoses, but fear of a police response, including concerns over outstanding warrants or potential criminal charges, can prevent or delay them from seeking help. 83 Good Samaritan laws can help address these barriers to seeking emergency assistance. While these laws vary in scope, they generally prevent arrest or prosecution for minor drug offenses, including possession of a controlled substance and drug paraphernalia. This limited immunity typically does not extend to more serious drug offenses involving violent crime and drug trafficking.⁸⁴ As of July 2015, 34 states and the District of Columbia have enacted Good Samaritan laws for those who act in good faith to seek medical assistance during an overdose event.85

 $^{^{77}}$ Strang J. Death matters: understanding heroin/opiate overdose risk and testing potential to prevent deaths. Addiction. 2015;110 Suppl 2:27-35.

Harm Reduct J. 2015 Nov 5;12(1):51. doi: 10.1186/s12954-015-0084-8. Overdose prevention for prisoners in New York: a novel program and collaboration. <u>Zucker H¹</u>, <u>Annucci AJ²</u>, <u>Stancliff S³</u>, <u>Catania H⁴</u>.

⁷⁹ https://www.bjatraining.org/tools/naloxone/Acquiring-Naloxone.

⁸⁰ CVS Health will allow CVS/pharmacy to dispense naloxone without patients needing to present an individual prescription pursuant to a standing order from a physician or collaborative practice agreement in an additional 20 states in 2016 and will launch a new drug abuse prevention program called Pharmacists Teach, where its pharmacists will make 2,500 presentations in high school health classes. Rite Aid will train 6,000 pharmacists on naloxone use over the next 12 months, and expand their naloxone dispensing program to additional states.

81 Rhode Island Governor's Overdose Prevention and Intervention Task Force, November 2015.

⁸² Davis, CS and Carr, D. 2015. Legal changes to increase access to naloxone for opioid overdose reversal in the United States. Drug and Alcohol Dependence 157:112-20.

Tracy, M. et. al. (2005). Circumstances of witnessed drug overdose in New York City: Implications for intervention. Drug and Alcohol Dependence 79:181-190.

The National Association of State Alcohol and Drug Abuse Directors. http://nasadad.org/wpontent/uploads/2015/09/Opioid-Overdose-Policy-Brief-2015-Update-FINAL1.pdf.

⁸⁵ See The Network for Public Law at https://www.networkforphl.org/_asset/qz5pvn/network-naloxone-10-4.pdf.

d. Develop public safety and public health real-time rapid response strategies for overdose events

The rapid increase in heroin overdose deaths⁸⁶ underscores the need for timely, drug-specific surveillance data at the local, tribal, state, and regional level that can help target resources, responses, and prevention efforts. State, local, and tribal agencies should develop rapid response teams that include law enforcement, public health, health care professionals, first responders, forensic laboratory analysts, and medical examiners/coroners and be ready to respond to spikes in overdoses. These teams should focus on establishing rapid and reliable lines of communication about drug trends and overdose events across public health and law enforcement disciplines.

Rapid response teams should identify or develop effective real-time reporting systems for overdose events with proactive measures to avert upsurges in use of particular trending substances. Teams should establish communication protocols among Federal, local, state, and tribal agencies and develop cross-system collaborative efforts for law enforcement, public health, health care providers, and community-based groups. Teams should also consider community-wide alert systems to warn law enforcement, first responders, and the public when surges of potentially contaminated heroin or heroin laced with fentanyl or other adulterants leads to an increase in overdose events within a particular community.

Research indicates that certain populations are more susceptible to prescription opioid-related drug overdose, such as people who nonmedically use opioids, people receiving high doses of opioids or receiving them in combination with benzodiazepines, and people who are exposed to such environmental factors as rural residence and high community prescribing rates.⁸⁷ Public safety and public health personnel should be equipped to prioritize help to these vulnerable populations, and research should continue to identify risk factors that increase the likelihood of overdose.

Finding 2: Policies regarding opioid and heroin use must be grounded in scientific understanding that substance use disorders are a chronic brain disease that can be prevented and treated, leading to recovery

Substance use disorders are treatable chronic brain diseases, presumed to be caused by changes to the structure and function of the brain due to repeated exposure to psychoactive substances. Chronic exposure to opioids can produce opioid use disorder which the American Psychiatric Association defines as "a problematic pattern of opioid use that leads to clinically significant impairment or distress." People with an opioid use disorder often need markedly increased doses or experience diminished effects with the same dose, a feature known as tolerance. Taking larger doses, seeking more potent opioids, or adopting methods of administration that result in a quicker drug action, such as snorting or injecting are some ways users have found to cope with tolerance.

Research shows people with heavy opioid use continue to use heroin or prescription opioid medications not to intensify effects but merely to avoid being "sick" as withdrawal is often described." Chronic dependence on opioids is extremely difficult to overcome, particularly without formal, evidence-based treatment services.

Additional research is needed to further understand opioid addiction and its effects on the brain. Examples of research areas currently underway and which should be further developed include: developing analgesic alternatives to opioids, addressing genetic and epigenetic susceptibility to opioid use disorder, and understanding heroin and fentanyl use in established users.

⁸⁶ Rudd RA, et al. Increase in drug and opioid overdose deaths, United States, 2000-2014. MMWR. 2015;64:1-5.

Paulozzi, L. 2012. Prescription drug overdoses: a review. Journal of Safety Research 43:283-289.

⁸⁸ Diagnostic and Statistical Manual of Mental Disorders Fifth Edition-DSM-5. 2013. American Psychiatric Association Washington, DC. Page 541.

⁸⁹ Mars, S.G., Bourgois, P. Karandinos, G., Montero, F., Ciccarone, D. Every 'Never' I Ever Said Came True': Transitions from opioid pills to heroin injecting Int J Drug Policy. Author manuscript; available in PMC 2015 March 1.Published in final edited form as: Int J Drug Policy. 2014 March; 25(2): 257–266. Published online 2013 October 19. doi: 10.1016/j.drugpo.2013.10.004 Available at

2.1 Recommendation: Provide linkages to services at the first sign of an opioid use disorder

As with other chronic diseases, the earlier that opioid use disorder treatment is initiated, the greater the likelihood of preventing serious or lasting consequences. In 2014, an estimated 1.9 million Americans met diagnostic criteria for prescription opioid use disorder and an estimated 586,000 people met criteria for a heroin use disorder.⁹⁰

a. Apply a continuum of care approach to the problem of opioid use disorder

For treatment to be the most effective, services need to be available for all those seeking treatment. No single treatment is appropriate for every person, so a range of evidence based forms of behavioral treatment and pharmacotherapy need to be available. Managing chronic conditions that are impacted by behavioral health problems requires a "continuum of care" approach that includes an integrated system of care that guides and treats patients through an array of health services. While older models of disease rely upon clear distinctions between prevention and treatment activities, this model focuses on long-term disease management similar to that provided for other chronic illness. ⁹¹ This model creates a system of care in partnership with other disciplines, such as mental health and primary care. A Recovery-Oriented System of Care (ROSC) encompasses a menu of individualized, person-centered, and strength-based services within a self-defined network. By design, ROSC provides individuals and families with more options to inform decisions regarding their care while building community safety and resiliency. ⁹² This approach should also incorporate linkage to bloodborne disease prevention activities.

b. Implement Screening, Assessment, and Linkage to Treatment

The first step to helping people with a substance use disorder is identifying individuals who should receive risk reduction, treatment, or recovery support services. This requires an understanding of potential intervention points where persons with a possible opioid use disorder or at risk of developing one can be identified. One approach for early detection and intervention in substance use involves screening, to identify people with a possible substance use disorder, assessment, and referral to and ideally linkage to treatment. Screening means identification of those persons who require further assessment leading to possible diagnosis. It also provides an opportunity for health care professionals to educate persons with opioid use disorders regarding: the effectiveness of treatment for their condition; how to minimize risk for infection with HIV, hepatitis B, and hepatitis C; the importance of testing; and overdose prevention. Screening should occur at all appropriate opportunities where an at-risk individual may present.

Programs are underway to train law enforcement officers, who often interact with persons with opioid use disorders, in opioid use disorder prevention and available treatment services. This training is similar to the training that medical services providers, other first-responders, emergency room personnel, school staff, family members, professional faith community members, jail and prison personnel, staff at syringe service programs, and volunteers at community centers receive.

Individual communities should identify their own appropriate intervention points in coordination with public safety, public health, and other community partners. Communities should consider potentially vulnerable members who may not be identified through traditional intervention points, such as homeless people and those living in correctional facilities, senior care centers, and rural and tribal communities. This will require adequate resources for social services and criminal justice programs.

http://www.samhsa.gov/sites/default/files/rosc_resource_guide_book.pdf.

⁹⁰ Substance Abuse and Mental Health Services Administration, Results from the 2014 National Survey on Drug Use and Health: Detailed Tables (September 2015). Available at http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.pdf. Accessed on October 21, 2015

October 21, 2015.

91 McLellan AT, O'Brien CP, Lewis D et al. (2000). Drug addiction as a chronic medical illness: Implications for treatment, insurance and evaluation. *Journal of the American Medical Association* 284:1689–1695.

92 SAMHSA. 2010. Recovery-Oriented Systems of Care (ROSC) Resource Guide. Rockville, MD.

2.2 Recommendation: Make effective treatment for opioid use disorder, including medication assisted treatment, readily available and as accessible as other chronic disease treatments

a. Make evidence-based medication assisted treatment readily available

Medication, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders, including opioid use disorders, plays an essential role in successful treatment and provides a foundation for recovery. However, only a small number of Americans who could benefit from such treatments are receiving them. Opioid Treatment Programs certified by SAMHSA for the provision of medication-assisted therapy with methadone and/or buprenorphine were provided by 8 to 9% of all facilities between 2003 and 2013.

Suitable medications for treating opioid use disorders should be available throughout the continuum of care in combination with appropriate counseling and behavioral services. Currently there are three FDA approved medications available in the United States for treatment of people with opioid use disorders: buprenorphine, methadone, and extended-release injectable naltrexone. Detoxification followed by a residential rehabilitation program has long been used as a treatment option, but relapse is common and associated with a high risk of subsequent fatal overdose. ⁹⁶ Individuals should be evaluated for possible transition to maintenance therapy with buprenorphine, methadone, or extended-release naltrexone.

The 2008 Mental Health Parity and Addiction Equity Act requires insurance plans that offer mental health and substance use disorder treatment services to offer coverage for mental health and substance use disorders that is comparable to medical and surgical coverage. Health plans and issuers have an obligation to meet the requirements of the law. Federal health benefit programs can help increase access for many individuals and the President has directed Federal departments and agencies that facilitate access to health benefits to identify barriers to MAT and to develop action plans to address these barriers.⁹⁷

b. Incorporate treatment for opioid use disorder, including medication assisted treatment, into the criminal justice system

Criminal justice programs should incorporate treatment options for individuals prior to, during, after, or in lieu of incarceration. Individuals under legal supervision tend to stay in treatment longer and do as well as or better than individuals not facing the same legal pressure. The National Institute on Drug Abuse (NIDA) provides principles of drug abuse treatment for criminal justice programs that should guide the development of treatment services for individuals who come in contact with the criminal justice system. 99

Drug courts are an evidence-based alternative to incarceration. They are dedicated court programs for adults and juveniles with substance use disorders, and parents with pending child welfare cases who have alcohol and other drug dependency problems. They are designed to reduce relapse and criminal recidivism through risk and needs assessment, judicial interaction, monitoring and supervision, graduated sanctions and incentives, treatment, and other services. Some other programs, such as Law Enforcement Assisted Diversion (LEAD), which originated in Seattle, allow officers to direct individuals to treatment pre-booking. ¹⁰⁰

SSATS National Survey of Substance Abuse Treatment Services/2013 N-SSATS National Survey of Substance Abuse Treatment Services.pdf.

96 Development of the Price of Substance Abuse Treatment Services.pdf.

⁹³ SAMHSA. 2008. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. A Treatment Improvement Protocol TIP 43. Rockville, MD.

⁹⁴ Jones CM et al. National and state treatment need and capacity for opioid agonist medication-assisted treatment. Am J Public Health, 2015;105(8):e55-63.

Am J Public Health. 2015;105(8):e55-63. http://www.samhsa.gov/data/sites/default/files/2013_N-

⁹⁶ Davoli M. et al. <u>Risk of fatal overdose during and after specialist drug treatment: the VEdeTTE study, a national multi-site prospective cohort study.</u> Addiction: 2007, 102, p. 1954–1959.

⁹⁷ Presidential Memorandum -- Addressing Prescription Drug Abuse and Heroin Use (October 21, 2015), retrieved from https://www.whitehouse.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescription-drug-abuse-and-heroin.

Brecht, ML; Anglin, MD; and Wang, JC. 1993. Treatment effectiveness for legally coerced versus voluntary methadone maintenance clients. American Journal of Drug and Alcohol Abuse 19(1);89-106.
 NIDA. 2014 (revised edition). Principles of Drug Abuse Treatment for Criminal Justice Populations. Rockville,

[&]quot;NIDA. 2014 (revised edition). Principles of Drug Abuse Treatment for Criminal Justice Populations. Rockville MD. https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/txcriminaljustice-0.pdf.

¹⁰⁰ Collins, SE; Lonczak, HS; and Clifasefi, SL. 2015. LEAD Program Evaluation: Recidivism Report. Harm Reduction Research and Treatment Lab, University of Washing-Harborview Medical Center. Retrieved from:

Compared to traditional criminal case processing and community supervision, adult drug courts reduce recidivism (40% vs. 53% report criminal activity; 52% vs. 62% rearrests) and drug use (56% vs. 76% report use; 29% vs. 46% positive drug tests). Investment costs - especially treatment services - are higher, but savings related to victim and criminal justice system costs are lower due to fewer crimes, rearrests, and incarceration (\$5,680 vs. \$6,208 per offender on average). Drug courts are not intended to supplant incarceration for narcotics traffickers or those for whom this alternative is not otherwise deemed viable (e.g., offenders assessed as low in risk or treatment need).

For drug courts to provide maximum benefit to communities, they need to accommodate the need for many persons with opioid use disorder to receive MAT. Cessation of buprenorphine or methadone for opioid use disorder treatment should not be a condition of participating in drug courts or other diversion programs for those with opioid use disorder.

State, local, and tribal communities also need to work collaboratively with their local leaders and medical providers to immediately increase access to medication assisted treatment to serve the health and safety needs of each community. Federal resources are available for communities. SAMHSA awarded 3-year grants to 11 states to increase MAT capacity and is preparing for another round of grant making. In addition, the Health Resources and Services Administration (HRSA) expects to make an grants to Federally Qualified Health Centers (FQHC) in early 2016. The Strategic Prevention Framework Partnerships for Success State and Tribal Initiative Grants (SPF-PFS) are designed to address the nation's top substance abuse prevention priorities. At their discretion, states and tribes may use SPF-PFS funds to target an additional data-driven prevention priority. ¹⁰²

2.3 Recommendation: Support the availability of long-term treatment and recovery services

The specific medical, psychiatric, and social needs of the individual should be considered in determining the appropriate treatment and recovery setting and form. The initial recovery period may be a critical time to involve family members and friends in the recovery planning process. Recovery planning should include how identified medical and psychiatric needs will be met and how social variables associated with treatment outcomes, such as homelessness, will be addressed. If the individual is under supervision within the criminal justice system or is in detention, this should be optimized as part of the individual's recovery resources. The therapy best suited to the needs of the person seeking recovery should be provided continuously even in a corrections environment, as successful treatment there is associated with decreased arrest rates, decreased recidivism, and decreased mortality following release from incarceration.

While persons with substance use disorder will require crisis and acute care services, recovery depends on long term supports, such as adequate housing, that promote inclusion in community life. With sufficient support services in place for the individual, recovery benefits the community as well. Each community should be involved in both identifying the solutions to local problems and incorporating those solutions into long term community prevention, treatment, and recovery strategies.

http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=4&cad=rja&uact=8&ved=0ahUKEwjg2MbJpMLJAhUEPCYKHYpwCYQQFgg5MAM&url=http%3A%2F%2Fstatic1.1.sqspcdn.com%2Fstatic%2Ff%2F185392%2F26121870%2F1428513375150%2FLEAD_EVALUATION_4-7-15.pdf&usg=AFQjCNGhYGI9jH_5-kvJVynZyZERv_BClQ.

kvJVynZyZERv BClQ.

101 Rossman, S.B, et. al. (2011). NIJ's Multisite Adult Drug Court Evaluation: Executive Summary. Washington, D.C.: Urban Institute, NCJ 237108, https://www.ncjrs.gov/pdffiles1/nij/grants/237108.pdf.

http://www.samhsa.gov/grants/grant-announcements/sp-14-004 on 12/4/15.

Banks, D. and Gottfredson, D. 2004. Participation in drug treatment court and time to rearrest. Justice Quarterly 21(3).

Hepburn, JR. 2005. Recidivism among drug offenders following exposure to treatment. Criminal Justice Policy Review 16(2):237-259. Retrieved from:

http://cjp.sagepub.com/content/16/2/237.full.pdf+html?ijkey=ZVQ6BJisXDEf2&keytype=ref&siteid=spcjp.

105 Gisey, N et al. 2015. A cost-effectiveness analysis of opioid substitution therapy upon prison release in reducing mortality among people with a history of opioid dependence. Addiction 110(12):1975-84.

Finding 3: Visible community-based recovery supports must be available, affordable, and accessible

3.1 Recommendation: Implement coordinated community responses to promote prevention at the local level

Prevention, treatment, and recovery services need to become a community empowerment activity. The United States Attorney, as the chief law enforcement officer in his or her Federal district meets regularly with Federal and state law enforcement, tribal members, and community groups and can serve as an important resource for developing Community Action Plans to combat the heroin crisis. For example, the United States Attorney's Office for the Western District of Pennsylvania convened a working group to address prevention, intervention, treatment, and recovery efforts to respond to Pennsylvania's rising drug overdose epidemic. 106 Public health officials in the district can play an important role in this effort as well.

Effective community responses will vary, but coordinated efforts should focus on public and private partnerships that leverage existing resources to facilitate visible treatment and recovery support services that are easily accessible and affordable. Federal and non-federal stakeholders need to work collaboratively to help make communities healthier and safer through funding and resource allocation to treat and support people affected by opioid use disorder.

Local communities need locally-driven solutions. Opportunities to engage with existing anti-drug coalitions, or health department-led, and faith-based groups should be used to increase awareness and build support. Community organizing and the use of innovative media platforms will allow community representatives and activists to disseminate information to the public about local epidemics. Health care professionals and law enforcement must help educate the public about the risks associated with opioid use and the relationships between prescription opioids and heroin. Rural and other underserved communities often lack capacity and resources to engage in this important work. State, local, and tribal officials, together with law enforcement agencies and health care professionals, should target outreach and identify resources in these communities to support trainings, the creation of toolkits, and the implementation of best practices. 107

Public education campaigns can also be a part of a community effort and should target a wide variety of audiences with special emphasis on youth, underserved communities, and individuals within the criminal justice system. These campaigns should emphasize that addiction is a treatable chronic disease requiring long-term management and recovery, and provide warnings about the addictive nature of opioid pain medications. HHS has launched an opioid website as a one stop Federal resource for family members, healthcare providers, and law enforcement with resources on prevention, treatment and recovery, and overdose response. 105

3.2 Recommendation: Improve opioid training and expertise of public and private healthcare providers

Ensure greater availability of substance use disorder and recovery support specialists throughout the country

Although there are a number of efforts underway regarding the development of a more robust behavioral health workforce, substance use disorder and recovery support specialists are needed throughout the country. Adequate and accessible treatment requires a well-trained network of recovery support specialists, health care providers, and therapists. Individuals affected by opioid use disorders often access medical services where primary care providers are not

¹⁰⁶ U.S. Attorney's Working Group on Drug Overdose and Addiction: Prevention, Intervention, Treatment and Recovery, retrieved from http://www.justice.gov/sites/default/files/usao- $\underline{wdpa/legacy/2014/09/29/US\%20Attorney\%27s\%20Working\%20Group\%20on\%20Addiction\%20Final\%20Report.pd}$

¹⁰⁷ See for example: National Training and Technical Assistance Center, *Law Enforcement Naloxone Toolkit*, retrieved from https://www.bjatraining.org/tools/naloxone/Naloxone-Background.

The Partnership for Drug-Free Kids' media campaign plans to increase education and awareness for parents and

youth about the dangers of misusing prescription opioids. As part of this effort several network stations and organizations have committed more than \$20 million in donated airtime and advertising space. See FACT SHEET: https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-andprivate-sector.

109 http://www.hhs.gov/opioids.

sufficiently trained to address substance use disorders or to provide MAT.¹¹⁰ Limited substance use disorder training among health care providers can be compounded by a negative perception of substance use disorder. In fact, the lack of exposure to training on substance use disorder and limited medical, dental, and nursing school training on issues associated with opioid abuse may contribute to negative attitudes among health care providers and a failure to treat people with opioid use disorders effectively.^{111, 112}

b. Improve training and expertise of all health care professionals on treatment options for substance use disorder

Health care providers must recognize that substance use disorders are a chronic brain disease, albeit one from which patients can and do recover, and assume responsibility for treating these patients with evidence-based treatments and improving public health. Despite the availability of effective treatments, only one person in ten suffering from addiction involving alcohol or drugs, other than nicotine, receives any form of treatment. Due limited training in health professional schools, residency programs, and continuing medical education (CME) resources, there is a drastic need for improved training throughout the medical education community. Medical schools and residency programs should identify physician champions who have experience in treating substance use disorder and who can help implement curricula changes and provide supervised training to medical students and residents. Students and residents need clinically relevant experiences that involve interactions with patients who have benefited from substance use disorder treatment.

Agencies within the federal government should encourage improved training and healthcare expertise on substance use disorder. HRSA should continue to expand its workforce portfolio, including medical doctors, nurse practitioners, and registered nurses specializing in Addiction Medicine or Addiction Psychiatry. The Department of Labor should support and incentivize certification and degree programs for recovery support, and support other behavioral health professionals and case managers trained in substance use disorder prevention, risk reduction, treatment, and recovery support.

3.3 Recommendation: Take steps to mitigate public health and public safety consequences of injection drug use at the local level

Heroin is most harmful when administered through intravenous or intramuscular needle injection. ¹¹⁴ Injection drug use is a well-known route of transmission of blood borne infections, particularly HIV and hepatitis B (HBV) and HCV. These and other infectious diseases can be transmitted by sharing contaminated injection equipment (e.g., needles and syringes) and drug preparation equipment. Use of illicit drugs is also associated with increased rates of tuberculosis and sexually transmitted diseases (STDs). ^{115, 116} Individuals who inject drugs need accurate information about these risks as well as access to comprehensive, integrated prevention services. ¹¹⁷ In addition, the U.S. Public Health Service's guidelines recommend those currently

¹¹⁰ The Specialty Care Access Network - Extension for Community Healthcare Outcomes (SCAN-ECHO) program in the Veterans Health Administration links specialists to primary care providers in rural areas to provide mentored training on treating special patient populations. The SCAN-ECHO program is offering a model to support training for medication-assisted treatment for opioid use disorders in rural primary care practice.

Isaacson, JH; et al. 2000. A national survey of training in substance use disorders in residency programs. J Stud Alcohol 61:912-915.

Geller, G et al. 1989. Knowledge, attitudes, and reported practices of medical students and staff regarding the diagnosis and treatment of alcoholism. JAMA 261:3115-3120.

See: http://bphc.hrsa.gov/programopportunities/fundingopportunities/substanceabuse/.

¹¹⁴Novak, SP & Kral, AH, Comparing Injection and Non-Injection Routes of Administration for Heroin, Methamphetamine, and Cocaine Uses in the United States, J. Addict. Dis. (Jul-Sep 2011) 30(3): 248-257, retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3225003/pdf/nihms331704.pdf. On 12/4/15.

Hwang, LY; Ross, MW; and Zack, C. 2000. Prevalence of sexually transmitted infections and associated risk factors among populations of drug abusers. Clinical Infectious Diseases 31:920-926.

factors among populations of drug abusers. Clinical Infectious Diseases 31:920-926.

Shafer, MA et al. 1993. Relationship between drug use and sexual behaviors and the occurrence of sexually transmitted diseases among high-risk male youth. Sex Transm Dis 20(6):307-313.

transmitted diseases among high-risk male youth. Sex Transm Dis 20(6):307-313.

117 Centers for Disease Control and Prevention. Integrated prevention services for HIV infection, viral hepatitis, sexually transmitted diseases, and tuberculosis for persons who use drugs illicitly: summary guidance from CDC and the US Department of Health and Human Services. MMWR. 2012;16.No5.

injecting and those at risk of relapse to injection should be tested to determine the utility of offering Pre-Exposure Prophylaxis (PrEP), a medicine regimen to prevent HIV. 118

Scott County, Indiana, provides an example of the potential public health consequences of injection drug use. A small rural area (population 4,200) in southern Indiana, Scott County saw alarming increases of both hepatitis C and HIV in 2015. As of April 21, 2015, the Indiana Department of Health, with assistance from CDC, diagnosed HIV infection in 135 persons; over 84% of these persons were also infected with hepatitis C; 80% of these individuals reported injection drug use with a prescription opioid. To address this public health crisis, the county is working to increase prevention, care, and treatment services and to provide training and continuing education for health care providers. The Governor of Indiana authorized establishment of a syringe services programs that counties can apply for to provide clean needles and injection equipment and provide testing and referrals to treatment.

The 2016 Consolidated Appropriations Act allows communities experiencing or at risk of hepatitis infections or HIV outbreaks to use federal funds to support certain elements of programs that provide for the distribution of needles or syringes. Individuals engaged in injection drug use may reduce their risk of acquiring and transmitting HIV by using a sterile needle or syringe for every injection. Where state and local laws and regulations allow, persons who inject drugs can access sterile needles and syringes through syringe services programs (SSPs), pharmacies, physician prescription, and healthcare services. State and local officials should consider ways to reduce barriers to accessing sterile injection equipment.

Conclusion

As a nation, we are losing far too many lives due to the current opioid abuse crisis. This is a situation that demands immediate and persistent action. This report identifies clear ways to mitigate the problem and have a measurable impact on overdose deaths and heroin use – if we all work together to do so. The recommendations in this report are actionable, and it is hoped that they will be implemented by the appropriate government, community, and private partners. We will continue our collective efforts to end the epidemic and look forward to working with Congress.

¹¹⁸ U.S. Public Health Service. Pre-expose Prophylaxis for the Prevention of HIV Infection in the United States-2014. A clinical Practice Guideline. Available at http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf downloaded 11-16-2015.

downloaded 11-16-2015.

119 CDC. Community Outbreak of HIV Infection Linked to Injection Drug Use of Oxymorphone – Indiana. 2015.

MMWR April 24, 2015; 64(16); 442-444. Retrieved from http://www.cdc.gov/mmwr/pdf/wk/mm64e0424.pdf on 12/4/15

¹²⁰ MacArthur, GJ et al. 2013. Interventions to prevent HIV and Hepatitis C in people who inject drugs: a review of reviews to assess evidence of effectiveness. Int J Drug Policy 25(1):34-52.

Appendix I

Participants of the National Heroin Task Force

Executive Office of the President (EOP)

- Office of National Drug Control Policy (ONDCP)
- Organized Crime Drug Enforcement Task Forces (OCDETF)
- Office of National AIDS Policy (ONAP)
- Office of Urban Affairs, Justice, and Opportunity (OUA)
- Office of the Vice President (OVP)
- National Security Council (NSC)

Department of Justice (DOJ)

- Drug Enforcement Agency (DEA)
- Executive Office for U.S. Attorneys (EOUSA)
- U.S. Attorney's Office for the Eastern District of Pennsylvania
- Office of Justice Programs (OJP)
 - o Bureau of Justice Assistance (BJA)
- Bureau of Prisons (BOP)
- Office of Community Oriented Policing Services (COPS)
- Office of the Deputy Attorney General (DAG)
- Federal Bureau of Investigation (FBI)

Department of Homeland Security (DHS)

- Immigration and Customs Enforcement (ICE)
 - o Homeland Security Investigations (HSI)
- Customs and Border Patrol (CBP)
- Office of Intergovernmental Affairs (OIA)
- Office for State and Local Law Enforcement (OSLLE)

Department of Health and Human Services (HHS)

- Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)
- Centers for Disease Control and Prevention (CDC)
 - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)
 - Division of HIV/AIDS Prevention (DHAP)
 - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of Adolescent and School Health (DASH)
 - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of STD Prevention (DSTDP)
 - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of Viral Hepatitis (DVH)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- Centers for Medicare and Medicaid Services (CMS)
- Assistant Secretary for Planning and Evaluation (ASPE)

National Institutes of Health (NIH)

• National Institute on Drug Abuse (NIDA)

Substance Abuse and Mental Health Services Administration (SAMHSA)

• Division of Pharmacological Therapy (DPT)

Department of Housing and Urban Development (HUD)

- Office of Public and Indian Housing (PIH)
- Public Housing Supportive Services

Food and Drug Administration (FDA)

Department of Education (ED)

The White House Office of the Press Secretary October 21, 2015

FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use

Prescription drug abuse and heroin use have taken a heartbreaking toll on too many Americans and their families, while straining law enforcement and treatment programs. Today, the President will travel to West Virginia to hear directly from individuals and families affected by this epidemic and the health care professionals, law enforcement officers, and community leaders working to prevent addiction and respond to its aftermath.

As part of today's event, the President will announce federal, state, local and private sector efforts aimed at addressing the prescription drug abuse and heroin epidemic. These include commitments by more than 40 provider groups – representing doctors, dentists, advanced practice registered nurses, physician assistants, physical therapists and educators – that more than 540,000 health care providers will complete opioid prescriber training in the next two years. In addition, CBS, ABC, the New York Times, Google, the National Basketball Association, Major League Baseball and other companies will donate millions of dollars in media space for PSAs about the risks of prescription drug misuse produced by the Partnership for Drug-Free Kids.

Today, the **President issued a Memorandum to Federal Departments and Agencies** directing two important steps to combat the prescription drug abuse and heroin epidemic:

- Prescriber Training: First, to help ensure that health care professionals who prescribe opioids are
 properly trained in opioid prescribing and to establish the Federal Government as a model, the
 Presidential Memorandum requires Federal Departments and Agencies to provide training on the
 prescribing of these medications to Federal health care professionals who prescribe controlled
 substances as part of their Federal responsibilities.
- *Improving Access to Treatment*: Second, to improve access to treatment for prescription drug abuse and heroin use, the Presidential Memorandum directs Federal Departments and Agencies that directly provide, contract to provide, reimburse for, or otherwise facilitate access to health benefits, to conduct a review to identify barriers to medication-assisted treatment for opioid use disorders and develop action plans to address these barriers.

More Americans now die every year from drug overdoses than they do in motor vehicle crashes and the majority of those overdoses involve prescription medications. Health care providers wrote 259 million prescriptions for opioid pain medications in 2012 – enough for every American adult to have a bottle of pills. Opioids are a class of prescription pain medications that includes hydrocodone, oxycodone, morphine, and methadone. Heroin belongs to the same class of drugs, and four in five heroin users started out by misusing prescription opioid pain medications.

In 2010, the President released his first National Drug Control Strategy, which emphasized the need for action to address opioid use disorders and overdose, while ensuring that individuals with pain receive safe, effective treatment. Since then, the Administration has supported and expanded community-based efforts to prevent drug use, pursue 'smart on crime' approaches to drug enforcement, improve prescribing practices for pain medication, increase access to treatment, work to reduce overdose deaths, and support the millions of Americans in recovery.

The most recent data show that the rate of overdoses involving prescription pain medication is leveling off, although it remains at an unacceptably high level. But the dramatic rise in heroin-related overdoses – which nearly doubled between 2011 and 2013 – shows the opioid crisis is far from over.

State, Local and Private Sector actions announced today include:

- More than 40 provider groups including physicians, dentists, advanced practice registered nurses, physician assistants, physical therapists and educators -- committed to:
- Have more than 540,000 health care providers complete opioid prescriber training in the next two years;
- Double the number of physicians certified to prescribe buprenorphine for opioid use disorder treatment, from 30,000 to 60,000 over the next three years;
- Double the number of providers that prescribe naloxone--a drug that can reverse an opioid overdose:
- Double the number of health care providers registered with their State Prescription Drug Monitoring Programs in the next two years; and
- Reach more than 4 million health care providers with awareness messaging on opioid abuse, appropriate prescribing practices, and actions providers can take to be a part of the solution in the next two years.

Groups include the American Medical Association, American Osteopathic Association, American Academy of Family Physicians, American College of Emergency Physicians, American Academy of Hospice and Palliative Medicine, American Congress of Obstetricians and Gynecologists, American Academy of Pediatricians, American Society of Anesthesiologists, American Society of Addiction Medicine, American College of Osteopathic Internists, American Pain Society, American Academy of Addiction Psychiatry, American College of Physicians, American College of Osteopathic Emergency Physicians, American Academy of Pain Medicine, Interstate Postgraduate Medical Association, Physician's Institute, American College of Osteopathic Surgeons, American College of Osteopathic Family Physicians, American Osteopathic Academy of Addiction Medicine, American Medical Student Association, American Medical Women's Association, Michigan Osteopathic Association, Ohio Osteopathic Association, Massachusetts Medical Society, Washington Osteopathic Medical Association, New Mexico Medical Society, California Academy of Family Physicians, Conjoint Committee on Continuing Education, Collaboration for REMS Education, American Nurses Association, American Association of Nurse Practitioners, American Association of Nurse Anesthetists, Association of Women's Health, Obstetric and Neonatal Nurses, American Psychiatric Nurses Association, American Association of Colleges of Nursing, National Association of Clinical Nurse Specialists, Nurse Practitioner Healthcare Foundation, American Academy of Physician Assistants, Physician Assistant Education Association, American Dental Association, American Physical Therapy Association, Association of American Medical Colleges, American Public Health Association, and Medscape.

CVS Health will allow CVS/pharmacy to dispense naloxone without patients needing to present an individual prescription pursuant to a standing order from a physician or collaborative practice agreement in an additional 20 states in 2016 and will launch a new drug abuse prevention program called Pharmacists Teach, where its pharmacists will make 2,500 presentations in high school health classes. **Rite Aid** will train 6,000 pharmacists on naloxone use over the next 12 months, and expand their naloxone dispensing program to additional states. The National **Association of Chain Drug Stores** will continue to educate their 125 chain member companies (40,000 pharmacies with 175,000 pharmacists) about opioid overdose and naloxone. **The** National Community Pharmacists Association, representing 23,000 pharmacies with over 62,000 pharmacists, will be distributing inserts to community pharmacists that highlight safe drug disposal and naloxone. The American Pharmacists Association, with an outreach capability to more than 250,000 individuals, will educate pharmacists, student pharmacists, and stakeholders through a new Resource Center on opioid use, misuse, and abuse. The American Society of **Health-System Pharmacists** will provide training and resources to 40,000 pharmacists, student pharmacists and pharmacy technicians. The National Association of Boards of Pharmacy will enhance access to prescription drug monitoring program data to thousands more physicians and pharmacists in Arizona, Delaware, Kentucky, and North Dakota in 2016.

- The **Fraternal Order of Police** will provide their 330,000 members with an Opioid Overdose Resuscitation card to help identify and respond to overdoses. They will also educate thousands of their members through in-person and webinar overdose prevention trainings over the next year. The **International Association of Chiefs of Police** will host several educational sessions on the role of law enforcement in overdose prevention at its annual conference and will also hold an overdose prevention training webinar for its members.
- The National Association of Counties, National League of Cities, and United States
 Conference of Mayors, in conjunction with U.S. Communities Purchasing Alliance and
 Premier, Inc., will secure industry-leading discounts for tens of thousands of public agencies on
 naloxone and medications for treatment through their purchasing program that pools the
 purchasing power of state and local governments.
- To support the Partnership for Drug-Free Kids' media campaign over the next year to increase the education and awareness of young people and their parents about the risks of prescription drug misuse, CBS Television Network, Turner Broadcasting, ABC owned and operated TV Stations, The New York Times, Google, Café Mom, and Meredith are committing more than \$20 million in donated airtime and advertising space, and additional commitments are expected. The National Basketball Association and Major League Baseball will also run public service announcements across their respective media assets. The Partnership is also releasing an online toolkit to help local governments, law enforcement, and other community jurisdictions implement local drug disposal programs.
- Because prescription opioid misuse is a growing concern in high school and college athletics, The National Collegiate Athletic Association will educate more than 30,000 student-athletes about the dangers of prescription drug misuse, publish best practices to support student-athlete behavioral health, and sponsor the third Step UP! Bystander Intervention conference to equip educators to assist their students and student-athletes in intervening with peers on a host of behavioral concerns, including prescription drug misuse. The National Association of High School Coaches will launch a drug prevention awareness campaign that will be shared with 320,000 head high school coaches and approximately 60,000 high school administrators. The American College of Sports Medicine will mobilize more than 500,000 sports medicine professionals in support of their "Better Move Campaign" to reduce the overuse and overdose of prescription pain medications. The National Athletic Trainers' Association will share educational materials on opioid misuse prevention to 40,000 athletic trainers. The National Interscholastic Athletic Administrators Association will educate its membership of over 9,500 secondary school athletic administrators about substance use and its relationship to health and performance through its professional development program.
- The National PTA, which has more than four million members, will distribute prescription drug
 misuse awareness and educational materials to its members and promote them through its digital
 assets.
- Governors and local governments will be taking new actions to reduce opioid misuse and overdose throughout the next year. The **National Association of Counties** will mobilize more county leaders to implement smart strategies to reduce opioid misuse and overdose through their *Safe and Secure Counties Initiative*. The **National Governors Association** will launch a *Developing Effective State Responses to the Heroin Epidemic* project to help states identify and implement effective strategies for reducing heroin use and overdose. The **United States Conference of Mayors,** through its new Substance Abuse, Prevention, and Recovery Services Task Force, will identify effective prevention, intervention, treatment, recovery, and support services to promote to city mayors nationwide.

- The **Harm Reduction Coalition** will increase the number of naloxone doses provided through its network of partners from 130,000 in 2013 to 400,000 in 2016 and will work with 10 state prisons to provide training and naloxone kits to 4,000 pre-release inmates and their family members in 2016. They will also convene a national summit on how syringe services programs are integrating broader prevention, counseling, care and treatment initiatives in response to the opioid epidemic.
- The Elks National Drug Awareness Program will purchase and install at least 500 prescription drug disposal boxes in communities where heroin use and prescription drug abuse are most prevalent by the end of 2016.
- The **Community Anti-Drug Coalitions of America** will train 2,000 youth leaders across the country about the dangers of prescription drug abuse; train 12,000 youth and adult leaders on effective prescription drug abuse prevention strategies; and hold 100 community forums to mobilize youth and adult leaders on this issue in 2016.
- The Dr. Oz Show will launch a campaign leading up to a *National Night of Conversation* event on November 19 to encourage parents to talk with their children about prescription pain medications, heroin, and other drugs. Dr. Oz will promote this prevention initiative to millions of Americans through his show, other media appearances, and his nationally syndicated newspaper column.
- The **Blue Cross Blue Shield Association** is launching a national opioid use awareness campaign to help communities find local solutions for prevention and treatment.
- The American Physical Therapy Association will reach more than 2.5 million members of the public and more than 100,000 of its members through awareness campaigns about the benefits of physical therapy as a potential alternative to prescription pain medications. The National Association of Social Workers will expand training for its 132,000 members on treatment of substance use disorders including opioid misuse, and will train school social workers to partner with parent and school organizations on prevention efforts. The American Public Health Association will provide continuing education credit training on prescription drug overdose to more than 1,500 health providers and distribute prescription drug misuse awareness materials to over 300,000 public health professionals.
- The American Association of Colleges of Nursing, the Association of American Medical
 Colleges, and the Physician Assistant Education Association will share professional guidance
 and best practices to better educate the next generation of health care workers on opioid misuse
 and substance use disorders.
- WebMD and Medscape are committed to increasing awareness of opioid issues and informing
 and educating consumer and professional audiences. In
 December, WebMD and Medscape will produce a report on consumer and health care
 professionals' awareness of issues surrounding opioid use. The report will be based on findings of
 a joint survey of consumers and health care professionals and explore issues ranging from
 prescribing practices and guidelines to the use and disposal of the drugs, as well as general levels
 of awareness around their misuse.

Additional Federal actions announced today include:

• The **Drug Enforcement Administration** announced that it will continue its National Prescription Drug Take-Back Day program events in the spring and fall of 2016. As the President highlighted in a recent Weekly Address, Take-Back Day aims to provide a safe, convenient, and responsible means of disposing of unused prescription drugs, while educating the public about the dangers of misusing medications.

- The **Department of Health and Human Services** (HHS) will undertake a review of how pain management is evaluated by patient satisfaction surveys used by hospitals and other health care providers, including review of how the questions these surveys use to assess pain management may relate to pain management practices and opioid prescribing.
- The Centers for Disease Control and Prevention (CDC) will invest \$8.5 million on the development of tools and resources to help inform prescribers about appropriate opioid prescribing; track data on prescribing trends; research, develop, and evaluate clinical quality improvement measures and programs on opioid prescribing; and improve public understanding of the risks and benefits of opioid use.
- **HHS** also launched HHS.gov/opioids as a one-stop federal resource with tools and information for families, health care providers, law enforcement, and other stakeholders on prescription drug abuse and heroin use prevention, treatment, and response.
- U.S. Surgeon General Vivek Murthy is developing an education campaign for doctors, dentists and other health care professionals who prescribe opioid pain medications. Earlier this month, Dr. Murthy also announced that work has begun on the first-ever Surgeon General's Report on substance use, addiction and health scheduled for publication in 2016.
- Centers for Medicare and Medicaid Services (CMS) will release an Information Bulletin to States by the end of the year on steps States can take through their Medicaid preferred drug lists (PDLs) and other utilization management mechanisms to reduce the risk of overdose. This includes a recommendation that they consider removing methadone from their PDLs for pain management. The Centers for Disease Control and Prevention has found that the use of methadone in pain treatment is associated with a disproportionately high number of overdose deaths compared to other opioid pain relievers.
- This fall, **CMS** is testing three new Medicare prescription drug plan measures designed to identify potential opioid overutilization, with the goal of proposing publicly reportable measures for Part D drug plans next year. These measures are based on the work of the Pharmacy Quality Alliance.
- The Department of Veterans Affairs will lead a research initiative to evaluate non-opioid alternative approaches to pain management. The Department of Defense (DoD) and VA are developing a standardized pain management curriculum for widespread use in education and training programs.
- The **Bureau of Indian Affairs** (BIA) and the **Indian Health Service** will provide BIA police officers and investigators the overdose reversal drug naloxone and training on its use. In 2016, the BIA, through the United States Indian Police Academy, will provide training to all BIA and tribal police officer cadets in recognizing opioid use disorders and overdose symptoms.
- The White House will host a **Champions of Change** event this spring to highlight individuals in communities across the country who are leading the fight to respond to prescription drug abuse and heroin use.

Today's actions build on the Administration's commitment to confronting this epidemic:

In 2010, the President released his first National Drug Control Strategy, emphasizing the need for action to address opioid use disorders and overdose, while ensuring that individuals with pain receive safe, effective treatment. The next year, the White House released its national Prescription Drug Abuse Prevention Plan to outline our goals for addressing prescription drug abuse and overdose.

The President's Fiscal Year 2016 budget includes \$133 million in new investments aimed at addressing the opioid epidemic, including expanding state-level prescription drug overdose prevention strategies, medication-assisted treatment programs, and access to the overdose-reversal drug naloxone.

Examples of additional actions by the Administration to address the opioid epidemic include:

Community Prevention and Overdose Response

- In 2015, the CDC launched the *Prescription Drug Overdose: Prevention for States Program*, which provided \$20 million to states to support strategies to improve prescribing practices and prevent opioid overdose deaths.
- Through the National Take Back Days to remove unused prescription drugs from the community, the Drug Enforcement Administration (DEA) has collected more than 5.5 million pounds of medication and introduced several new ways to dispose of unused prescription drugs – including pre-paid return-mail packages. DEA also finalized a new rule making it easier for communities to establish ongoing drug take-back programs.
- In 2012, the Department of Veterans Affairs established an Opioid Safety Initiative to enhance safe and effective pain care for veterans. VA medical centers have filled more than 6,500 naloxone kit prescriptions, and VA's efforts to make opioid overdose kits available has resulted in at least 100 lives saved.
- With support from the Department of Justice (DOJ) and other funders, 49 states have established Prescription Drug Monitoring Programs to help prescribers identify potential opioid misuse issues.
- In 2015, HHS announced a targeted initiative to combat opioid related overdose, death, and dependence focused on increasing prescriber training, increasing the use of the overdose reversal drug naloxone, and expanding the use of medication-assisted treatment.
- The federal government is expanding access to prescription drug monitoring program data throughout federal agencies. DoD's Pharmacy Data Transaction Service automatically screens all new medication orders against a patient's computerized medication history and permits DoD to monitor for concerning drug usage patterns. DoD's Polypharmacy Medication Analysis Reporting is being used to identify high risk active duty service members based on their medication use and emergency department encounters. The Indian Health Service has successfully piloted integrating this data into their electronic systems, and a pilot to integrate data into the workflow of physicians in the DoD health system is slated to launch in 2016.
- The DOJ Bureau of Justice Assistance released a Law Enforcement Naloxone Toolkit to support law enforcement agencies in establishing naloxone programs. The toolkit has been downloaded more than 2,200 times in the last year.
- DOD is ensuring that opioid overdose reversal kits and training are available to every first responder on military bases or other areas under its control.
- The Office of National Drug Control Policy supports local Drug Free Communities coalitions to reduce youth substance use through evidence-based prevention. In recent years, hundreds of these coalitions have specifically focused on prescription drug misuse issues in their areas.

Treatment

- Thanks to the Affordable Care Act, substance use disorder and mental health services are essential
 health benefits that are required to be covered by health plans in the Health Insurance
 Marketplace.
- New rules finalized by this Administration ensure that covered mental health and substance use disorder benefits are comparable to medical and surgical benefits.
- HHS is investing up to \$100 million in Affordable Care Act funding to expand substance use disorder treatment, with a focus on medication-assisted treatment for opioid use disorders, in community health centers across the country.

- HHS Secretary Burwell announced that the Department will engage in rulemaking related to the
 prescribing of buprenorphine-containing products approved by the FDA for treatment of opioid
 dependence to expand access to medication-assisted treatment for opioid use disorders. HHS will
 take a strategic approach in order to minimize diversion and ensure evidence-based treatment.
- The CDC has been working over the last year with clinical experts and other stakeholders to develop new, peer-reviewed guidelines on prescribing opioids for chronic pain outside end of life settings to help improve the way opioids are prescribed and ensure patients have access to safer, more effective chronic pain treatment, while reducing opioid misuse and overdose.
- HHS recently awarded \$11 million in new grants to States to support medication-assisted treatment and \$1.8 million to help rural communities purchase naloxone and train first responders in its use.

Enforcement and Supply Reduction

- The White House Office of National Drug Control Policy's High Intensity Drug Trafficking Areas program is funding an unprecedented network of public health and law enforcement partnerships to address the heroin threat across 15 states.
- In October of 2015, DOJ's Office of Community Oriented Policing Services (COPS Office) awarded \$6 million through the Anti-Heroin Task Force Program, which is designed to advance public safety by providing funds to investigate illicit activities related to the distribution of heroin or unlawful distribution of prescriptive opioids, or unlawful heroin and prescription opioid traffickers through statewide collaboration.
- DOJ's enforcement efforts include targeting the illegal opioid supply chain, thwarting doctorshopping attempts, and disrupting so-called "pill mills."
- DOJ has cracked down on those who use the Internet to buy and sell controlled substances.
- DEA agents and investigators are integrating with other federal, state, and local law enforcement officers in 66 Tactical Diversion Squads stationed across 41 states, Puerto Rico, and the District of Columbia. Outcomes of this effort include the largest pharmaceutical-related takedown in the DEA's history in an operation that resulted in 280 arrests.
- Since 2007, through the Merida Initiative, the Department of State has been working with the
 Government of Mexico to help build the capacity of Mexico's law enforcement and justice sector
 institutions to disrupt drug trafficking organizations and to stop the flow of illicit drugs including
 heroin from Mexico to the United States.

###

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 21, 2015

October 21, 2015

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Addressing Prescription Drug Abuse and Heroin Use

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to reduce prescription pain medication and heroin overdose deaths, promote the appropriate and effective prescribing of pain medications, and improve access to treatment, I hereby direct the following:

Section 1. Policy. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country. Prescription drugs — especially opioid pain medications — have been implicated increasingly in drug overdose deaths over the last decade. According to the Centers for Disease Control and Prevention (CDC), the number of overdose deaths involving prescription opioids quadrupled between 1999 and 2013, with more than 16,000 deaths in 2013. In recent years, overdose deaths involving heroin have sharply increased, nearly doubling between 2011 and 2013. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

One of the most significant ways to address these issues is to ensure that medical professionals receive adequate training on appropriate pain medication prescribing practices, and the risks associated with these medications. The Federal Government must do more to ensure that such training is provided on an ongoing basis to health care professionals prescribing pain medications. Work is already underway to achieve this goal across executive departments and agencies, but these efforts must be accelerated given the urgency of the problem. The training of Federal health care personnel in appropriate prescribing of controlled substances should be a model for similar initiatives developed across the country.

An additional priority in addressing prescription opioid pain medication misuse and heroin use is improved access to medication-assisted treatment (MAT). MAT is the use of Food and Drug Administration (FDA)-approved medications, such as buprenorphine, buprenorphine-naloxone combination products, methadone, and naltrexone -- in combination with counseling, other behavioral therapies, and patient monitoring -- to provide treatment for opioid use disorders. Only a small minority of Americans who might benefit from this treatment are receiving it. Federally administered health benefit programs can help to increase access to these services. These programs also can

2

serve as models for reviewing and modernizing coverage policies and benefit management strategies in response to clinical prescribing guidelines and recommendations for the treatment of chronic pain. For example, a CDC study found that the use of methadone in pain treatment is associated with a disproportionately high number of overdose deaths compared to other opioid pain relievers. Federally administered health benefit programs can use benefit design and formulary management to take steps to reduce the risk of opioid use disorders.

- Training for Federal Prescribers. (a) Executive departments and agencies (agencies) shall, to the extent permitted by law, provide training on the appropriate and effective prescribing of opioid medications to all employees who are health care professionals and who prescribe controlled substances as part of their Federal responsibilities and duties. Agencies also shall require all contractors who are health care professionals, spend 50 percent or more of their clinical time under contract with the Federal Government, and prescribe controlled substances under the terms and conditions of their contract or agreement with the Federal Government to obtain such training. These training requirements shall also be implemented for clinical residents and other clinical trainees who spend 50 percent or more of their clinical time practicing in an executive department or agency facility.
- (b) The training must address, at a minimum, best practices for appropriate and effective prescribing of pain medications, principles of pain management, the misuse potential of controlled substances, identification of potential substance use disorders and referral to further evaluation and treatment, and proper methods for disposing of controlled substances. Training approaches may include both traditional continuing education models and models that pair intensive coaching for the highest volume prescribers with case-based courses for other prescribers. To the extent feasible, training adopted by agencies should be consistent with consensus guidelines on pain medication prescribing developed by the CDC.
- (c) Agencies shall require all employees, contractors, and clinical residents and trainees described in subsection (a) of this section to complete training within 18 months of the date of this memorandum and a refresher course every 3 years thereafter.
- Sec. 3. Improving Access to Medication-Assisted Treatment and Modernizing Benefit Design. (a) Agencies that directly provide health care services, contract to provide health care services, reimburse for health care services, or facilitate access to health benefits shall, to the extent available and permitted by law, review all health benefit requirements, drug formularies, program guidelines, medical management strategies, drug utilization review programs, and all other relevant policies, tools, and strategies in order to identify any barriers individuals with opioid use disorders would encounter in accessing MAT. This review also shall identify any current practices, such as use of methadone as a preferred or first-line pain management drug that are inconsistent with the goals of reducing opioid use disorders and overdoses.
- (b) Not later than 90 days after the date of this memorandum, each agency described in subsection (a) of this

section shall submit an action plan to the Directors of the White House Domestic Policy Council and the White House Office of National Drug Control Policy addressing the barriers and practices identified in their reviews.

- (c) The Secretary of Health and Human Services shall make clinical and other experts from agencies within the Department of Health and Human Services, such as the National Institutes of Health, the CDC, the Substance Abuse and Mental Health Services Administration, and the FDA, available to consult with other agencies on their reviews as necessary.
- Sec. 4. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:
 - (i) the authority granted by law to a department or agency, or the head thereof; or
 - (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA