The Problem of Prescription Drug Use in the United States

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Table of Contents

EXECUTIVE SUMMARY

Introduction

The United States is in the midst of an unprecedented drug overdose epidemic. Drug overdose death rates have increased five-fold since 1980.[1] By 2009, drug overdose deaths outnumbered deaths due to motor vehicle crashes for the first time in the U.S. Prescription drugs, especially opioid analgesics, have been increasingly involved in drug overdose deaths.[2] Opioid analgesics were involved in 30% of drug overdose deaths where a drug was specified in 1999, compared to nearly 60% in 2010. Opioid-related overdose deaths now outnumber overdose deaths involving all illicit drugs such as heroin and cocaine combined.[3] In addition to overdose deaths, emergency department visits, substance treatment admissions and economic costs associated with opioid abuse have all increased in recent years.

The problem of prescription drug abuse and overdose is complex and multi-faceted. There are multiple drivers of the problem, such as provider clinical practices; insufficient oversight to curb inappropriate prescribing; insurance and pharmacy benefit policies; and a belief by many people that prescription drugs are not dangerous, which is associated with increased use. An effective response therefore requires a multi-pronged, targeted, and sustained approach that can only be achieved through a coordinated effort among public health, clinical medicine, public safety, and other stakeholders. Additionally, because opioid analgesics are centrally involved in prescription drug abuse and overdose, the situation is further complicated because of the often unmet need for adequate pain treatment. Therefore, any strategy to address prescription drug abuse must also balance the legitimate needs of patients and ensure that access to pain treatment is not unnecessarily restricted.

HHS has been at the forefront on this issue, working with partners at the federal, state, and local levels to implement policies and programs to reduce prescription drug abuse and improve public health. HHS routinely coordinates with the Office of National Drug Control Policy (ONDCP) and the Departments of Justice, Education, Veterans Affairs, and Defense on this issue.

Purpose of the Report

This report was prepared in response to a congressional directive (Section 1122 of the Food and Drug Administration Safety and Innovation Act of 2012,[4]) to the Department of Health and Human Services (HHS) to improve the understanding of current prescription drug abuse activities and produce a report which provides a review of current initiatives and identifies opportunities to ensure the safe use of prescription drugs with the potential for abuse and the treatment of prescription drug dependence.

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[1] Warner M, Chen LH, Makuc DM, Anderson RN, Miniño AM. Drug poisoning deaths in the United States, 1980–2008. NCHS data brief, no 81. Hyattsville, MD: National Center for Health Statistics. 2011.
[2] 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.
[3] Centers for Disease Control and Prevention. WONDER [database]. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2013. Available at http://wonder.cdc.gov.
[4] Public Law 112-144. Food and Drug Administration Safety and Innovation Act of 2012, Section 1122. Available at: http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf

Findings in the Report

Although other prescription drugs are involved in abuse and overdose, the findings in this report primarily focus on opioid analgesics due to the significant role these drugs play in abuse and overdose. As described in this report, current HHS prescription drug abuse activities fall within the following eight domains: 1) surveillance, 2) drug abuse prevention, 3) patient and public education, 4) provider education, 5) clinical practice tools, 6) regulatory and oversight activities, 7) drug abuse treatment, and 8) overdose prevention. Each of these areas contributes to ensuring the safe use of prescription drugs and the treatment of prescription drug dependence. Although significant efforts are already underway, a review of current activities along with a review of the prescription drug abuse literature, identified opportunities to enhance policy and programmatic efforts as well as future research are presented. Below are the overarching opportunities to enhance current activities identified in this report.

- Strengthen surveillance systems and capacity
- Build the evidence-base for prescription drug abuse prevention programs
- Enhance coordination of patient, public, and provider education programs among federal agencies
- Further develop targeted patient, public, and provider education programs
- Support efforts to increase provider use of prescription drug monitoring programs (PDMPs)
- Leverage health information technology to improve clinical care and reduce abuse
- Synthesize pain management guideline recommendations and incorporate into clinical decision support tools
- Collaborate with insurers and pharmacy benefit managers to implement robust claims review programs
- Collaborate with insurers, and pharmacy benefit managers to identify and implement programs that improve oversight of high-risk prescribing.
- Improve analytic tools for regulatory and oversight purposes
- Continue efforts to integrate drug abuse treatment and primary care
- Expand efforts to increase access to medication-assisted treatment
- Expand Screening, Brief Intervention, and Referral to Treatment services
- Prevent opioid overdose through new formulations of naloxone

Described more fully in Section III of the report, the opportunities listed above serve to strengthen programs and policies to reduce prescription drug abuse and overdose in the U.S. HHS has been at the forefront of the response to this serious public health issue and is committed to working with our federal, state, local governmental and non-governmental partners to further the actions included in this report.

I. BACKGROUND

Introduction

The problem of prescription drug abuse and its related health consequences is a significant public health concern in the U.S. Drug overdose death rates in the U.S. have increased five-fold since 1980.[5] In 2009, for the first time in the U.S., drug overdose deaths outnumbered deaths due to motor vehicle crashes. Prescription drugs, especially opioid analgesics, have been increasingly involved in overdose deaths over the last decade.[6] Opioid analgesics were involved in 30% of drug overdose deaths where a drug was specified in 1999; by 2010, this had increased to nearly 60% of overdose deaths. In 2010 alone, opioid analgesics were involved in 16,651 deaths – far exceeding deaths from any other drug or drug class, licit or illicit.[7]

Morbidity associated with prescription drug abuse has also increased. Rates of prescription drug abuse related emergency department visits and treatment admissions have risen significantly in recent years.[8,9] Additional adverse health consequences that may result from prescription drug misuse and abuse include transitions to injection drug use with resulting risk for infections such as hepatitis C and HIV[10,11], falls and fractures in older adults[12,13], and neonatal opioid withdrawal syndrome[14,15]. Moreover, the economic costs of prescription drug abuse are substantial. It is estimated that the abuse of opioid analgesics results in over $72 billion in medical costs alone each year.[16] This is comparable to costs related to other chronic diseases such as asthma and HIV.[17,18]

The problem of prescription drug abuse and overdose is complex and multi-faceted. The prevalence and type of health consequence varies depending on age, gender, race, ethnicity, geography, socioeconomic factors, and diagnosed medical conditions. There are multiple drivers of the problem, such as provider clinical practices; insufficient oversight to curb inappropriate

[5] Warner M, Chen L, Makuc D, Anderson R, Miniño A. Drug poisoning deaths in the United States, 1980–2008. NCHS Data Brief, no 81. Hyattsville, MD: National Center for Health Statistics; 2011.
[6] 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.
[7] Jones CM, Mack KA, Paulozzi LJ. Pharmaceutical overdose deaths, United States, 2010. JAMA 2013;20;309(7):657-659.
[8] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *The DAWN Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits*. Rockville, MD.
[9] 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.
[10] Havens, JR, Lofwall MR, Frost SD, et al. Individual and network factors associated with prevalent hepatitis C infection among rural Appalachian injection drug users. Am J Public Health 2013;103(1):e44-52.
[11] Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010. Drug Alcohol Depend. 2013. doi: 10.1016/j.drugalcdep.2013.01.007.
[12] Miller M, Sturmer T, Azrael D, Levin R, Solomon DH. Opioid analgesics and the risk of fractures in older adults with arthirits. J Am Geriatr Soc. 2011;59(3):430-438.
[13] Rolita L, Spegman A, Tang X, Cronstein BN. Greater number of narcotic analgesic prescriptions for osteoarthritis is associated with falls and fractures in elderly adults. J Am Geriatr Soc. 2013;61(3):335-340.
[14] Creanga AA, Sabel JC, Ko JY, Wasserman CR, Shapiro-Medoza CK, Taylor P, Barfield W, et al. Maternal drug use and its effect on neonates: a population-based study in Washington State. Obstet Gynecol. 2012;199(5):924-933.
[15] Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. JAMA. 2012;9;307(18):1934-1940.
[16] Coalition Against Insurance Fraud. Prescription for peril: how insurance fraud finances theft and abuse of addictive prescription drugs. Washington, DC: Coalition Against Insurance Fraud; 2007. Available at http://www.insurancefraud.org/downloads/drugDiversion.pdf.
[17] Asthma and Allergy Foundation of America. The costs of asthma: Asthma and Allergy Foundation 1992 and 1998 Study, 2000 Update. Available at http://www.aafa.org/display.cfm?id=9&sub=42#_ftn18.
[18] Hutchinson AB, Farnham PG, Dean HD, et al. The economic burden of HIV in the United States in the era of highly active antiretroviral therapy: evidence of continuing racial and ethnic differences. J Acquir Immune Defic Snydr. 2006;43(4):451-457.

prescribing; insurance and pharmacy benefit policies; and a belief by young people that prescription drugs are not dangerous, which is associated with increased use. An effective response therefore requires a multi-pronged, targeted, and sustained approach that can only be achieved through a coordinated effort among public health, clinical medicine, public safety, and other stakeholders. Any such strategy must also balance the legitimate needs of patients and ensure that access to pain treatment is not unnecessarily restricted.

Over several years, the Department of Health and Human Services (HHS) has undertaken a range of activities to better understand the patient and clinical practice risk factors contributing to prescription drug abuse and overdose. HHS is a strong partner in the implementation of the Administration's National Drug Control Strategy and Prescription Drug Abuse Prevention Plan, leading or supporting 53 of the 90 action items in the Strategy and 29 of the 35 action items in the Prevention Plan. This is in addition to long-standing coordination with the Departments of Justice (DOJ), Education (ED), Veterans Affairs (VA), and Defense (DOD), among others. These activities have led to the identification, development, and implementation of promising interventions and partnerships with a number of stakeholders, and significant advances in efforts to reduce the health consequences associated with prescription drug abuse.

Purpose of the Report

This report was developed pursuant to Section 1122 of the Food and Drug Administration Safety and Innovation Act of 2012 (hereafter, referred to as FDASIA). Section 1122 of FDASIA requires the Secretary of HHS, in coordination with other federal agencies, as appropriate, to review current federal initiatives and identify gaps and opportunities with respect to 1) ensuring the safe use of prescription drugs with the potential for abuse; and 2) the treatment of prescription drug dependence.[19]

The report provides information on current prescription drug abuse activities and future opportunities to enhance activities within HHS. A brief review of the evidence to support interventions is included where appropriate. Federal initiatives conducted outside of HHS are referenced throughout the document, when appropriate, but are not reviewed comprehensively. Non-federal activities are not discussed unless they specifically involve collaboration with HHS. The findings in the report are intended to help strengthen programs and policies and future research on prescription drug abuse and overdose.

Structure and Approach of the Report

Following the Executive Summary, the *first section* of the report contains the purpose, structure, and methods of the report. The *second section* describes the epidemiology and drivers of prescription drug abuse in the U.S. The *third section* highlights current HHS activities to address prescription drug abuse within eight domains: 1) surveillance, 2) drug abuse prevention, 3) patient and public education, 4) provider education, 5) clinical practice tools, 6) regulatory and oversight activities, 7) drug abuse treatment, and 8) overdose prevention initiatives. In addition,

[19] Public Law 112-144. Food and Drug Administration Safety and Innovation Act of 2012, Section 1122. Available at: http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf

this section describes opportunities to enhance current activities. The *fourth section* of the report contains conclusions and next steps.

The report is grounded in the epidemiological data on prescription drug abuse. The eight domains in the report were selected because they each address specific drivers of the problem. Specifically, *surveillance* is discussed because it is essential for understanding the problem and targeting the most heavily impacted populations. *Drug abuse prevention*, *patient and public education*, and *provider education* and *clinical practice tools* are included because preventing dangerous or inappropriate use of prescription drugs is the most effective way to avert negative consequences such as overdose deaths. *Regulatory and oversight activities* are leveraged to promote product safety and assure that clinical practices occur within appropriate standards of care. Finally, *drug abuse treatment* and *overdose prevention* activities are included because they target interventions to the populations at greatest risk for overdose. In addition, although other prescription drugs are involved in abuse and overdose, the findings in this report primarily focus on opioid analgesics due to the significant role they play in abuse and overdose.

Methods

This report was developed by the HHS Behavioral Health Coordinating Committee's (BHCC) Prescription Drug Abuse Subcommittee (Subcommittee). Formed in 2010 and co-chaired by the Assistant Secretary for Health and the Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA), the BHCC is charged with coordinating behavioral health activities across HHS and promoting collaborations in five topic areas – prescription drug abuse, behavioral health communications, primary care/behavioral health integration, trauma and early intervention, and underage drinking and alcohol policy. The Subcommittee is comprised of staff from 13 HHS operating and staff divisions[20] and is co-chaired by the Food and Drug Administration (FDA) and the National Institutes of Health's (NIH) National Institute on Drug Abuse (NIDA).

To identify current HHS prescription drug abuse activities, representatives of the Subcommittee completed a survey identifying activities for their operating or staff division within the eight domains outlined above. Opportunities to enhance these activities were identified based on the review of current activities and a review of the prescription drug abuse literature. Further, the Office of National Drug Control Policy (ONDCP) Interagency Working Group on Prescription Drug Abuse was used as a forum to discuss the current progress of prescription drug abuse activities conducted by other federal agencies and to identify additional opportunities for activity enhancement. The Working Group consists of representatives from HHS, DOJ, DOD, and VA, and meets regularly to discuss progress toward attaining the Administration's prescription drug abuse prevention goals.[21]

[20] Operating and staff divisions represented on the subcommittee include: Administration for Community Living, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes on Drug Abuse, Office of the Assistant Secretary for Health, Office of the Assistant Secretary for Planning and Evaluation, Office of the National Coordinator for Health Information Technology, Office of the Secretary, and Substance Abuse and Mental Health Services Administration.

[21] Goals for the National Drug Control Strategy and Prescription Drug Abuse Prevention Plan can be found at the following links: http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs2010.pdf and http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf

II. EPIDEMIOLOGY AND DRIVERS OF PRESCRIPTION DRUG ABUSE IN THE UNITED STATES

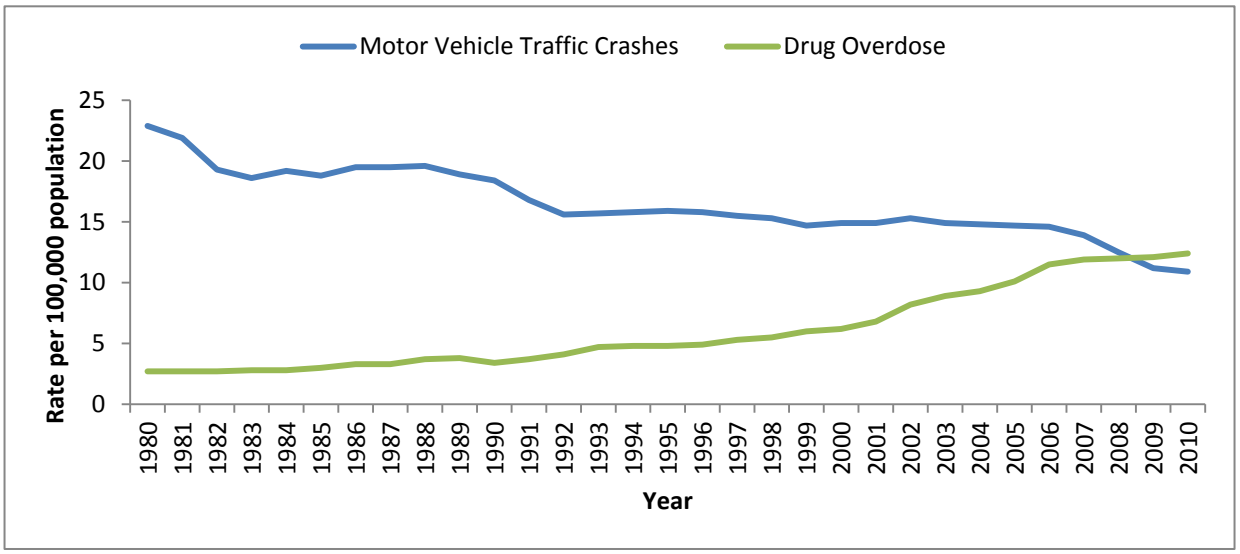
This section provides a review of the epidemiology and drivers of prescription drug abuse in the United States. The first part of this section contains an overview of the public health consequences, demographic and socioeconomic factors, clinical factors, and economic burden. The second part describes the drivers of prescription drug abuse. Understanding both the epidemiology and drivers of the problem are critical for tailoring interventions to best address the problem.

Epidemiology of Prescription Drug Abuse

Public Health Consequences

Drug overdose death rates have increased five-fold since 1980. This dramatic increase in deaths made poisoning deaths, of which nearly 90% are drug overdoses, the leading cause of injury death in the United States in 2008.[22] By 2009, drug overdose deaths in the U.S. outnumbered deaths due to motor vehicle crashes for the first time. That trend continued in 2010, the latest year for which national data are available. (**Figure 1**) The majority of these deaths are unintentional (78.3%); suicide and deaths of undetermined intent account for a much smaller percentage of drug overdose deaths (13.8% and 7.7%, respectively).[23]

Figure 1. Rates of motor vehicle traffic and drug overdose deaths, United States, 1980-2010.



Over the last decade, prescription drugs, especially the opioid analgesics, have been increasingly

[22] Warner M, Chen L, Makuc D, Anderson R, Miniño A. Drug poisoning deaths in the United States, 1980–2008. NCHS Data Brief, no 81. Hyattsville, MD: National Center for Health Statistics; 2011.
[23] Centers for Disease Control and Prevention. CDC Multiple Cause of Death Mortality file. 2012. Available at http://wonder.cdc.gov/mcd.html

involved in overdose deaths.[24] Opioids, alone or in combination with other drugs or alcohol, were involved in 30% of drug overdose deaths where a drug was specified in 1999, compared to nearly 60% in 2010. In 2010 alone, opioid analgesics were involved in 16,651 deaths – far exceeding deaths from any other drug or drug class, licit or illicit.[25] In addition to opioid analgesics, other prescription drugs are involved in overdose deaths. Benzodiazepines were involved in 6,497 overdose deaths and antidepressants were involved in 3,889 overdose deaths in 2010, often in combination with opioid analgesics.[26,27,28,29]

Morbidity associated with prescription drug abuse also has been increasing. Rates of emergency department (ED) visits associated with pharmaceutical misuse or abuse increased 114% between 2004 and 2011. In 2011, more than 1.4 million ED visits annually were due to the misuse or abuse of pharmaceuticals, with 420,000 involving opioid analgesics and 425,000 involving benzodiazepines. In approximately 18% of the pharmaceutical misuse or abuse ED visits, alcohol also was involved. [30] Substance abuse treatment admission rates for opioid analgesic abuse increased six-fold between 1999 and 2010.[31] Additional adverse health consequences that may result from prescription drug misuse and abuse include transitions to injection drug use with resulting risk for infections such as hepatitis C and HIV[32,33], falls and fractures in older adults[34,35], and neonatal opioid withdrawal syndrome[36,37].

Underlying the morbidity and mortality is the large number of people who report nonmedical use of prescription drugs – use without a prescription or use for the feeling or experience the drug caused. In 2011, more than 14 million people reported nonmedical use of prescription drugs in the past year, with 11 million reporting nonmedical use of opioid analgesics.[38] Moreover, chronic nonmedical use of opioid analgesics (i.e. nonmedical use on 200 days or more in the past year) increased roughly 75% between 2002-2003 and 2009-2010 (**Table 1**). This increase means that

[24] 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.
[25] Jones CM, Mack KA, Paulozzi LJ. Pharmaceutical overdose deaths, United States, 2010. JAMA 2013;20;309(7):657-659.
[26] Hall AJ, Logan JE, Toblin RL, Kalpan JA, Kraner JC, Bixler D, Crosby AE, et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. JAMA. 2008;300:2613-2620.
[27] Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, et al. Opioid prescriptions for chronic pain and overdose: a cohort study. Ann Intern Med. 201019;152(2):85-92.
[28] Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA et al. Association between opioid prescribing patterns and opioid overdose-related deaths. JAMA. 2011;305(13):1315-21.
[29] Jones CM, Mack KA, Paulozzi LJ. Pharmaceutical overdose deaths, United States, 2010. JAMA 2013;20;309(7):657-659.
[30] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *The DAWN Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits*. Rockville, MD.
[31] 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.
[32] Havens JR, Lofwall MR Frost SD, et al. Individual and network factors associated with prevalent hepatitis C infection among rural Appalachian injection drug users. Am J Public Health 2013;103(1):e44-52.
[33] Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010. Drug Alcohol Depend. 2013. doi: 10.1016/j.drugalcdep.2013.01.007.
[34] Miller M, Sturmer T, Azrael D, Levin R, Solomon DH. Opioid analgesics and the risk of fractures in older adults with arthirits. J Am Geriatr Soc. 2011;59(3):430-438.
[35] Rolita L, Spegman A, Tang X, Cronstein BN. Greater number of narcotic analgesic prescriptions for osteoarthritis is associated with falls and fractures in elderly adults. J Am Geriatr Soc. 2013;61(3):335-340.
[36] Creanga AA, Sabel JC, Ko JY, Wasserman CR, Shapiro-Medoza CK, Taylor P, Barfield W, et al. Maternal drug use and its effect on neonates: a population-based study in Washington State. Obstet Gynecol. 2012;199(5):924-933.
[37] Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. JAMA. 2012;9;307(18):1934-1940.
[38] Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health: Detailed tables. In *NSDUH Series H-41*. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. 2012.

on average in 2009-2010 there were nearly 1 million people in the U.S. with chronic nonmedical use of opioid analgesics.[39]

Table 1. Average Annual Rates of Past Year Chronic Non-Medical Use of Opioid Analgesics among People 12 Years and Older by Age and Sex, U.S. 2002-2003 and 2009-2010.

Characteristic	2002-2003	2009-2010	Percent Change¥
All Nonmedical Users	2.2	3.8*	74.6
Age			
12-17	4.0	3.0	-25.7
18-25	4.2	7.4*	77.6
26-34	2.8	5.0±	81.0
35-49	1.7	4.0*	134.6
≥ 50	0.9	2.1	124.3
Sex			
Male	2.5	5.1*	105.3
Female	1.9	2.6	36.4

¥ Percent change between 2009-2010 and 2003-2002 annual average rate

± Difference between the 2002-2003 and 2009-2010 annual average rate is statistically significant at the <0.05 level

* Difference between the 2002-2003 and 2009-2010 annual average rate is statistically significant at the <0.01 level

Costs

The economic consequences of prescription drug abuse are substantial. It is estimated that opioid analgesic abuse results in over $72 billion in medical costs each year.[40] Other studies estimate the cost of opioid abuse to be between $53-$56 billion annually, accounting for medical and substance abuse treatment costs, lost work productivity, and criminal justice costs.[41,42] This is comparable to the costs related to other diseases such as asthma and HIV.[43,44] In many instances, public payers are responsible for covering the costs of prescription drug abuse.[45,46]

[39] Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267.
[40] Coalition Against Insurance Fraud. Prescription for peril: how insurance fraud finances theft and abuse of addictive prescription drugs. Washington, DC: Coalition Against Insurance Fraud; 2007. Available at http://www.insurancefraud.org/downloads/drugDiversion.pdf.
[41] Hansen RN, Oster G, Edelsberg J, Woody GE, Sullivan SD. Economic costs of nonmedical use of prescription opioids. Clin J Pain. 2011;27(3):194-202.
[42] Birnbaum HG, White AG, Schiller M, Waldman T, Cleveland JM, Roland CL. Societal costs of prescription opioid abuse, dependence, and misuse in the United States. Pain Med. 2011;12(4):657-667.
[43] Asthma and Allergy Foundation of America. The costs of asthma: Asthma and Allergy Foundation 1992 and 1998 Study, 2000 Update. Available at http://www.aafa.org/display.cfm?id=9&sub=42#_ftn18.
[44] Hutchinson AB, Farnham PG, Dean HD, et al. The economic burden of HIV in the United States in the era of highly active antiretroviral therapy: evidence of continuing racial and ethnic differences. J Acquir Immune Defic Syndr. 2006;43(4):451-457.
[45] Government Accountability Office. Medicaid: Fraud and abuse related to controlled substances identified in selected states. Washington, DC; 2009.
[46] Government Accountability Office. Medicare Part D: Instances of questionable access to prescription drugs. Washington, DC; 2011.

Demographic, Socioeconomic, Geographic and Clinical Factors

Discussed below are the known demographic, socioeconomic, geographic, and clinical factors underlying prescription drug abuse and overdose. Understanding these factors is important to enable the identification of the populations at highest risk for abuse and overdose as well as for the development of interventions that target these high-risk groups.

The rate of chronic nonmedical use of opioids among men is nearly twice that of women,[47] yet more women are prescribed drugs prone to abuse.[48,49] Rates of ED visits for misuse or abuse are roughly equal among men and women.[50] More men die of prescription drug overdoses than women.[51] In 2010, men accounted for a greater percentage of opioid-related substance abuse treatment admissions (53.9% compared to 46.1% for women).[52]

Rates of chronic nonmedical use of opioids are highest among 18-25 year olds, followed by 26-34 year olds, and 35-49 year olds.[53] Rates of ED visits due to misuse or abuse of opioids or benzodiazepines are highest among 21-29 year olds followed by 30-44 and 45-54 year olds.[54] Substance abuse treatment admissions for opioid analgesics are highest for 25-34 year olds, followed by 18-24 year olds, and 35-44 year olds.[55] Drug overdose death rates for opioids are highest among people aged 45-54 years old, followed by 35-44, 25-34, and 55-64 year olds.[56]

There is significant variation in abuse and overdose death rates by race and ethnicity. American Indians/Alaska Natives and Whites report the highest rates of nonmedical use of opioids and also have the highest rates of opioid overdose deaths.[57] Whites also have some of the highest rates for ED visits and substance abuse treatment admissions associated with opioid analgesics.

Socioeconomic Factors

The relationship of opioid overdose risk to socioeconomic status has not been well studied. People who are eligible for Medicaid are more likely to be prescribed opioid analgesics and to be prescribed them at higher doses and for longer periods of time compared to other patient populations.[58,59,60] Overdose deaths are also more common among Medicaid-eligible populations.[61,62]

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[47] Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267.
[48] Raofi S, Schappert, SM. Medication therapy in ambulatory medical care; United States, 2003-2004. *Vital Health Stat*. 2006;*13*(163):1-40.
[49] Simoni-Wastila L, Ritter G, Strickler G. Gender and other factors associated with the nonmedical use of abusable prescription drugs. *Subst Use* Misuse. 2004;39(1):1-23.
[50] Substance Abuse and Mental Health Services Administration. Drug Abuse Warning Network Emergency Department Visit Excel Files. Available at http://www.samhsa.gov/data/DAWN.aspx#DAWN 2010 ED Excel Files - National Tables. Accessed on October 2012.
[51] Paulozzi LJ, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487- 1492.
[52] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2000-2010. National Admissions to Substance Abuse Treatment Services*. DASIS Series S-61, HHS Publication No. (SMA) 12-4701. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.
[53] Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267.
[54] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (July 2, 2012). *The DAWN Report: Highlights of the 2010 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits*. Rockville, MD.
[55] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2000-2010. National Admissions to Substance Abuse Treatment Services*. DASIS Series S-61, HHS Publication No. (SMA) 12-4701. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.
[56] CDC analysis of the 2010 Multiple Cause of Death Mortality File. 2012.
[57] Paulozzi LJ, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487- 1492.
[58] Edlund MJ, Martin BC, Fan M, Braden JB, Devries A, Sullivan M**.** An analysis of heavy utilizers of opioids for chronic noncancer pain in the TROUP Study. J Pain Symptom Manage. 2010;40(2):279-89.

Geographic Factors

In general, the highest rates of death, opioid sales, and nonmedical use are clustered in the Southeast, especially the Appalachian region, and the Northwest.[63,64] Overdose rates also vary by urban-rural county type, based on information from death certificates – with more rural areas having higher overdose death rates for prescription opioids compared to urban areas.[65,66,67,68,69]

Clinical Factors

Fifty to eighty percent of people dying from prescription opioid overdoses have a history of chronic pain.[70,71] Further, studies have found that the risk of overdose increases with increasing doses of opioids.[72,73,74,75] Having a history of mental health and substance abuse problems is also common among people dying from prescription drug overdoses. Studies have found that people with mental health disorders and/or substance use disorders are at increased risk for overdose death.[76,77,78] Studies also indicate that people with mental health or substance use disorders are more likely to be prescribed higher opioid doses and are at increased risk for nonmedical use.[79,80,81,82]

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[59] Platts-Mills T, Hunold K, Bortsov A, Soward A, Peak D, Jones J, Swor, RA, et al. More educated emergency department patients are less likely to receive opioids for acute pain. Pain. 2012;153:967-73.
[60] Raofi S, Schappert, SM. Medication therapy in ambulatory medical care; United States, 2003-2004. *Vital Health Stat*. 2006;*13*(163):1-40.
[61] Whitmire JT, Adams G**.** Unintentional overdose deaths in the North Carolina Medicaid population: prevalence, prescription drug use, and medical care services. Raleigh, NC: State Center for Health Statistics; 2010.
[62] Coolen P, Best S, Lima A, Sabel J, Paulozzi L**.** Overdose deaths involving prescription opioids among Medicaid enrollees -- Washington, 2004-2007. MMWR. 2009;58(42):1171-5.
[63] Paulozzi LJ, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487- 1492.
[64] McDonald DC, Carlson K, Izrael D. Geographic variation in opioid prescribing in the U.S. J Pain. 2012;13(10):988-996.
[65] Centers for Disease Control and Prevention. WONDER [database]. Atlanta, GA: US Dept of Health and Human Services, Centers for Disease Control and Prevention; 2013. Available at http://wonder.cdc.gov.
[66] Johnson EM, Lanier WA, Merrill RM, Crook J, Porucznik CA, Rolfs RT, et al. Unintentional prescription opioid-related overdose deaths: description of decedents by next of kin or best contact, Utah, 2008-2009. J Gen Intern Med. 2012. Doi:10.1007/s11606-012-2225-z.
[67] Piercefield E, Archer P, Kemp P, Mallonee S. Increase in unintentional medication overdose deaths Oklahoma, 1994-2006. Am J Prev Med. 2010;39(4):357-363.
[68] Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. JAMA. 2008;300:2613-2620.
[69] Green TC, Grau LE, Carver HW, Kinzly M, Heimer R. Epidemiologic trends and geographic patterns of fatal opioid intoxications in Connecticut, USA: 1997-2007. Drug Alcohol Depend. 2011;115(3):221-228.
.[70] Lanier WA. Prescription opioid overdose deaths – Utah, 2008-2009. Epidemic Intelligence Service Conference. Atlanta, GA Centers for Disease Control and Prevention. 2010.
[71] Paulozzi LJ, Logan JE, Hall AJ, McKinstry E, Kaplan JA, Crosby AE. A comparison of drug overdose deaths involving methadone and other opioid analgesics in West Virginia. Addiction. 2009;104(9):1541-1548.
[72] Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, et al. Opioid prescriptions for chronic pain and overdose: a cohort study. Ann Intern Med. 201019;152(2):85-92.
[73] Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA et al. Association between opioid prescribing patterns and opioid overdose-related deaths. JAMA. 2011;305(13):1315-21.
[74]Gomes T, Mamdani MM, Dhalla IA, Paterson JM, Juurlink DN. Opioid dose and drug-related mortality in patients with nonmalignant pain. Arch Intern Med 2011;171(7): 686–91.
[75] Paulozzi LJ, Kilbourne EM, Shah NG, Nolte KB, Desai HA, Landen MG et al. A history of being prescribed controlled substances and risk of drug overdose death. Pain Med. 2012;13(1):87-95.
[76] Porucznik CA, Johnson E, Sauer B, Crook J, Rolfs R. Studying adverse events related to prescription opioids: the Utah experience. Pain Med. 2011;12 Suppl 2:S16-25.
[77] Johnson EM, Lanier WA, Merrill RM, Crook J, Porucznik CA, Rolfs RT, et al. Unintentional prescription opioid-related overdose deaths: description of decedents by next of kin or best contact, Utah, 2008-2009. J Gen Intern Med. 2012. Doi:10.1007/s11606-012-2225-z.
[78] Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. JAMA. 2008;300:2613-2620.
[79] Kobus AM, Smith DH, MOrasco BJ, et al. Correlates of higher-dose opioid medication use for low back pain in primary care. J Pain 2012;13(11):1131-1138.
[80] Becker WC, Sullivan LE, Tetrault JM, Desai RA, Fiellin DA. Non-medical use, abuse and dependence on prescription opioids among U.S. adults: psychiatric, medical, and substance use correlates. Drug Alcohol Depend. 2008;94(1-3):38-47.
[81] Tetrault JM, Desai RA, Becker WC, Fiellin DA, Concato J, Sullivan LE. Gender and non-medical use of prescription opioids: results from a national US survey. Addiction. 2008;103(2):258-268.

Having a history of seeing multiple prescribers and pharmacies to obtain controlled substances is also a marker of increased overdose risk.[83,84] Consistent with overdose risk, having a greater number of prescriptions and/or going to a greater number of providers or pharmacies have been identified as predictors of opioid misuse or abuse.[85,86]

The sources of prescription drugs involved in abuse and overdose are a mix of medical and nonmedical sources. Among nonmedical users of opioid analgesics, most report getting them for free from a friend or relative; few bought them from a drug dealer. However, most of the friends or relatives got them from a single doctor.[87] Among high-risk individuals entering methadone treatment, the most common source is a drug dealer.[88] Several studies have underscored the role diversion plays in drug overdose deaths with between 25% and 74% of overdose decedents lacking a prescription for at least one of the drugs that contributed to their death.[89,90,91]

Drivers of the epidemic

Prescribing Trends

Coinciding with the rise in opioid-related morbidity and mortality is an increase in opioid analgesic prescribing, primarily for chronic non-cancer pain.[92,93,94] Since at least 1991, the number of opioid prescriptions dispensed by retail pharmacies has increased each year.[95] Not only has the number of opioid prescriptions increased, the amount prescribed per prescription, the days supply, and the cumulative dose prescribed to individuals has increased too. A study examining national prescribing trends found the average amount of opioid per prescription, in morphine milligram equivalents, increased 69.7% for oxycodone, 69.4% for hydrocodone, and

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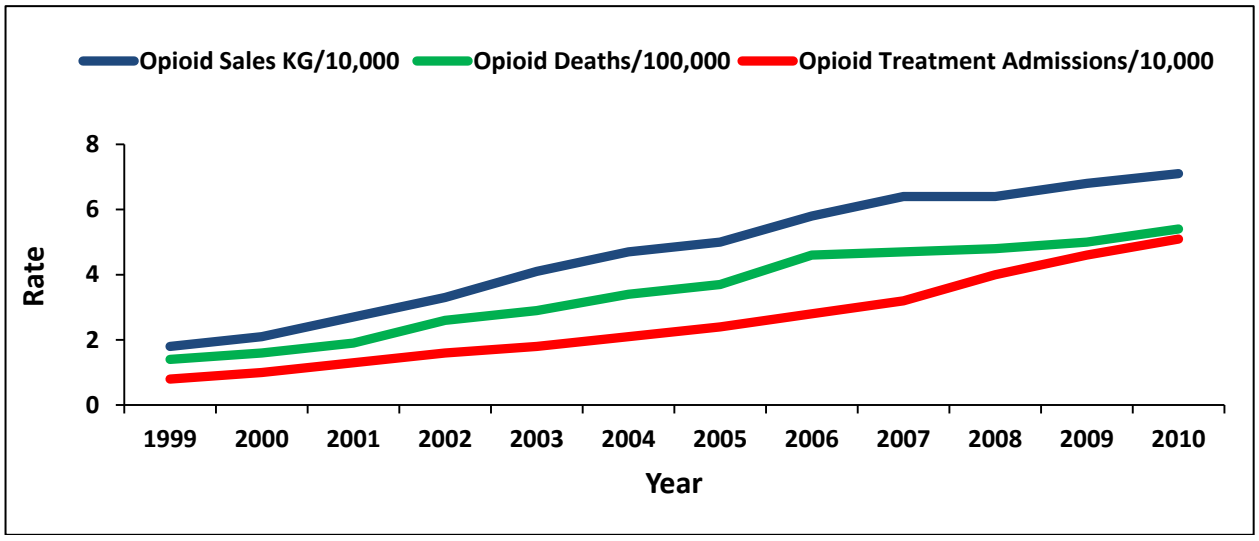
[82] Grattan A, Sullivan MD, Saunders KW, Campbell CI, Von Korff MR. Depression and prescription opioid misuse among chronic opioid therapy recipients with no history of substance abuse. Ann Fam Med. 2012;10(4):304-311.
[83] Pierce GL, Smith MJ, Abate MA, Halverson J. Doctor and pharmacy shopping for controlled substances. Med Care. 2012;50(6):494-500.
[84] Gomes T, Mamdani MM, Dhalla IA, Paterson JM, Juurlink DN. Opioid dose and drug-related mortality in patients with nonmalignant pain. Arch Intern Med 2011;171(7): 686–691.
[85] Rice JB, White AG, Birnbaum HG, Schiller M, Brown DA, Roland CL. A model to identify patients at risk for prescription opioid abuse, dependence, and misuse. Pain Med. 2012;13:1162-1173.
[86] White AG, Birnbaum HG, Schiller M. Tang J, Katz NP. Analytic models to identify patients at risk for prescription opioid abuse. Am J Manag Care. 2009;15(12):897-906.
[87] Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health: Detailed tables. In *NSDUH Series H-41*. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. 2012.
[88] Parrino, M. (2011). Changing drug use patterns among patient admissions to the methadone treatment programs in the U.S. *National Harold Rogers Prescription Monitoring Program Meeting*. Washington, DC.
[89] Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. JAMA. 2008;300:2613-2620.
[90] Johnson EM, Lanier WA, Merrill RM, Crook J, Porucznik CA, Rolfs RT, et al. Unintentional prescription opioid-related overdose deaths: description of decedents by next of kin or best contact, Utah, 2008-2009. J Gen Intern Med. 2012. Doi:10.1007/s11606-012-2225-z.
[91] Whitmire JT, Adams G**.** Unintentional overdose deaths in the North Carolina Medicaid population: prevalence, prescription drug use, and medical care services. Raleigh, NC: State Center for Health Statistics; 2010.
[92] Braden JB, Fan MY, Edlund MJ, Martin BC, DeVries A, Sullivan MD. Trends in use of opioids by non-cancer pain type 200-2005 among Arkansas Medicaid and HealthCore enrollees: Results from the TROUP Study. J Pain. 2008;9(11):1026-1035.
[93] Sullivan MD, Edlund MJ, Fan MY, DeVries A, Braden JB, Martin BC. Trends in use of opioids for non-cancer pain conditions 2000-2005 in commercial and Medicaid insurance plans: The TROUP Study. Pain. 2008;138(2):440-449.
[94] Food and Drug Administration. Risk Evaluation and Mitigation Strategies (REMS) for Extended-Release and Long-Acting Opioid Analgesics Briefing Material. 2010. Available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM217510.pdf
[95] Volkow N. "Prescription Drug Abuse : It's Not what the doctor ordered" presented by Dr. Nora Volkow at the National Prescription Drug Abuse Summit April 2012. Available at: http://www.slideshare.net/OPUNITE/nora-volkow-final-edits

20.9% for fentanyl nationally between 2000 and 2009.[96] Other studies have also documented an increase in either daily opioid dose or cumulative opioid dose over time among different populations including privately insured, Medicaid, and workers compensation.[97,98,99,100,101,102]

An analysis by the Centers for Disease Control and Prevention (CDC) found that opioid analgesic sales increased four-fold between 1999 and 2010, and this was paralleled by an increase in opioid overdose deaths and substance abuse treatment admissions during the same time period.[103] (**Figure 2**) A similar trend was noted for rates of chronic nonmedical use of opioids, opioid sales, opioid overdose deaths, and substance abuse treatment admissions between 2002 and 2010.[104] Other studies have reported an association between opioid prescribing, nonmedical use, and ED visits.[105,106,107]

Figure 2. Rates of opioid overdose deaths, opioid sales, and opioid substance abuse treatment admissions, United States, 1999-2010



[96] Kenan K. Mack K, Paulozzi L. Trends in prescriptions for oxycodone and other commonly used opioids in the United States, 2000-2010. *Open Med*.2012;6(2):41–47.
[97] Braden JB, Fan MY, Edlund MJ, Martin BC, DeVries A, Sullivan MD. Trends in use of opioids by non-cancer pain type 200-2005 among Arkansas Medicaid and HealthCore enrollees: Results from the TROUP Study. J Pain. 2008;9(11):1026-1035.
[98] Tao XG, Lavin RA, Yupeh L, Bernacki EJ. Natural history of opioid dosage escalation post-injury a cohort study of injured workers in the State of Louisiana. J Occup Environ Med. 2012;54(4):439-44.
[99] Sullivan MD, Edlund MJ, Fan MY, DeVries A, Braden JB, Martin BC. Trends in use of opioids for non-cancer pain conditions 2000-2005 in commercial and Medicaid insurance plans: The TROUP Study. Pain. 2008;138(2):440-449.
[100] Franklin GM, Mai J, Wickizer T, Turner JA, Fulton-Kehoe D, Grant L. Opioid dosing trends and mortality in Washington State workers' compensation, 1996-2002. Am J Ind Med. 2005;48:91-99.
[101] Franklin GM, Mai J, Turner J, Sullivan M, Wickizer T, Fulton-Kehoe D. Bending the prescription opioid dosing and mortality curves: impact of the Washington State opioid dosing guideline. Am J Ind Med. 2012;55(4):325-31.
[102] Boudreau D, Von Korff M, Rutter CM, Saunders K, Ray GT, Sullivan MD, et al. Trends in long-term opioid therapy for chronic non-cancer pain. Pharmacoepidemiol Drug Saf. 2009;18(12):1166-1175.
[103] Paulozzi LJ, Jones C, Mack K, Rudd R; Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999-2008. MMWR Morb Mortal Wkly Rep. 2011;60(43):1487- 1492.
[104] Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267.
[105] Wisniewski AM, Purdy CH, Blondell RD. The epidemiologic association between opioid prescribing, non-medical use, and emergency department visits. J Addict Dis. 2008;27(11):1-11.
[106] Braden JB, Russo J, Fan MY, et al. Emergency department visits among recipients of chronic opioid therapy. Arch Intern Med 2010;170:1425-32.
[107] Compton WM, Volkow ND. Major increases in opioid analgesic abuse in the United States: concerns and strategies. Drug Alcohol Depend. 2006;81(2):103-107.

High-Volume Prescribing

Multiple studies have shown that a small percentage of prescribers are responsible for prescribing the majority of opioids. Eighty-two percent of controlled substance prescriptions written in Kentucky in 2009 came from the top 20% of prescribers.[108] An examination of Oregon's prescription drug monitoring program (PDMP) found that 2,000 of the state's 49,330 prescribers (4.1% of all prescribers) were responsible for 60% of all schedule II-IV controlled substance prescriptions dispensed during a six-month period.[109]

Multiple other studies conducted confirm the high concentration of prescribing by a relatively small subset of providers.[110][111] Considering there were less than 4,000 pain specialist board-certified in the U.S. between 2000 and 2009,[112] pain specialists represent only a fraction of these high-volume prescribers.

General Prescribing

Providers who are not high-volume prescribers may also contribute to opioid abuse and overdose because of a lack of education and awareness about appropriate opioid prescribing. The majority of opioid analgesics in the U.S. are prescribed by primary care physicians and internists[113] and most were not trained in pain management or addiction.[114] Further, new formulations of opioids, revised clinical guidelines and new information on opioid risks such as increased overdose risk at higher doses, have only emerged in the last few years. Without up-to-date information and training, providers may be unwittingly contributing to community risk by failing to monitor whether their patient's treatment is improving function, failing to determine whether patients are seeing multiple providers, prescribing at too high a dose, and prescribing more than patients will use – making medication available for diversion and nonmedical use. Even when sufficient information exists, studies show that some providers do not follow risk mitigation strategies even for patients known to be at high risk for abuse.[115,116,117]

Pill Mills

The problem of unethical pain clinics, or "pill mills," was particularly egregious in Florida, where over 1,000 pain clinics operated until recently. In 2010, 90 of the top 100 oxycodone

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[108] Blumenschein K, Fink JL, Freeman PR, et al. Independent evaluation of the impact and effectiveness of the Kentucky All Schedule Prescription Electronic Reporting Program (KASPER). Available at: http://chfs.ky.gov/NR/rdonlyres/24493B2E-B1A1-4399-89AD-1625953BAD43/0/KASPEREvaluationFinalReport10152010.pdf Accessed October 2012.

[109] Oregon Health Authority. Prescription drug dispensing in Oregon. October 2011-March 2012. Available at http://www.orpdmp.com/orpdmpfiles/PDF_Files/Reports/Statewide_10.01.11_to_03.31.12.pdf.

[110] Dhalla IA, Mamdani MM, Gomes T, Juurlink DN. Clustering of opioid prescribing and opioid related mortality among family physicians in Ontario. Can Fam Physician. 2011;57(3):e92-96.

[111] Swedlow A, Ireland J, Johnson G. Prescribing patterns of schedule II opioids in California Workers' Compensation. Oakland, CA: California Workers' Compensation Institute; 2011. Available at http://www.cwci.org/document.php?file=1438.pdf..

[112] Institute of Medicine. Relieving pain in America: a blueprint for transforming prevention, care, education, and research. Washington, DC: The National Academies Press, 2011.

[113] Volkow ND, McLellan TA, Cotto JH, Karithanom M, Weiss SR. Characteristics of opioid prescriptions in 2009. JAMA 2011;6;305(13):1299-1301.

[114] Volkow ND, McLellan TA. Curtailing diversion and abuse of opioid analgesics without jeopardizing pain treatment. JAMA. 2011;305(13):1346-1347.

[115] Starrels JL, Becker WC, Weiner MG, Li X, Heo M, Turner BJ. Low use of opioid risk reduction strategies in primary care even for high risk patients with chronic pain. J Gen Intern Med. 2011;26(9):958-64.

[116] Morasco BJ, Duckart JP, Dobscha SK. Adherence to clinical guidelines for opioid therapy for chronic pain in patients with substance use disorder. J Gen Intern Med. 2011;26(9):965-971.

[117] Gupta A, Patton C, Diskina D, Cheatle M. Retrospective review of physician opioid prescribing practices in patients with aberrant behaviors. Pain Physician. 2011;14:383-389.

purchasing practitioners in the US were in Florida.[118] These pain clinics typically operated as cash-only establishments, and providers only performed a cursory physical exam, if any at all, prior to dispensing or prescribing large quantities of opioids, often in combination with benzodiazepines. Similar problems have been seen in a number of other states.

Emergency Departments and Hospital Providers

Approximately 10% of opioid analgesic prescriptions for people 20-39 years of age are written in EDs.[119] Among people entering treatment for opioid abuse, 13% cite EDs as a source for drugs.[120] ED providers are often unaware of the full prescription history of patients requiring or requesting pain treatment in EDs. Prescribing practices in EDs identified as potentially problematic include prescriptions for high daily doses of opioids, overlapping ED prescriptions for opioids or opioids and benzodiazepines, and receiving long-acting/extended release opioids for acute pain conditions.[121]

Pharmacies

Almost all prescription drugs involved in abuse come from prescriptions originally.[122] However, once they are prescribed and dispensed, prescription drugs are frequently diverted to people using them without prescriptions. There are instances where pharmacies are dispensing large quantities of opioids as part of an illegal distribution scheme as well as pharmacists who fail to meet their obligation to determine that a prescription was issued for a legitimate medical purpose.[123] The majorities of pharmacists, however, are attempting to practice appropriately, but may not have complete information to identify illegal or problem prescribing or doctor- or pharmacy-shopping.

Insurers and Pharmacy Benefit Managers

Insurer and pharmacy benefit manager (PBM) policies such as covering methadone as a first-line agent for pain because it is inexpensive, not covering non-opioid and non-pharmacological therapies, and not reimbursing for screening and risk mitigation activities likely contribute to abuse and overdose.[124,125]

People at High-Risk for Overdose

Similar to the small percentage of prescribers who prescribe the majority of opioids, a small percentage of patients receive a disproportionately large amount of opioid analgesics. A recent

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[118] Drug Enforcement Administration. Florida law enforcement prescription drug efforts produce positive results. Washington, DC: Drug Enforcement Administration; 2012 January 30, 2012.

[119] Volkow ND, McLellan TA, Cotto JH, Karithanom M, Weiss SR. Characteristics of opioid prescriptions in 2009. JAMA. 2011;305(13):1299-1301.

[120] Rosenblum A., Parrino M., Schnoll S.H., Fong C., Maxwell C., Cleland C.M., et al. Prescription opioid abuse among enrollees into methadone maintenance treatment. Drug Alcohol Depend. 2007;90(1): 64-71.

[121] Logan J, Liu Y, Paulozzi L, Zhang K, Jones C. Opioid prescribing in emergency departments: the prevalence of potentially inappropriate prescribing and misuse. Med Care. 2013. In Press.

[122] Substance Abuse and Mental Health Services Administration. Results from the 2010 National Survey on Drug Use and Health: Detailed tables. In *NSDUH Series H-41*. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. 2011.

[123] Drug Enforcement Administration. Press Release "Holiday CVS Final Order Reveals Gross Negligence By Two CVS Pharmacies in Stanford, Florida". Available at http://www.justice.gov/dea/divisions/mia/2012/mia101512.shtml

[124] Paulozzi LJ, Mack K, Jones, CM. Vital Signs – Risk for overdose from methadone used for pain relief – United States, 1999-2010. MMWR Morb Mortal Wkly Rep. 2012 Jul 6;61(26):493-7.

[125] Webster LR, Cochella S, Dasgupta N, Fakata KL, Fine PG, Fishman SM, et al. An analysis of the root causes for opioid-related overdose deaths in the United States. Pain Med. 2011;12 Suppl 2:S26-35.

analysis by CMS found that roughly 220,000 Part D beneficiaries, or 0.7% of all beneficiaries, were receiving prescriptions totaling 120 morphine milligram equivalents (MME) or more for at least 90 consecutive days in 2011.[126] Among a large commercially insured population, the top 5% of opioid users accounted for 70% of the total MME.[127] Similarly, the top 1% of workers compensation patients receiving schedule II opioids in California accounted for 25% of all morphine equivalents.[128] A 2012 study by CDC found that on average over 2 million Americans report using opioid analgesics nonmedically for 100 days or more in the past year. This group likely represents those at greatest risk for overdose.[129]

General Patients and the Public

Opioid analgesic use is common and growing in the U.S. In 2011, over 200 million prescriptions were dispensed for opioid analgesics – a nearly 200% increase since 1991.[130] In fact, enough opioid analgesics were sold in the U.S. in 2010 to give every adult the equivalent of 5mg of hydrocodone every 4 hours for a month.[131] According to the 2011 NSDUH, approximately 70% of people who used a pain reliever nonmedically in the past year say they got the drug from a friend or relative – with most saying they got it for free.[132] Patients receiving legitimate prescriptions for opioids and other prescription drugs prone to abuse may be knowingly or unknowingly contributing to prescription drug abuse by sharing medications with people who abuse them or not storing or disposing of them properly leaving them available for diversion.

Conclusion

The problem of prescription drug abuse is complex. Many factors have contributed to the increase in prescription drug abuse and its associated morbidity and mortality over the last decade. In general, the data indicate that a small percentage of providers are responsible for prescribing the majority of opioids. Similarly, a small percent of patients are responsible for consuming the majority of opioids and this group represents those at greatest risk for overdose. Further, high-volume prescribers are more likely to write prescriptions for patients who overdose on opioids. Although any strategy must address all of the drivers of the problem, taken in aggregate, these data support the need for a strategy that particularly focuses on addressing the minority of providers and patients that account for the majority of risk, while balancing the legitimate needs of patients for pain treatment.

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[126] Centers for Medicare and Medicaid Services. CMS analysis of Medicare Part D. 2012. Available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.

[127] Edlund MJ, Martin BC, Fan MY, Braden JB, Devries A, Sullivan MD. An analysis of heavy utilizers of opioids for chronic noncancer pain in the TROUP study. J Pain Symptom Manage. 2010;40(2):279-289.

[128] Swedlow A, Ireland J, Johnson G. Prescribing patterns of schedule II opioids in California Workers' Compensation. Oakland, CA: California Workers' Compensation Institute; 2011. Available at http://www.cwci.org/document.php?file=1438.pdf.

[129] Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267.

[130] IMS Health Vector One. From "Prescription drug abuse : it's not what the doctor ordered" Nora Volkow National Prescription Drug Abuse Summit April 2012. Available at: http://www.slideshare.net/OPUNITE/nora-volkow-final-edits

[131] 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.

[132] Substance Abuse and Mental Health Services Administration. Results from the 2010 National Survey on Drug Use and Health: detailed tables. In *NSDUH Series H-41*. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. 2011.

III. CURRENT HHS PRESCRIPTION DRUG ABUSE ACTIVITIES AND OPPORTUNITIES TO ENHANCE ACTIVITIES

This section of the report highlights current HHS prescription drug abuse activities within the following eight domains: 1) surveillance, 2) drug abuse prevention, 3) patient and public education, 4) provider education, 5) clinical practice tools, 6) regulatory and oversight activities, 7) drug abuse treatment, and 8) overdose prevention initiatives. These domains were selected because they each play a role in addressing the drivers of prescription drug abuse and include interventions that reach the high-risk populations in the U.S. Moreover, they represent central tenets of the Administration's approach to addressing prescription drug abuse and its related health consequences. Plans and opportunities to enhance current activities are also included for each domain based on an assessment of current activities as well as a review of the prescription drug abuse literature.

1. SURVEILLANCE

The CDC has defined public health surveillance as the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health.[133]

Surveillance data underpins all efforts to address prescription drug abuse because it is used to:

- Measure the burden of prescription drug abuse
- Identify populations at risk for abuse and overdose
- Identify new or emerging prescription drug abuse issues
- Guide the planning, implementation, and evaluation of programs to prevent prescription drug abuse
- Identify areas in clinical practice that need to be changed and the effects of these changes
- Prioritize the allocation of resources
- Provide a basis for epidemiologic research
- Inform policy/regulatory decision making.[134]

Key Surveillance Activities

HHS manages essential surveillance systems that track indicators of prescription drug abuse and its related health consequences in the U.S. Primary among these are the National Survey on Drug Use and Health (NSDUH), which tracks nonmedical use of prescription drugs in addition to the use of illicit drugs, alcohol, and tobacco; the Monitoring the Future Survey (MTF) survey, which measures alcohol, cigarette, and drug, including prescription drug, use and related attitudes among 8th, 10th, and 12th grade students nationwide; the Drug Abuse Warning Network (DAWN), which monitors ED visits associated with misuse and abuse of pharmaceuticals and

[133] Centers for Disease Control and Prevention. Updated guidelines for evaluating public health surveillance systems: recommendations from the guidelines working group. MMWR 2001:50(No. RR-13).
[134] Adapted from Centers for Disease Control and Prevention. Updated guidelines for evaluating public health surveillance systems: recommendations from the guidelines working group. MMWR 2001:50(No. RR-13).

illicit drugs; the Treatment Episode Data Set (TEDS), which provides information about the national flow of substance abuse treatment admissions; and the National Vital Statistics System (NVSS) which tracks deaths based on death certificates filed by states and territories in the U.S.

HHS also conducts and funds surveillance-related research to better understand prescription drug abuse patterns, examine clinical practices that may contribute to abuse, and evaluate the impact of interventions. In addition, CDC provides technical assistance to over 20 states as part of ongoing projects with the National Governors Association (NGA), Association of State and Territorial Health Officials (ASTHO), and CDC's Core Violence and Injury Prevention Programs in state health departments.

Opportunities to Enhance Surveillance Activities

Opportunities identified to enhance current surveillance activities include strengthening surveillance systems and conducting additional surveillance-related research to better understand prescription drug abuse and overdose. Proposed actions are to:

- Review current surveillance systems to identify ways to better detect changing patterns of abuse and health outcomes, and inform policy decisions and programmatic interventions.
- Explore the predictive value of potential measures of abuse such as doctor-shopping metrics in claims data and other data sources.
- Examine the role of prescriber dispensing in prescription drug abuse and overdose.
- Better understand the relationship of opioid dose and duration that increases the risk of abuse and overdose.
- Explore risk factors for addiction among patients receiving opioids for legitimate medical purposes.
- Examine potential unintended consequences that may result of interventions aimed at reducing prescription drug abuse, such as a decrease in legitimate access to pain treatment.

2. DRUG ABUSE PREVENTION

Preventing drug use before it begins is a common-sense, cost-effective approach to promoting safe and healthy communities.[135] Preventing drug abuse, including prescription drug abuse, increases people's chances of living long, healthy, and productive lives; improves quality of life, academic performance, and lowers health care costs for acute and chronic conditions.[136]

Research has shown that the most effective drug abuse prevention programs are those that help individuals to develop the intentions and skills to act in a healthy manner, and those that create an environment that supports healthy behaviors.[137] Until recently, there had been little research

[135] Office of National Drug Control Policy. National Drug Control Strategy. 2010. Available at: http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs2010.pdf
[136] National Prevention Council, *National Prevention Strategy*, Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General, 2011.
[137] Substance Abuse and Mental Health Services Administration. 2013. Available at: http://captus.samhsa.gov/prevention-practice/prevention-approaches

specifically examining the impact of prevention programs on prescription drug abuse. However, a review of three recent randomized controlled trials, funded by NIH, suggests that brief universal prevention interventions conducted during middle school led to reductions in prescription drug misuse during adolescence and young adulthood.[138] These findings provide the basis for future efforts to identify and evaluate existing prevention programs and to develop prevention programs specifically aimed at reducing or preventing prescription drug abuse.

Another potential drug abuse prevention strategy is medication disposal. Medication disposal programs are intended to reduce easy access to opioid analgesics and other abused prescription drugs for nonmedical use. The increasing popularity of these programs presents an opportunity to evaluate their utility in preventing prescription drug abuse and overdose. To date, no evaluations assessing the impact of these programs have been conducted.

Key Drug Abuse Prevention Activities

Some HHS-funded drug abuse prevention and technical assistance programs are specific to prescription drug abuse prevention, while others focus on the prevention of prescription drug use in addition to other substances such as alcohol and illicit drugs. Highlighted below are examples of HHS drug abuse prevention activities that have broad reach across the U.S. or strong potential to impact specific populations.

SAMHSA's Substance Abuse Prevention and Treatment Block Grant, Strategic Prevention Framework – Partnerships for Success II (SPF-PFS II) cooperative agreements, and the Drug Free Communities (DFC) support program (in partnership with ONDCP), are the primary sources of funding for state and community drug abuse prevention programs and serve as the infrastructure for drug abuse prevention programs across the U.S. In both the SPF-PFS II and DFC programs, grantees/coalitions utilize SAMHSA's Strategic Prevention Framework (SPF), a five-step, data-driven process, which includes the implementation of a comprehensive, evidence-based prevention approach. The use of the SPF process helps ensure that states and their communities work together to use data-driven decision making to develop effective prevention strategies and sustainable prevention infrastructures.

HHS also provides technical assistance and funds research to inform drug abuse prevention. SAMHSA's Prevention of Prescription Drug Abuse in the Workplace broadens the understanding of workplace-based prevention of prescription drug misuse and abuse and provides assistance and resources including occupational-specific screening tools, training, and informational products to SAMHSA grantees, employers, unions, and other communities. The Health Resources and Services Administration (HRSA) has provided technical assistance to help build community capacity to address substance abuse in the Appalachian Region – a region particularly impacted by prescription drug abuse. NIH is supporting research to inform the development of effective prescription drug abuse approaches, including resources to help school personnel implement policies and procedures to reduce prescription drug abuse, studying the

[138] Spoth R, Trudeau L, Shin C, et al. Longitudinal effects of universal prevention intervention on prescription drug misuse: three randomized controlled trials with late adolescents and young adults. Am J Public Health 2013;103(4):665-672.

impact of environmental policies on prescription drug abuse, and development and testing of prevention interventions.

Opportunities to Enhance Drug Abuse Prevention

Opportunities to strengthen drug abuse prevention activities focus on additional research to build the evidence base for drug abuse prevention programs targeting prescription drug abuse, improve understanding of prescription drug abuse initiation, and evaluate the impact of medication disposal programs. Proposed actions are to:

- Evaluate the effectiveness of drug abuse prevention programs to reduce prescription drug abuse in order to inform the implementation of evidence-based programs.
- Conduct social science research to understand the initiation of prescription drug abuse and to identify risk and protective factors to prevent initiation.
- Evaluate the impact of medication disposal programs on prescription drug abuse and overdose. Evaluations should include sampling to determine the proportion of returned drugs that are controlled substances.

3. PATIENT AND PUBLIC EDUCATION

Patient and public education are necessary to counteract a potent driver of abuse – the misperception about prescription drug risks and subsequent abuse of these drugs. Studies show that teens and young adults perceive prescription drug abuse as safer, less addictive, and less risky than using illicit drugs, and that drugs obtained from a medicine cabinet or pharmacy are believed to be less risky than drugs obtained from a drug dealer, and that such perceptions result in subsequent abuse.[139,140,141,142]

The evidence supporting patient and public education program is limited but shows some promise. An evaluation of Utah's public education campaign, "Use Only As Directed", found that the campaign may have contributed to a reduction in overdose deaths in Utah.[143] A small pilot study testing a patient-tailored, brief, web-based intervention designed to improve knowledge of safe medication use, storage and disposal found that such knowledge improved significantly after the intervention and that these changes were sustained at follow-up.[144] Additional research and evaluation are needed to inform the development of effective patient and public education interventions.

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[139] Wu L, Pilowsky DJ, Patkar AA. Non-prescribed use of pain relievers among adolescents in the United States. Drug Alcohol Depend. 2008;941(1-3):1-11.

[140] Generation Rx. National study confirms abuse of prescription and over the counter drugs. 18th Annual Study of Teen Abuse by the Partnership for a Drug Free America. 2006

[141] Daniulaityte R, Falck R. Carlson RG. "I'm not afraid of those ones just 'cause they've been prescribed": perceptions or risk among illicit users of pharmaceutical opioids. Int J Drug Policy 2012;23(5):374-384.

[142] Johnston LD, O'Malley PM, Bachman, JG, Schulenberg, JE. (2013). *Monitoring the Future national results on adolescent drug use: Overview of key findings, 2012*. Ann Arbor: Institute for Social Research, The University of Michigan, 83pp.

[143] Johnson EM, et al. State-Level Strategies for Reducing Prescription Drug Overdose Deaths: Utah's Prescription Safety Program. Pain Medicine. 12: S66-S72; 2011.

[144] McCauley JL, Back SE, Brady KT. Pilot of a brief, web-based educational intervention targeting safe storage and disposal of prescription opioids. Addict Behav. 2013;38(6):2230-2235.

Key Patient and Public Education Activities

HHS offers a number of web-based and print materials to educate patients and the public about prescription drug abuse. Select examples of these programs are included below. These examples were chosen because they have wide reach to educate patients about the risks of opioid analgesics or have broad applicability to various audiences.

Among the most wide-reaching, yet targeted educational materials for patients are FDA's Risk Evaluation and Mitigation Strategy (REMS) for extended-release/long-acting (ER/LA) opioid analgesics and CDC's *Vital Signs* series. Under FDA's REMS program, drug companies are required, among other things, to develop a one-page Medication Guide that is given to patients when they obtain their opioid prescription at the pharmacy. The Medication Guide contains consumer-friendly information on the safe use and disposal of these medications. Through its monthly *Vital Signs* series, CDC has produced a variety of patient education materials including fact sheets, podcasts, and social media tools to raise awareness about the abuse of opioid analgesics and other prescription drugs.

Examples of programs developed for a general audience include SAMHSA's *Not Worth the Risk, Even If It's Legal* campaign and NIH's *PEERx* initiative. The *Not Worth the Risk, Even If It's Legal* campaign, developed in partnership with the National Council on Patient Information and Education, includes a range of educational and outreach messages encouraging parents to talk to their teens about preventing prescription drug abuse. NIH's *PEERx* initiative reaches out to teens, providing factual information about the harmful effects of prescription drug abuse on the brain and body and encouraging them to spread the word. NIH also has a *Prescription Drug Abuse Mind Over Matter* magazine developed for youth in grades five through nine as well as a number of resources to educate people of all ages about prescription drug abuse, including a *Prescription Drug Research Report* which provides information on the latest research.

The selected programs above along with other patient and public education programs developed by HHS complement those programs offered by other federal agencies such as ONDCP's *National Youth Anti-Drug Media Campaign* and the Drug Enforcement Administration's (DEA) *Get Smart About Drugs*, and public education associated with DEA's National Take-Back Initiative.

Opportunities to Enhance Patient and Public Education

Opportunities to enhance patient and public education include strengthening the coordination of patient and public education activities among federal agencies and furthering the development of targeted patient and public education programs. Proposed actions are to:

- Convene federal agencies to assure that patient education activities and messaging is evidence-based and consistent across agencies.
- Leverage DEA's National Take Back Days, International Overdose Awareness Day, National Substance Abuse Prevention Month, National Drug Facts Week, and other special occasions as opportunities to highlight the dangers of prescription drug abuse to patients across the U.S.

- Partner with professional societies, patient education organizations, and others to expand targeted patient education programs, focusing on the addiction risks of medications, the dangers of mixing medications or mixing them with alcohol, and what patients can do to safeguard their medications.
- Work with public and private insurers and pharmacy benefit managers to include targeted educational information to beneficiaries receiving opioid analgesics and other prescription drugs prone to abuse based on demographics, medications prescribed, and conditions being treated.
- Conduct research to determine the effectiveness of patient education programs and use the findings to inform future educational programs.

4. PROVIDER EDUCATION

Education and training in both pain management and substance abuse, especially how to identify patients who may be at risk for abuse and ensure patients treated with opioids receive the appropriate dose and quantity of medication for their condition, are important to address the significant percentage of providers who may be contributing to abuse and overdose because of a lack of training in these areas. Such activities are important to meet the dual goal to reduce abuse of and overdose from opioid analgesics and to maintain legitimate and appropriate access to these drugs.

Surveys of healthcare providers indicate that they receive inadequate training on pain management, and often feel uncomfortable managing patients with pain.[145,146,147] Significant gaps and fragmentation in pain education in medical schools have also been identified.[148] A recent study found that primary care providers do not adequately perform or interpret opioid risk assessments, resulting in misestimated risk, and that physicians and pharmacists often omit key messages about safe use and storage of opioids when counseling patients.[149] Education for healthcare providers on substance abuse, like education for pain management, is limited. A national survey of medical residency programs in 2000 found that, of the programs studied, only 56% required substance use disorder training, and the number of curricular hours in the required programs varied between 3 and 12 hours.[150]

There is little information assessing the impact of provider education on prescription drug abuse or on the best types and way of providing education. A study in Utah employed an individual-level intervention to educate providers about opioid prescribing, and found reductions in

[145] Upshur CC, Luckmann RS, Savageau JA. Primary care provider concerns about management of chronic pain in community clinic populations. J Gen Intern Med. 2006;21:652–655.
[146] O'Rorke JE, Chen I, Genao I, et al. Physicians' comfort in caring for patients with chronic nonmalignant pain. Am J Med Sci. 2007;333:93–100.
[147] Fox AD, Kunins HV, Starrels JL. Which skills are associated with residents' sense of preparedness to manage chronic pain? J Opioid Manag 2013;8(5):328-336
[148] Mezei L, Murinson BB, Johns Hopkins Pain Curriculum Development Team. Pain education in North American medical schools. J Pain 2011;12(12):1199-1208.
[149] Salinas GD, Susalka D, Burton BS, et al. Risk assessment and counseling behaviors of healthcare professionals managing patients with chronic pain: a national multifaceted assessment of physicians, pharmacists, and their patients. J Opioid Manag. 2013;8(5):273-284.
[150] Isaacson JH, Fleming M, Kraus M, Kahn R, Mundt M. A National Survey of Training in Substance Use Disorders in Residency Programs. *J Stud Alcohol*. 2000;61(6):912-915.

inappropriate prescribing after the intervention.[151] Another study examining the impact of continuing education on buprenorphine diversion found that physician knowledge and practice behaviors significantly improved, at least through the short-term follow up, after the educational intervention.[152] Additional research is needed to help tailor provider education programs for maximal benefit.

Key Provider Education Activities

HHS has taken significant strides to improve education across the spectrum of health professional training. Discussed below are examples of innovative provider education activities that were selected because they stand to change how pain education is taught in health professional schools or have the ability to reach a wide and diverse group of providers.
To improve education among health professional students and residents, NIH's Centers of Excellence for Physician Information has developed five curriculum resources focusing on prescription opioid abuse. In addition, the NIH Pain Consortium has selected 12 health professional schools as designated Centers of Excellence in Pain Education (CoEPEs). The CoEPEs act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing and pharmacy schools to improve how healthcare providers are taught about pain and its treatment, while minimizing the risk of abuse.

HHS also provides a number of educational programs for clinicians already in practice. These programs are offered in a variety of formats (in-person, web-based, paper format, etc.) to increase access to the largest number of providers possible. Examples include FDA's ER/LA opioid analgesic REMS, which requires manufacturers to make available continuing education (CE) courses that contain key concepts on appropriate opioid prescribing. It is expected that nearly 200,000 prescribers of ER/LA opioids will be trained through the REMS within three years. NIH, in partnership with ONDCP and Medscape, developed two innovative, video-based Opioid and Pain Management CE modules that provide practical guidance to physicians and other clinicians on prescription drug abuse and pain management. More than 50,000 providers have completed these CE courses since they were launched in October 2012.

SAMHSA offers an in-person CE course, *Clinical Challenges in Prescribing Controlled Drugs: Prescribing Opioids for Chronic Pain*. The course, targeted to primary care providers, typically provides specific knowledge and skills associated with safe prescribing of opioids for chronic pain and clinical strategies for managing challenging patient situations. SAMHSA also has partnered with Medscape in developing a video-based version of this course titled *Prescribing Opioids for Chronic Pain* with a special emphasis on methadone. In addition, SAMHSA's Prescribers' Clinical Support System for Opioid Therapies (PCSS-O) provides support, training, and mentoring services to a variety of healthcare providers on the safe and appropriate prescribing of opioids. CMS has also developed and distributed to states a Medicaid Education Toolkit targeted to pharmacy staff which discusses drug diversion, prevention, benefits of PDMPs, and the consequences for providers and patients involved in drug diversion activities.

[151] Cochella S, Bateman K. Provider detailing: an intervention to decrease prescription opioid deaths in Utah. Pain Medicine, 12(Suppl 2), S73-76, 2012.
[152] Lofwal MR, Wunsch MJ, Nuzzo PA, et al. Efficacy of continuing medical education to reduce the risk of buprenorphine diversion. J Subst Abuse Treat. 2011;41(3):321-329.

In addition to offering multiple educational programs to meet the needs of a wide variety of providers, HHS conducts research to inform future provider education activities. CDC is funding an evaluation of a state-wide, community-level response that includes a focus on educating providers about appropriate opioid prescribing and overdose prevention. FDA is supporting an analysis that examines the impact on prescribing after distributing educational materials to prescribers who regularly prescribe high doses of opioids (e.g., ≥ 100 morphine milligram equivalents per day) or prescribe opioids in combination with benzodiazepines.

Opportunities to Enhance Provider Education

The two main opportunities identified to enhance provider education focus on strengthening coordination among federal agency provider education programs, and continuing to develop and refine targeted educational materials for different types of providers. Proposed actions are to:

- Convene federal agencies to further coordinate the development and dissemination of provider education programs to ensure maximum reach and benefit.
- Partner with health professional schools, educational accrediting bodies and professional societies to continue development of targeted educational programs to meet the needs of different types of providers and practice settings.
- Evaluate educational programs to determine the most effective programs with respect to changing provider behavior, improving prescribing, and reducing abuse and overdose.
- Conduct research to determine the most effective ways to provide educational programs and training to providers.

5. CLINICAL PRACTICE TOOLS

Equipping clinicians with clinical tools, such as ready access to prescription drug monitoring program (PDMP) data, prescribing guidelines, and electronic health records with integrated clinical decision support can address several drivers of prescription drug abuse. Specifically, such tools can improve care through the rapid identification of high-risk patients, provide complete prescription history information to emergency department providers, and convey current and accurate information to guide appropriate clinical decision making.

Prescription Drug Monitoring Programs
One of the most promising clinical tools to address prescription drug abuse are state PDMPs. These programs are designed to monitor prescribing and dispensing of controlled substances and can provide a prescriber or pharmacist with critical information regarding a patient's prescription history. This information can have a direct impact on reducing a patient's risk for overdose and provide an opportunity to intervene with patients who are abusing medications. As of July 2013, 47 states had operational PDMPs. However, they are significantly underutilized by providers. A number of factors contribute to this underutilization, including the cumbersome nature of accessing current systems and privacy concerns.[153]

[153] Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. Sept 20, 2012. http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PDMP%20Update%201-31-2013.pdf

Research suggests PDMPs reduce the prescribing of Schedule II opioid analgesics, lower substance abuse treatment admission rates, and result in lower annual increases in opioid misuse or abuse in states with PDMPs compared to those without them.[154,155,156,157] In a study examining the impact of PDMPs on changes in clinical practice, clinician review of PDMP data changed clinical management in 41% of cases. Of these cases, 61% percent received fewer or no opioids than the clinician originally planned to prescribe prior to reviewing the PDMP data, and 39% received more opioid medication than previously planned because the clinician was able to confirm the patient didn't have a recent history of opioid use. [158] Other tools such as clinical decision support tools and use of electronic health records that incorporate PDMP and other pertinent clinical data show promise for improving prescribing behaviors and reducing adverse events.[159,160,161]

Prescribing Guidelines

Prescribing guidelines for the use of opioids in the treatment of pain have been issued by various medical societies.[162] In recent years, a growing number of states have issued guidelines. They are intended to help providers identify patients who are appropriate candidates for opioids and provide information on treating and monitoring them. If followed and universally implemented, including integrating them into EHRs, guidelines may help reduce inappropriate prescribing of drugs commonly involved in overdose deaths. There is limited research assessing the impact of prescribing guidelines. A recent study of workers compensation patients in Washington State found a 27% decline in the mean dose for long-acting opioids, a 35% decline in the percentage of patients receiving 120 morphine milligram equivalents per day or more, and a 50% reduction in opioid-related overdose deaths among injured workers after introduction of the voluntary opioid guidelines in 2007.[163] More study is needed to best understand how to implement and operationalize guidelines to improve care and reduce abuse.

Key Clinical Practice Tools

HHS is engaged in a number of initiatives aimed at equipping providers with tools to improve clinical practice and reduce prescription drug abuse. These activities encompass systematic

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[154] Simeone R, Holland L. Washington, D.C.: U.S. Dept. of Justice, Office of Justice Programs2006.. http://www.simeoneassociates.com/simeone3.pdf

[155] Curtis LH, Stoddard J, Radeva JI, Hutchison S, Dans PE, Wright A, et al. Geographic variation in the prescription of schedule II opioid analgesics among outpatients in the United States. Health Serv Res. 2006 2006;41:837-55.

[156] Reisman RM, Shenoy PJ, Atherly AJ, Flowers CR. Prescription opioid usage and abuse relationships: an evaluation of state prescription drug monitoring program efficacy. Substance Abuse: Research and Treatment. 2009;3(SART-3-Shenoy-et-al):41.

[157] Reifler L, Droz D, Bailey J, Schnoll S, Fant R, Dart R, et al. Do prescription monitoring programs impact state trends in opioid abuse/misuse? Pain Medicine. 2012;13(3):355-6.

[158] Baehren DF, Marco CA, Droz DE, Sinha S, Callan EM, Akpunonu P. A statewide prescription monitoring program affects emergency department prescribing behaviors. Ann Emerg Med. 2009 2009;doi:10.1016/j.annemergmed.2009.12.011.

[159]Department of Health and Human Services. Connecting Prescribers and Dispensers to PDMPs through Health IT; 2013. Available at http://www.healthit.gov/sites/default/files/pdmp_pilot_studies_summary.pdf.

[160] Nicholas R, Roche A, Dobbin M, et al. Beyond the paper trail: using technology to reduce escalating harms from opioid prescribing in Australia. Aust N Z J Public Health 2013;37(2):139-147.

[161] Nieuwlaat R, Connolly SJ, Mackay JA, et al. Computerized clinical decision support systems for therapeutic drug monitoring and dosing: a decision-maker-researcher partnership systemic review. Implement Sci. 2011;6:90.

[162] Hughes MA, Biggs JJ, Thiese MS, Graziano K, Robbins RR, Effiong AC. Recommended opioid prescribing practices for use in chronic non-malignant pain: a systematic review of treatment guidelines. J Manage Care Med. 2011;14(3):52-58.

[163] Franklin GM, Mai J, Turner J, Sullivan M, Wickizer T, Fulton-Kehoe D. Bending the prescription opioid dosing and mortality curves: impact of the Washington State opioid dosing guideline. Am J Ind Med. 2012;55(4):325-31.

practice changes and technological advancements to facilitate provider behavior change. HHS also conducts research to inform clinical practice and the development of tools to assist providers. Highlighted below are examples of current activities that show the greatest promise to impact clinical practice.

The Office of the National Coordinator for Health Information Technology (ONC), in collaboration with SAMHSA, CDC, and ONDCP, launched the *Enhancing Access to Prescription Drug Monitoring Programs using Health Information Technology* project in 2011. This project is designed to facilitate the implementation of technologies that provide timely access to PDMP data for primary care and emergency department providers, and pharmacists by integrating existing technologies like electronic health records (EHRs), health information exchanges (HIEs) and pharmacy systems to securely connected state PDMPs. In addition, a resource center, *PDMPConnect*, was created under the project to serve as a forum to connect interested stakeholders and to share information, advancements, and lessons learned.

Expanding on the innovations of the *Enhancing Access* project, the *PDMP Electronic Health Record Integration and Interoperability Expansion* and the Electronic Health Record and PDMP Data Integration Cooperative Agreements, are providing funding to states to further improve real-time access to PDMP data by integrating PDMPs into existing technologies like EHRs and/or strengthening state PDMP interoperability. Nine states were provided funding for the former program in 2011; the latter program was announced in May 2013and SAMHSA expects to fund approximately eight additional states. NIH, through its NIDAMED initiative, developed a variety of clinical decision support resources and tools for assessing and treating patients, including an interactive online (and mobile) drug use screening tool and procedures for screening, brief intervention, and/or treatment referral for patients at risk of developing a substance use disorder.

In addition, HHS is conducting research to examine the effectiveness of PDMPs, determine the effectiveness of Patient Prescriber Agreements and urine drug testing, and evaluate two state-wide opioid prescribing guidelines. This important research will improve the current understanding of clinical practice tools and help to inform future efforts.

Opportunities to Enhance Clinical Practice Tools

Building on current efforts, opportunities for enhancement include the continuation of efforts to increase provider use of PDMPs; leveraging health information technology to improve clinical care and reduce abuse; and synthesizing pain management guideline recommendations and incorporating them into clinical decision support tools. Proposed actions are to:

- Convene professional societies to identify barriers and potential incentives to increase provider use of PDMPs.
- Partner with EHR/HIT stakeholders to expand the ongoing work of the Health eDecisions (HeD) project to identify, define, and harmonize standards to transmit data for use in clinical decision support, including incorporating data from state PDMPs, screening tools such as Screening, Brief Intervention, and Referral to Treatment clinical decision support, and other relevant clinical information.

- Work with stakeholders to harmonize the data standards necessary for the interoperable exchange of PDMP data with EHRs.
- Support pilot projects focused on the use of EHRs and health information exchanges (HIEs) to improve clinical decision making through real-time access to intrastate and interstate PDMP data.
- Support efforts to integrate clinical tools into EHRs and other electronic media to provide just in time information to improve clinical decision-making.
- Convene professional societies and subject matter experts to synthesize information from available pain management guidelines and the published literature to develop a set of prescribing recommendations that can be incorporated into clinical decision support tools.
- Conduct research to determine the impact of opioid prescribing guidelines on prescribing behaviors and health outcomes such as opioid abuse and overdose.
- Test the effectiveness of clinical decision support tools designed to improve care and reduce prescription drug abuse and overdose.
- Partner with health information technology developers and healthcare providers to validate electronic screening tools and clinical decision support tools in EHRs.

6. REGULATORY AND OVERSIGHT ACTIVITIES

Regulatory actions at the Federal, state, and local level can be powerful levers for behavior change among providers and patients. Primary regulatory functions residing within HHS at the federal level include FDA's oversight of drug approval and post-market monitoring, CMS's oversight and management of Medicaid and Medicare, and SAMHSA's oversight of opioid treatment programs (OTPs).

States regulate the practice of the health professions and can foster the implementation of evidence-based guidelines for the safe and effective use of opioid analgesics and other prescription drugs prone to abuse. In addition, states can enact and enforce laws to prevent the operation of rogue pain clinics or "pill mills," doctor shopping, and other laws to reduce prescription drug diversion and abuse while safeguarding legitimate access to pain management.

Through the operation of state Medicaid and other public insurance programs, states can implement requirements that improve oversight of prescriptions for high risk patients. For example, the majority of state Medicaid programs have implemented Patient Review and Restriction Programs (PRRs), also called Lock-In Programs. These programs require patients with patterns of inappropriate use of medical and pharmacy services to receive controlled substance prescriptions from one provider and one pharmacy in an effort to improve the coordination of care and reduce overutilization of medical services for patients at high risk for overdose.

The evidence base supporting regulatory and oversight interventions such as Patient Review and Restriction programs, pill mill and doctor shopping laws, and insurer or pharmacy benefit mechanisms is limited. Most available evaluations or reports on PRRs report cost savings and/or

reductions in the numbers of prescriptions and providers among patients subject to the PRR program.[164,165,166,167,168,169,170] Washington State provides the most recent evaluation of a PRR. An initial evaluation of their PRR showed a 37% decrease in physician visits, a 33% decrease in ED visits, a 24% decrease in numbers of prescriptions, and a decrease in total MMEs, from 312 MME/day to 185 MME/day after enrolling in the PRR. Total savings associated with this state PRR from 2005 through 2012 are estimated at $120 million.[171]

Policies such as pill mill laws are promising approaches to reduce abuse and overdose. As of May 2013, approximately 10 states had enacted a pill mill law.[172] No published evaluations of a state pill mill law are available, but non-academic reports suggest they have an impact on the number of pain clinics and the supply of opioid analgesic, potentially reducing abuse and overdose. Louisiana reported a decline in the number of pain clinics operating in the state after passage of their pain clinic law in 2005.[173] In Texas, prescriptions for the 3-drug combination of hydrocodone, alprazolam, and carisoprodol associated with their pill mills declined, but the impact on overdoses has not yet been reported.[174] In Florida, enactment of their law was followed by a 29% reduction in the volume of oxycodone purchased by state pharmacies and the closure of over 400 clinics.[175,176] Data on 2011 overdose deaths show a decline in deaths involving oxycodone and alprazolam, the two drugs most commonly associated with Florida pill mills.[177]

Key Regulatory and Oversight Activities

HHS agencies are applying their regulatory and oversight authority to address prescription drug abuse and providing technical assistance to states to improve their regulatory and oversight efforts. In addition, HHS is conducting research to better understand the impact of regulatory and oversight interventions. These regulatory activities complement the regulatory activities conducted by the DEA. Highlighted below are selected high-impact activities currently being conducted by HHS.

FDA is supporting efforts to reduce prescription drug abuse through public meetings, scientific exchange, revising drug labeling, and requiring a REMS for long-acting/extended-release opioids

[164]Singleton TE. Missouri's Lock-In: Control of Recipient Misutilization. J Medicaid Management. 1977;1:3.
[165] Florida Medicaid. Medicaid Prescribed Drug Spending Control Program Initiatives: Quarterly Report January 1-March 31, 2005,. 2005. Available at: http://ahca.myflorida.com/medicaid/Prescribed_Drug/pdf%5Cquarterly_report_03_31_05.pdf.
[166] Centers for Medicare and Medicaid Services, Medicaid Integrity Program, Division of Field Operations Internal Survey. 2012.
[167] Chinn FJ. Medicaid Recipient Lock-In Program – Hawaii's Experience in Six Years. *Hawaii Medical Journal*. 44:9-18. 1985.
[168]Blake SG. Drug Expenditures: The Effect of the Louisiana Medicaid Lock-In on Prescription Drug Utilization and Expenditure. *Drug Benefit Trends*. 1999.
[169] Mitchell L. Pharmacy lock-in program promotes appropriate use of resources. *The Journal of the Oklahoma State Medical Association*. Aug 2009;102(8):276.
[170] Tanenbaum SJ, Dyer JL. The dynamics of prescription drug abuse and its correctives in one state Medicaid program. American Medical Association, Department of Substance Abuse. Wilford BB, Ed. P229-238. 1990.
[171] Best S. Presentation on Washington State's Patient Review and Coordination program. CDC Expert Panel meeting, Atlanta, GA. August 2012.
[172] Centers for Disease Control and Prevention Public Health Law Program. 2013.
[173] DeRosier JF. Pain clinic legislation in Louisiana, in Promising legal responses to the epidemic of prescription drug overdoses in the United States. 2008 [cited 2011 JUne 13]; Available from: http://safestates.org/displaycommon.cfm?an=1&subarticlenbr=202
[174] Horswell C. Despite state crackdown, orders rise for hydrocodone. Houston Chronicle 2011 November 24, 2011.
[175] Drug Enforcement Administration. Florida law enforcement prescription drug efforts produce positive results. Washington, DC: Drug Enforcement Administration; 2012 January 30, 2012.
[176] Alvarez L. Florida shutting "pill mill" clinics. New York Times 2011 August 31, 2011.
[177] Florida Department of Law Enforcement. Drugs identified in deceased persons by Florida medical examiners 2012. Available at http://www.fdle.state.fl.us/Content/getdoc/fa86790e-7b50-45f3-909d-c0a4759fefa8/2011-Drug-Report_Final.aspx Accessed October 2012.

to ensure the benefits of these drugs outweigh their risks. To assist the development of abuse-deterrent products, FDA published a draft *Guidance for Industry: Abuse-Deterrent Formulations Opioids – Evaluation and Labeling* in January 2013. In April 2013, FDA approved updated labeling for abuse-resistant extended-release OxyContin tablets that indicates it has physical and chemical properties that are expected to make abuse via injection difficult and to reduce abuse via the intranasal route. FDA is also engaged in ongoing public-private partnerships aimed at improving the science that underlies the use of opioids in pain.

In 2012, CMS implemented a new policy in Medicare Part D that identifies minimum standards for plan sponsors to manage the use of opioid analgesics in their prescription drug plans through improved drug utilization controls and case management. CMS provided guidance on data sharing between Part D plans for patients who overutilize opioids and move from one Part D plan to another. To ensure a robust program, CMS continues to develop systems to identify beneficiaries who are at-risk for opioid overutilization, follow-up with their plan sponsors, and monitor the impact of this program.

In addition, CMS issued a National Bulletin entitled, *Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid*, and held drug diversion webinars for State Medicaid Educational Coordinators and Program Integrity Directors that included train-the-trainer presentations to 164 attendees from 40 states. CMS developed prescriber education focused on FDA-approved dosage guidelines and promoted best practices for five therapeutic drug classes that have high potential for improper payments and has now posted these guidelines on the CMS website. CMS has also developed and distributed to states a Medicaid Education Toolkit targeted to pharmacy staff which discusses drug diversion, prevention, benefits of PDMPs, and the consequences for providers and patients involved in drug diversion activities.

Under its regulatory authority, SAMHSA provides oversight of opioid agonist therapy by reviewing applications for OTPs, and conducts site visits to assess program compliance with federal regulations. SAMHSA also is responsible for reviewing physician requests for Drug Addiction Treatment Act, 2000 waivers to provide medication assisted treatment with buprenorphine for opioid dependence in the outpatient office setting.

To assist states with their regulatory and oversight efforts, CDC conducted an environmental scan of seven types of laws – pill mill and doctor shopping laws, physical exam, photo identification, and tamper-resistant form requirements, prescription limits, and immunity from prosecution laws – among all 50 states and the District of Columbia. Based on the scan, a state laws website was developed to provide a state-by-state picture of the some of the legal and regulatory strategies that have been used to address prescription drug abuse and overdose.

In addition, CDC convened a meeting in August 2012 with representatives from state Medicaid programs, private insurers, pharmacy benefit managers and other experts to discuss current practices among Medicaid PRR programs and to develop a set of best practices to help move these programs forward. CDC and CMS are now developing a set of technical assistance documents to help states implement robust PRRs.

Opportunities to Enhance Regulatory and Oversight Activities

The primary opportunities to enhance regulatory and oversight activities include improving analytic tools to identify high-risk providers and patients, collaborating with insurers and pharmacy benefit managers to implement robust claims review programs, and furthering efforts to identify and implement effective strategies to improve oversight of prescriptions for high-risk patients. Proposed actions are to:

- Convene partners to develop indicators of inappropriate prescribing and patient abuse that can be applied in regulatory and oversight settings.
- Encourage insurers and pharmacy benefit managers to regularly review claims data and PDMP data, where available, to identify and address healthcare providers prescribing outside of accepted medical standards and patients at high-risk for overdose.
- Collaborate with state Medicaid programs, other public and private insurers, and pharmacy benefit managers to identify and implement robust programs that improve oversight of high-risk prescribing.
- Collaborate with stakeholders to research the effectiveness of insurer benefit designs aimed at reducing prescription drug abuse, and pill mill and doctor shopping laws, including unintended consequences of these laws.

7. DRUG ABUSE TREATMENT

Although effective drug abuse treatment exists, the majority of people who need treatment do not receive it. Primary reasons for not receiving treatment include: inadequate accessibility or availability of treatment; a belief on the part of patients that they can handle the problem without treatment; not being ready to stop using; and lack of health insurance coverage; privacy concerns; and inability to afford treatment.[178,179,180] Additionally, healthcare providers often lack adequate training and knowledge to refer or treat patients once they are identified as needing treatment for a substance use disorder.

Increasing access to substance abuse treatment, including medication-assisted treatment with methadone, buprenorphine, and naltrexone, is essential to effectively address the prescription drug abuse problem in the U.S. Because most people do not seek treatment on their own, primary care providers are in a unique position to identify people in need and refer them to treatment. Studies have also shown that the most effective treatments are those that include a set of comprehensive medical, social, psychological and rehabilitative services that address all the needs of the individual.[181] Therefore, integrating substance abuse and mental health services into primary care is a high priority.

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[178] Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health: Detailed tables. In *NSDUH Series H-41*. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. 2012.

[179] Appel PW, Oldak R. A preliminary comparison of major kinds of obstacles to enrolling in substance abuse treatment reported by injecting street outreach clients and other stakeholders. Am J Drug Alcohol Abuse 2007;33(5):699-705.

[180] Roman PM, Abraham AJ, Knudesen Hk. Using medication-assisted treatment for substance use disorders: evidence of barriers and facilitators of implementation. Addict Behav. 2011;36(6):584-589.

[181] Kresina TF, Lubran RL. Improving public health through access to and utilization of medication assisted treatment. Int J Environ Res Public Health. 2011;8:4102-4117.

Investing in drug abuse treatment is cost-effective. According to several conservative estimates, every $1 invested in addiction treatment programs yields a return on investment of between $4 and $7 in reduced drug-related crime, criminal justice costs, and theft alone. When savings related to health care are included, total savings can exceed costs by a ratio of 12 to 1. Savings to the individual and to society also come from significant drops in interpersonal conflicts, improvements in workplace productivity, and reductions in drug-related accidents.[182,183,184]

Key Drug Abuse Treatment Activities

HHS provides funding and technical assistance to strengthen the provision of drug abuse treatment services in the U.S. These activities include grants to fund treatment services at the state and local level, the direct provision of treatment services to specific populations, providing technical assistance to states, local governments, and other stakeholders, and conducting research to inform drug abuse treatment. Highlighted below are those activities that have broad reach across the U.S., target specific high-risk populations, or describe innovative activities designed to improve the understanding and effectiveness of drug abuse treatment. Some programs specifically target prescription drug abuse, while others focus on substance abuse treatment in general.

SAMHSA is the major funding source for state drug abuse treatment through the Substance Abuse Prevention and Treatment Block Grant. SAMHSA also funds screening, brief intervention, and referral to treatment (SBIRT) programs in states, territories, and medical school residency programs in the U.S. SBIRT is a public health approach to identify individuals with harmful or hazardous substance use behaviors or who have already developed substance use disorders and refer them to treatment.[185,186]

HRSA funds the direct provision of SBIRT services within Health Centers and continues to encourage adoption by including SBIRT as an allowable and reportable service under HRSA's Health Center Section 330 grants. In addition, HRSA supported the development of the Integrating Buprenorphine Therapy into HIV Primary Care Settings Monograph and curriculum to assist Ryan White HIV/AIDS Program grantees and others to design or refine the delivery of public health services that include the integration of buprenorphine medication- assisted treatment into HIV treatment services/programs. IHS provides drug abuse treatment services to the American Indian and Alaska Native population at its healthcare facilities throughout the U.S. In addition, SAMHSA's Physician Clinical Support System – Buprenorphine (PCSS-B) provides

[182] National Institutes on Drug Abuse. Cost effectiveness of drug treatment. Available at: http://www.drugabuse.gov/publications/teaching-packets/understanding-drug-abuse-addiction/section-iv/6-cost-effectiveness-drug-treatment
[183] Ettner, S.L., D. Huang, et al. Benefit-cost in the California treatment outcome project: does substance abuse treatment 'pay for itself'? Health Services Research 2006;41(1): 192-213.
[184] Hartz, D.T., P. Meel, et al. A cost-effectiveness and cost-benefit analysis of contingency contracting-enhanced methadone detoxification. American Journal of Drug and Alcohol Abuse 1999;25(2):207-18.
[185] Agerwala SM, McCance-Katz EF. Integrating screening, brief intervention, and referral to treatment (SBIRT) into clinical practice settings: a brief review. J Psychoactive Drugs. 2012 Sep-Oct;44(4):307-17.
[186] Substance Abuse and Mental Health Services Administration. US Department of Health and Human Services. Screening, Brief Intervention and Referral to Treatment (SBIRT) in Behavioral Healthcare. 2011 http://www.samhsa.gov/prevention/sbirt/SBIRTwhitepaper.pdfhttp://www.samhsa.gov/prevention/sbirt/SBIRTwhitepaper.pdf.

immediate mentor resources, guidance documents, and training to physicians prescribing buprenorphine to patients for opioid addiction.

HHS is providing technical assistance to help improve and expand drug abuse treatment services. In conjunction with NIH, SAMHSA developed and funds a network of Addiction Technology Transfer Centers (ATTCs). The ATTCs assess the training and development needs of the treatment workforce and develop and conduct training and technology transfer activities to meet identified needs. The ATTCs have developed and disseminated a suite of treatment and training products on the use of buprenorphine with one devoted to use for the treatment of prescription opioid addiction. In addition, SAMHSA/HRSA's Center for Integrated Health Solutions is promoting SBIRT and medication assisted treatment services in health centers and providing guidance that can assist other health centers in developing and implementing these services.

Research to improve future drug abuse treatment services is also an important component of HHS activity in this area. NIH is funding an extensive research portfolio to evaluate the effectiveness of current treatment options, examine how best to provide treatment services, and identify new treatments for prescription drug addiction. For example, a recent NIH funded study demonstrated the efficacy of buprenorphine for the treatment of prescription opioid addiction. As a result, the NIH's NIDA-SAMHSA Blending Initiative developed the Prescription Opioid Addiction Treatment Study (POATS) Blending Product to help treatment providers incorporate study findings into their practice.

Opportunities to Enhance Drug Abuse Treatment

HHS has established a strong foundation for drug abuse treatment in the U.S. Opportunities for enhancement include continuing efforts to integrate drug abuse treatment and primary care and expand access to medication assisted treatment and SBIRT services. Proposed actions are to:

- Partner with professional societies to identify barriers and promote the integration of drug abuse treatment, including SBIRT and medication assisted treatment, and primary care.
- Collaborate with states, national associations, insurers, and PBMS to assure standard benefit packages cover medication-assisted treatment and SBIRT, and to develop reimbursement strategies that will increase the number of primary care providers offering such treatment in a variety of medical settings.
- Partner with public and private insurers to develop and disseminate materials to inform healthcare providers about SBIRT billing codes and other administrative information.
- Work with researchers and drug manufacturers to develop additional medical treatments for opioid addiction and new medical treatments for addiction to other abused prescription drugs.
- Support the development and testing of behavioral interventions for screening and treating prescription drug abuse, including interventions targeting youth and pregnant women.

8. OVERDOSE PREVENTION

Overdose from opioid analgesics is a potential risk for patients who are prescribed these medications for pain-related conditions and for those who misuse or abuse them. Naloxone, an opioid antagonist that can reverse respiratory depression associated with opioid overdose,[187] has been used for many years by healthcare and emergency medical services providers. Some providers are now prescribing naloxone to patients taking high doses of opioids as an overdose risk mitigation intervention. Educating individuals on overdose prevention, including how to recognize and respond to an overdose and how to obtain and administer an opioid overdose reversal medication, is an important public health intervention to reduce mortality.

In recent years, community-based programs that provide naloxone and train at-risk individuals and their loved ones on overdose prevention have been implemented. At least 188 programs were operating in the US in 2010.[188] A growing evidence base supports naloxone's use and cost-effectiveness to reduce opioid overdose deaths.[189,190] An evaluation of Massachusetts' overdose education and nasal naloxone distribution program found that opioid overdose death rates declined in communities where the program was implemented.[191]

In addition to developing overdose prevention programs, some states have passed immunity from prosecution laws to encourage people to seek help during an overdose emergency. These laws provide legal protection to an individual seeking help for themselves or for another person experiencing an overdose. Studies show that people witnessing an overdose may not call emergency services because of a fear of arrest for drug use or sale.[192] An initial evaluation of Washington's Good Samaritan law found that drug users in Seattle were more comfortable calling 911 after implementation of the law.[193] As of April 2013, 11 states had immunity from prosecution laws.[194] To date, no evaluations of the health impacts of immunity from prosecution laws in the U.S. have been conducted.[195]

Key Overdose Prevention Activities

Reducing the number of people dying from prescription drug overdoses is a top priority for HHS. In this report, overdose prevention activities are defined as those activities related to the education, training, and safe and effective response to or treatment of an acute overdose event. Highlighted below are some key activities.

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[187] Boyer EW. Management of opioid analgesic overdose. N Engl J Med. 2012;367(2):145-155.
[188] Wheeler E., Davidson P, Jones T, Irwin K. Community based opioid overdose prevention programs providing naloxone – United States, 2010. MMWR. 2012;61:101-105.
[189] Coffin PO, Sullivan SD. Cost-effectiveness of distributing naloxone to heroin users for lay overdose reversal. Ann Intern Med.2013;158(1):1-9.
[190] Enteen L, Bauer J, McLean R, et al. Overdose prevention and naloxone prescription for opioid users in San Francisco. J Urban Health 2010;87(6):931-941.
[191] Walley AY, Xuan Z, Hackman HH, et al. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. BMJ. 2013;30;346:F174.
[192] Baca C, Grant K. What heroin users tell us about overdose. J Addict Dis 2007;26(4):63-68.
[193] Banta-Green C, Kuszler PC, Coffin PO, JA. S. Washington's 911 Good Samaritan Drug Overdose Law - Initial Evaluation Results. . In. Seattle, WA: Alcohol & Drug Abuse Institute, University of Washington; 2011.
[194] Centers for Disease Control and Prevention. Law: providing immunity from prosecution or mitigation at sentencing for individuals seeking assistance during an overdose 2013. Available at: http://www.cdc.gov/homeandrecreationalsafety/Poisoning/laws/immunity.html
[195] Davis C, Webb D, Burris S. Changing law from barrier to facilitator of opioid overdose prevention. J Law Med Ethics. 2013;41 Suppl 1:33-36.

In April 2012, FDA, in collaboration with OASH, NIH, SAMHSA, and CDC, held a public meeting to discuss the regulatory pathways available to expand access to naloxone that do not require needles or syringes, making them potentially safer and easier to use. FDA and NIH are working with drug manufacturers to support the development of new formulations of naloxone, such as nasal spray or autoinjector formulations.

In addition, HHS is providing funding and technical assistance to increase awareness of overdose prevention and to expand the number of people able to respond to an overdose, including certain first responders not traditionally trained in overdose prevention and response. CDC is conducting research to understand the circumstances and risk factors for overdose. NIH is funding a Small Business Innovation Research Grant to develop a comprehensive, low-cost, easily accessible, computer-assisted training curriculum on overdose for public safety personnel (PSP), including police, firefighters and emergency medical technicians.

Opportunities to Enhance Overdose Prevention

Expanding current efforts to improve access to and use of naloxone is the primary opportunity identified among overdose prevention activities.[196,197] Proposed actions are to:

- Expand efforts to support the development of new formulations of naloxone, such as nasal spray or auto-injector formulations.
- Partner with national, state and local EMS and other first responder organizations to disseminate information on the use of naloxone.
- Evaluate naloxone programs to better understand how and under what conditions it is most effectively being used.
- Examine the impact of immunity from prosecution laws.

[196] Compton WM, Volkow ND, Throckmorton DC, Lurie P. Expanded access to opioid overdose intervention: research, practice, and policy needs. Ann Intern Med. 2013;158(1):65-66.
[197] Throckmorton DC, Compton WM, Lurie P. Management of opioid analgesic overdose. N Engl J Med. 2012;367(14):1371.

IV. CONCLUSIONS

HHS recognizes that prescription drug abuse is a serious public health issue in the U.S. The burden of prescription drug abuse not only impacts individuals but communities, employers, the healthcare system, and public and private insurers. Addressing this complex problem requires a multi-faceted approach and collaboration between public health, clinical medicine, and public safety at the federal, state, and local level.

As outlined in this report, current HHS efforts span eight domains that address the primary drivers of abuse and overdose: surveillance, drug abuse prevention, patient and public education, provider education, clinical practice tools, regulatory and oversight activities, drug abuse treatment, and overdose prevention. In addition to activities underway, overarching opportunities to enhance current efforts were identified and are listed below.

- Strengthen surveillance systems and capacity
- Build the evidence-base for prescription drug abuse prevention programs
- Enhance coordination of patient, public, and provider education programs among federal agencies
- Further develop targeted patient, public, and provider education programs
- Support efforts to increase provider use of PDMPs
- Leverage health information technology to improve clinical care and reduce abuse
- Synthesize pain management guideline recommendations and incorporate into clinical decision support tools
- Collaborate with insurers and pharmacy benefit managers to implement robust claims review programs
- Collaborate with insurers, and pharmacy benefit managers to identify and implement robust programs that improve oversight of high-risk prescribing.
- Improve analytic tools for regulatory and oversight purposes
- Continue efforts to integrate drug abuse treatment and primary care
- Expand efforts to increase access to medication-assisted treatment
- Expand Screening, Brief Intervention, and Referral to Treatment services
- Prevent opioid overdose through new formulations of naloxone

HHS has been at the forefront of the response to this public health issue and is committed to implementing a coordinated strategy among its agencies to address prescription drug abuse and continuing to collaborate with federal, state, local governmental and non-governmental partners.

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