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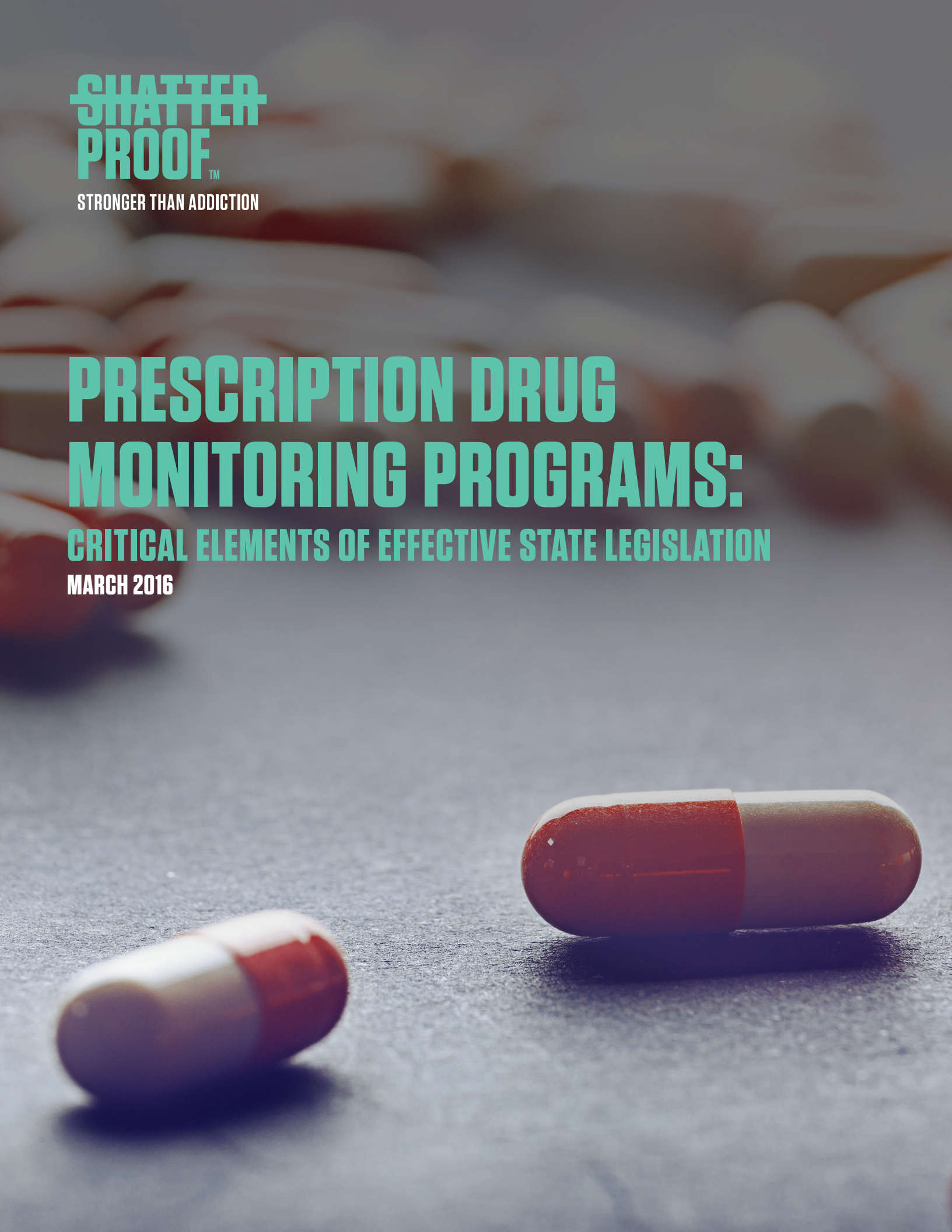
PRESCRIPTION DRUG MONITORING PROGRAMS:

CRITICAL ELEMENTS OF EFFECTIVE STATE LEGISLATION

MARCH 2016



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ABOUT SHATTERPROOF

Shatterproof is a national organization committed to preventing substance use disorder and facilitating access to evidence-based treatments without shame or stigma for those afflicted.

Shatterproof believes in the efficacy of PDMPs when used appropriately, and urges states to optimize the effectiveness of their PDMPs by adopting its Critical Elements of Effective State Legislation recommended in this document. PDMPs are essential tools in the quest to break the cycle of the misuse of prescription and illegal drugs that is devastating our families.

SIGNATORIES

G. Caleb Alexander, Co-Director, Center for Drug Safety & Effectiveness, Johns Hopkins Bloomberg School of Public Health

Alex Cahana, Affiliate Professor of Science, Technology and Health Studies, University of Washington

Thomas Clark, Clearinghouse Manager at the Prescription Drug Monitoring Program (PDMP) Center for Excellence and Senior Research Associate with the Institute for Behavioral Health, Brandeis University

John Eadie, Public Health and PDMP Project Coordinator, National Emerging Threat Initiative of the National High Intensity Drug Trafficking Areas (HIDTA) Assistance Center and former Director, PDMP Center of Excellence at Brandeis University

Gary Franklin, MD, MPH, Research Professor, Environmental and Occupational Health Services, University of Washington

Van Ingram, Executive Director, Kentucky Office of Drug Control Policy

Andrew Kolodny, MD, Senior Scientist, Heller School for Social Policy and Management, Brandeis University

Gary Mendell, Founder & Chairman, Shatterproof

Alex Swedlow, President, California Workers' Compensation Institute

Bruce Wood, Vice President & Associate General Counsel, American Insurance Association

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National Alliance for Model State Drug Laws

PDMP Center of Excellence at Brandeis University

National Emerging Threats Initiative of the National HIDTA Assistance Center

Grant Baldwin, PhD, MPH, Director of the Division of Unintentional Injury Prevention at the National Center for Injury Prevention and Control, CDC

Deborah Dowell, MD, MPH, Senior Medical Advisor for the Division of Unintentional Injury Prevention at the Centers for Disease Control and Prevention (CDC) and Commander in the U.S. Public Health Service

PREFACE

As Shatterproof joins fellow stakeholders from around the country to convene for the 5th National Rx Drug Abuse & Heroin Summit, the shared sense of urgency is palpable. Collaboration across our communities, states and federal government is the single most powerful weapon within our grasp. However this collaboration is itself fueled by something far more individual, infinitely more intimate.

While we can certainly quantify the vastness of this epidemic and measure the effectiveness of solutions with various statistics, there is ultimately a single number that stands above all others as the driving force behind our collective purpose. That number is One. For me, the devastating loss of one life – my son – was a transformative event that redefined my sense of purpose. One life lost. One more hug I will never share. One family shattered, forever.

However, Jewish tradition has taught that when you save a single life, you've saved the whole world. Several months ago I received an email from a legislator with whom we worked in West Virginia to pass legislation to expand access to naloxone; "Tonight I watched naloxone save a life. Because of the availability of this medication a 24 year old young man will live to get another chance at life. Well done, well done." Save one life, save a whole world.

Since my journey began I have been honored and moved to be with other individuals with similar stories of purpose borne from grief. Our power of one is unleashed at the National Summit as we are here to understand what's working, and what gaps we must bridge to make more of a life-saving difference. To that end, I am proud to introduce the first edition of this important report about Prescription Drug Monitoring Programs (PDMPs). PDMPs can save a life; someone's son or daughter, brother or sister, father or mother.

The central question surrounding PDMPs is not whether they should exist or can save lives. The answer to both is a definitive yes. Rather, the question at hand is how quickly states will enact legislation that mandates participation. The fact that most do not is the gating factor that often prevents a life from being saved. And then another life.

This report provides compelling examples of states whose legislation has saved lives, and clear guidance for other states to achieve this. By summoning the political will of our leadership and inherent compassion of our citizenship, we can help make a life-saving difference in every community today. Save one life, save a whole world.

Gary Mendell

Founder, Chairman
Shatterproof...Stronger Than Addiction
March 28, 2016

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EXECUTIVE SUMMARY

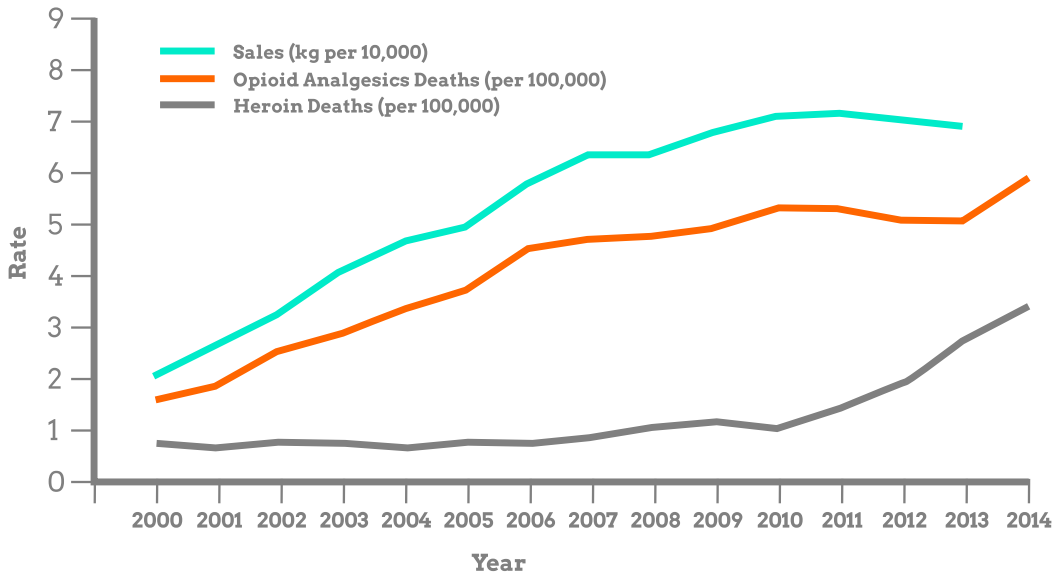
Tens of thousands of our sons, daughters, and loved ones die every year as a consequence of prescription opioid and heroin use. In 1999, death from opioid overdose claimed 6,000 American lives. By 2014, increasing 14% from 2013, this number spiked to nearly 30,000.[1] And this is not simply a number... It is real people with real names and real families.

Many in our society still associate substance use disorders mostly with heroin and other illicit drugs, and have dated socioeconomic stereotypes about those affected. However, this alarming escalation in loss of life and devastation to surviving families is most directly linked to the overprescribing of opioids that now routinely populate U.S. household medicine cabinets. These all-too-familiar instruments of death by overdose include medicines such as OxyContin, Vicodin and Percocet.

"Overall, 1 of every 550 patients started on opioid therapy died of opioid-related causes a median of 2.6 years after the first opioid prescription.[2] We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

- Dr. Thomas Frieden and Dr. Debra Houry for the CDC in the New England Journal of Medicine

PRESCRIPTION PAINKILLER SALES AND AGE-ADJUSTED RATES FOR DRUG-POISONING DEATHS, BY TYPE OF DRUG: UNITED STATES, 2000–2014



NOTES: The number of drug-poisoning deaths in 2013 was 43,982, the number of drug-poisoning deaths involving opioid analgesics was 16,235, and the number of drug-poisoning deaths involving heroin was 8,257. A small subset of 1,342 deaths involved both opioid analgesics and heroin. Deaths involving both opioid analgesics and heroin are included in both the rate of deaths involving opioid analgesics and the rate of deaths involving heroin.

SOURCE: Center for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, Mortality File. (2015). Number and Age-Adjusted Rates of Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 2000–2014. Atlanta, GA: Center for Disease Control and Prevention. Available at http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.

[1] Prescription Drug Monitoring Programs. (2016). U.S. Centers for Disease Control and Prevention. Retrieved from: http://www.cdc.gov/drugoverdose/pdmp/

[2] Kaplovitch E, Gomes T, Camacho X, Dhalla IA, Mamdani MM, Juurlink DN. Sex differences in dose escalation and overdose death during chronic opioid therapy: a population-based cohort study. PLoS One 2015; 10(8): e0134550.

Since 1999, prescription opioid consumption in the U.S. has quadrupled.[3] We can no longer question a causal link between opioid overprescribing and opioid overdose deaths.

The impact of prescription painkillers on the size and scope of this crisis demands that evidence-based solutions available to prevent and treat this brain disease must be powerfully advocated for, established and enforced. One such solution is the design, enactment and effective utilization of Prescription Drug Monitoring Programs (PDMPs).

A PDMP employs a statewide electronic database that collects designated data on controlled substances dispensed within the state. When properly used, PDMPs identify and prevent drug misuse or diversion, identify polypharmacy, and offer treatment to patients in need of support, while ensuring the legitimate medical use of painkillers. The data collected can also be used more broadly to analyze prescribing patterns and trends in use, and ultimately inform patient-centered public health initiatives.

[3] Prescription drug monitoring frequently asked questions. Prescription Drug Monitoring Program Training and Technical Assistance Center. Retrieved from: http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq

Contrary to some concerns that have been raised about PDMPs, there is no evidence to suggest that mandating their use will limit appropriate access to prescription opioids for patients in need. The objective is to protect people from being prescribed opioids they either don't need, in volumes that are unnecessary, or in combination with benzodiazepines, thus minimizing the potential for developing an addiction and/or death from an overdose.

To date, 49 states and the District of Columbia have enacted legislation authorizing the creation and operation of a PDMP.[4] However, in the vast majority of states, PDMP participation by prescribers is extremely low, and the effectiveness of this clinical tool is therefore compromised. A 2015 study of primary care prescribers found that while a majority reported having obtained data from their PDMP at some point in time, prescribers consulted PDMP data in fewer than one-quarter of instances when they prescribed opioids to patients.[5] In a recent review of 2015 prescribing data in a sample of states where participation in the PDMP is voluntary, prescribers checked the patient history in the PDMP only 14% of the time before prescribing an opioid.[6]

State legislation mandating healthcare providers to record, consult and proactively monitor prescribing data will help reverse the current course of this tragic epidemic, reducing the enormous suffering and loss of life.

After knee surgery, Faye Roscoe's 23-year-old son Chris was prescribed Vicodin against her wishes. Chris had a history of drug issues, but she says that was overlooked. "Had stricter guidelines been in place, discussing other alternatives for pain medication, I believe Vicodin would not have been prescribed," Roscoe said.

Based on current program designs and successes, Shatterproof has analyzed PDMP practices and policies to identify a proven model that states can adopt. Herein are 12 guiding practices and recommended legislation to maximize the effectiveness of state-level PDMPs. By heeding this guidance, state leadership will be taking concrete action to save the lives of its residents by systematically preventing future overprescribing and dangerous co-prescribing of prescription painkillers.

[4] Prescription Drug Monitoring Program Training and Technical Assistance Center. Prescription Drug Monitoring Frequently Asked Questions. Retrieved from: http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq

[5] Rutkow, L. et al., Many primary care physicians are aware of prescription drug monitoring programs, but many find the data difficult to access. Health Affairs 34, No. 3 (2015): 484-492. Retrieved from: http://content.healthaffairs.org/content/34/3/484.abstract.

[6] Prescription Behavior Surveillance System (PBSS). Definitions of PBSS Measures. PDMP Center of Excellence at Brandeis University. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/Definitions%20of%20PBSS%20Measures.pdf

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CRITICAL ELEMENTS OF EFFECTIVE STATE LEGISLATION

1

DISPENSERS REPORT SPECIFIED INFORMATION EXPEDITIOUSLY

2

PRESCRIBERS QUERY PDMP BEFORE PRESCRIBING DRUGS IN SCHEDULES II, III AND IV

3

LICENSED PRESCRIBERS REGISTER WITH PDMP

4

ENABLE DELEGATION OF PDMP DATA QUERIES

5

AUTHORIZE SPECIFIED RECIPIENTS OF PDMP DATA

6

PROACTIVELY ANALYZE AND DISTRIBUTE PDMP DATA

7

REQUIRE INTERSTATE SHARING OF PDMP DATA

8

PROVIDE DE-IDENTIFIED INFORMATION

9

TAKE A COMMUNITY-BASED APPROACH TO PDMP DATA

10

LINK PDMP DATA TO PAIN AND ADDICTION TREATMENT

11

INSTITUTE CONFIDENTIALITY PROTECTIONS

12

TRACK AND REPORT EVALUATION MEASURES

OUR MOST URGENT HEALTH CRISIS

Opioids were collectively responsible for 29,467 deaths in 2014 alone, including 18,893 resulting from opioid pain relievers and 10,574 from heroin. Drug overdose death rates have increased more than five times since 1980.[7] In 2014, more Americans died of drug overdoses than car crashes, making drug overdose now the leading cause of accidental death in the United States.[8]

According to the United States Centers for Disease Control and Prevention (CDC), this is the "worst drug overdose epidemic in [U.S.] history."[9] The problem has grown so severe that, in 2014, the CDC added opioid overdose prevention to its list of top five public health challenges.[10]

While the rapidly escalating number of deaths in this country due to opioid overdose makes headlines, little is said about the sheer number of Americans across all demographics who continue to suffer from substance abuse disorders related to opioids. Today, it is estimated 4.5 million people in the U.S. are addicted to prescription opioids, and 467,000 to heroin.[11,12] These individuals struggle daily with a devastating cycle between managing their disorder and relapse.

It is estimated 4.5 million people in the U.S. are addicted to prescription opioids, and 467,000 to heroin.

These numbers do not account for the millions of family members fighting to understand this disease, struggling to steer their loved ones toward treatment and continuously waiting for that dreaded phone call letting them know that their child, parent or loved one has overdosed and died.

"The root cause of our nation's opioid epidemic is not unethical or illegal medical practice, but the well-intentioned yet tragically misguided practice of over-prescribing opioids for common conditions. To prevent new cases of opioid addiction clinicians must prescribe more cautiously. On March 15th the CDC took an enormous step in this regard by releasing the CDC Guideline for Prescribing Opioids for Chronic Pain. This report, Prescription Drug Monitoring Programs: Critical Elements of Effective State Legislation, is another vitally important step forward."

- Andrew Kolodny, MD, Executive Director of Physicians for Responsible Prescribing and Chief Medical Officer of Phoenix House Foundation and senior scientist at Brandeis University's Heller School for Social Policy and Management

[7] Addressing prescription drug abuse in the United States: Current activities and future opportunities. Developed by the Behavioral Health Coordinating Committee Prescription Drug Abuse Subcommittee. US Department of Health and Human Services.

[8] CDC/NHS, National Vital Statistics System, Mortality File. Retrieved from: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm

[9] Paulozzi LJ. 2010. The epidemiology of drug overdoses in the United States. Presented at Promis. Leg. Responses to the Epidemic of Prescr. Drug Overdoses in the U.S., Maimonides Med. Cent.Dep. Psychiatry, Dec. 2, Grand Rounds, Brooklyn

[10] CDC (Cent. Dis. Control Prev.). 2014. CDC's Top Ten: 5 Health Achievements in 2013 and 5 Health Threats in 2014. Atlanta, GA: CDC.

[11] Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[12] Kolodny, A, et al. (2015). The prescription opioid and heroin crisis: A public health approach to an epidemic of addiction. Annual Review of Public Health. 36:559-574.

Opioid Use Disorder (OUD)

Opioids such as legally available pain relievers (e.g. oxycodone and hydrocodone) and heroin reduce the perception of pain but can also produce drowsiness, mental confusion, euphoria, nausea, constipation, and, depending upon the amount of drug taken, can depress respiration. If a person uses opioids for a long time, they develop physical dependence and tolerance, and require more of the drug to continue to get high. If a person stops or attempts to reduce using opioids after they become physically dependent on the drug, they will experience drug withdrawal symptoms which can include anxiety, irritability, muscle aches, vomiting, sweating and tremors.

Individuals who develop an OUD experience a strong desire for opioids. When prescription opioids are no longer available, many switch to heroin because it is less expensive and easier to obtain. Presently, four out of five of those who use heroin report that their use started with prescription painkillers. Because of variable purity and other chemicals and drugs mixed with heroin on the black market, this also increases risk of overdose.

The mother of Britt Doyle's children succumbed to a 15-year battle with addiction to opioids that began with her third c-section childbirth. Doyle says she was an extensive "doctor shopper." She told her family she was "following doctor's orders" by taking nearly 50 pills a day. She underwent 13 different treatment programs, but could not break the grasp of her addiction.

Opioid use disorders do not discriminate based on age, race, gender, or socioeconomic status. According to a recent report by the New York Times, drug overdoses are driving up the death rate of young white adults in the United States to levels not seen since the end of the AIDS epidemic more than two decades ago.[13]

Also tragic is the stigma related to addiction that pervades both public and self-perception, and is often a barrier to individuals getting necessary treatment. In a recent study, among those who needed and made an effort to get treatment, but did not receive it, 24% cited the reason as either possible negative effect on job prospects or concern that receiving treatment might cause neighbors/community to form a negative opinion.[14] On a broad scale, the perpetuation of stigma blocks acknowledgment of this public health crisis as a non-discriminatory killer. It is imperative that community members, law enforcement, and health care providers treat addiction as the disease that it is and put aside the unjust stigma and stereotypes.

Brian Mendell

Shatterproof founder Gary Mendell believes society must look inward, because pervasive stigmatization of addiction is as deadly as the neurological consequences of the disease his organization is driven to eradicate: "My son Brian did not die of an overdose. After not having used a substance for 13 months, he woke up on October 20th, 2011 and took his own life out of shame; stigma," Mendell states. "He told me often that he felt like an outcast, not a patient."

[13] http://www.nytimes.com/2016/01/17/science/drug-overdoses-propel-rise-in-mortality-rates-of-young-whiteshtml?action=click&contentCollection=Politics&module=RelatedCoverage%C2%AEion=Marginalia&pgtype=article

[14] Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health. (2015, September). Substance Abuse and Mental Health Services Administration.

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DRIVERS OF THIS EPIDEMIC

While the true impact of this epidemic on the lives of individuals across our nation can only be estimated, its causes are well-known. Researchers and experts have identified several key drivers of this epidemic.[15]

PRESCRIBING TRENDS

Up until the late 20th Century, medical convention held that prescription opioids were only to be prescribed in rare instances involving acute pain (e.g. surgery), chronic pain from illnesses like cancer and in end of life care. Physicians were cautious about long-term opioid use given its linkage to addiction, tolerance and physiological dependence.[16]

In 2012, doctors wrote 259 million prescriptions for opioids – enough for every adult in the United States to have a bottle of pills for a month.

This prevailing thought was questioned in 1986 when a paper published in the journal Pain describing treatment of 38 chronic pain patients concluded that opioid painkillers could be prescribed safely on a long-term basis.[17] In 1996, the rate of opioid prescribing began to rapidly increase following the 1995 FDA approval of OxyContin.[18] The drug's manufacturer, Purdue Pharma, subsequently funded more than 20,000 pain-related educational programs through sponsorships or financial grants and launched a campaign to promote long-term use of opioid painkillers for chronic, non-cancer pain.[19]

[15] Addressing prescription drug abuse in the United States: Current activities and future opportunities. Developed by the Behavioral Health Coordinating Committee Prescription Drug Abuse Subcommittee. US Department of Health and Human Services.

[16] Turk DC, Brody MC, Okifuji EA. 1994. Physicians' attitudes and practices regarding the long-term prescribing of opioids for non-cancer pain. Pain 59:201–8

[17] Portenoy RK, Foley KM. (1986). Chronic use of opioid analgesics in non-malignant pain: report of 38 cases. Pain 25:171–86

[18] The report of the International Narcotics Control Board for 2007. International Narcotics Control Board. Retrieved from: https://www.incb.org/incb/en/publications/annual-reports/annual-report-2007.html

[19] Prescription drugs: Oxycontin abuse and diversion and efforts to address the problem. (December 2003). Report to congressional requesters. United States General Accounting Office. Retrieved from: http://www.gao.gov/new.items/d04110.pdf

Growing concern about systemic under-treatment of pain galvanized physicians and pain societies to successfully lobby for increased use of opioids for all pain types, regardless of the patient's diagnosis.[20] In 1995, the American Pain Society introduced a campaign entitled, "Pain is the Fifth Vital Sign," championing the idea that clinicians should assess and treat pain with the same urgency as other vital signs and use opioids for non-cancer pain.[21] The Veterans Affairs health system and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), a group that accredits hospitals and health care organizations, endorsed this campaign to increase pain treatment with opioids.

In the 1990s and 2000s, physicians expanded their treatment of pain through use of the growing number of approved prescription opioids. Today, pain management is a fully actualized medical practice. Clinical inquiry about a patient's pain status is ubiquitous across the settings, specialties and continuum of healthcare. The therapeutic response too often involves opioid medication, with far-reaching, sometimes tragic consequences.

1983

Vicodin becomes available as a generic.

1986

Published paper concludes that opioid painkillers could be prescribed safely on a long-term basis.

1995

OxyContin receives approval from FDA.

American Pain Society introduces a campaign entitled, "Pain is the Fifth Vital Sign."

1996

Purdue Pharma begins multi-year educational programs promoting long-term use of opiod painkillers.

2000s

Physicians expand their treatment of pain through use of the growing number of approved prescription opioids.

Prescription painkillers flood the market

2014

4x annual increase in prescriptions from 1999 - 2014.
5x annual increase in overdose deaths related to opioids.

[20] A pain drug champion has second thoughts. Wall Street Journal Published Dec. 17, 2012. Retrieved from: http://www.wsj.com/news/articles/SB10001424127887324478304578173342657044604

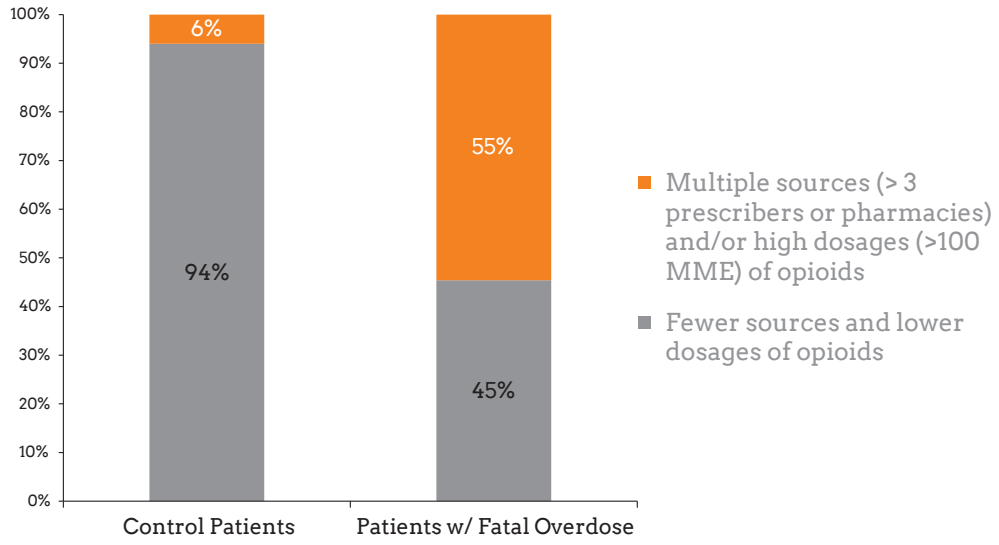
[21] Haddox JD, Joranson D, Angarola RT, Brady A, Carr DB, et al. (1997). The use of opioids for the treatment of chronic pain: a consensus statement from the American Academy of Pain Medicine and the American Pain Society. Clin. J. Pain 13:6–8

HIGH DOSAGE PRESCRIBING

With daily use of opioids, physiological dependence and tolerance set in rapidly. For patients to continue to achieve pain relief, dose increases are often required. Over time, the dose required to obtain an analgesic effect can approach the lethal dose that will cause respiratory depression. Studies indicate that as doses increase beyond the equivalent of 90mg of morphine, the risk of overdose increases exponentially.[22] High dose opioid therapy is also associated with other serious adverse effects including neuroendocrine suppression, cognitive impairment, and hyperalgesia (worsening of pain). For individuals who feign pain to obtain opioids to sell, high dose prescribing may also account for significant diversion on to the black market.

The average amount of opioid per prescription, in morphine milligram equivalents, increased 69.7 percent for oxycodone, 69.4 percent for hydrocodone, and 20.9 percent for fentanyl nationally between 2000 and 2009.[23]

MAJORITY OF OPIOID OVERDOSE DEATHS ASSOCIATED WITH MULTIPLE SOURCES AND/OR HIGH DOSAGES



Baumblatt JAG et al. High Risk Use by Patients Prescribed Opioids for Pain and its Role in Overdose Deaths. JAMA Intern Med 2014; 174: 796-801.

[22] Addressing prescription drug abuse in the United States: Current activities and future opportunities. Developed by the Behavioral Health Coordinating Committee Prescription Drug Abuse Subcommittee. US Department of Health and Human Services.

[23] Addressing prescription drug abuse in the United States: Current activities and future opportunities. Developed by the Behavioral Health Coordinating Committee Prescription Drug Abuse Subcommittee. US Department of Health and Human Services.

GENERAL PRESCRIBING

A majority of opioid analgesics in the US are prescribed by primary care physicians, dentists and internists, most of whom are not trained in pain management or addiction. 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.[24]

EMERGENCY DEPARTMENTS AND HOSPITAL PROVIDERS

Among people entering treatment for opioid abuse, 13% cite emergency departments as a source for drugs while 10% of opioid analgesic prescriptions for people ages 20-39 are written in emergency departments. Problematic prescribing practices in emergency departments include high daily doses of opioids, overlapping prescriptions for opioids or a combination of opioids and benzodiazepines, and receiving long-acting/extended release opioids for acute pain.[25]

INSURERS AND PHARMACY BENEFIT MANAGERS

Policies by insurers and pharmacy benefit managers contribute to abuse and overdose. Several examples include: 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.[26] Additionally, prior authorization requirements for buprenorphine serve as a barrier to a first-line treatment for opioid use disorders.

CO-PRESCRIBING OPIOIDS AND BENZODIAZDEPINES

Not publicly well known is that the co-prescribing of opioids and benzodiazepines (a sedative) is also a significant contributor to the overdose crisis. Benzodiazepines and opioids both cause central nervous system depression and can decrease respiratory drive. Between 2005 and 2009 this combination was the most common cause of overdose deaths involving multiple drugs.[27]

Co-prescribing can arise when two providers treating the same patient for different problems unknowingly issue prescriptions for medicines whose combination is unsafe. Today, most of the attention is given to opioids classified within Schedules II and III by the Controlled Substances Act, however reporting of medications in Schedules II, III and IV to PDMPs will provide practitioners the information necessary to protect their patients' safety.

Without a mandate to check the PDMP before prescribing schedule IV drugs, which include sedatives, health care providers are unable to detect this potentially dangerous, and often fatal drug combination.

[24-26] Addressing prescription drug abuse in the United States: Current activities and future opportunities. Developed by the Behavioral Health Coordinating Committee Prescription Drug Abuse Subcommittee. US Department of Health and Human Services.

[27] Calcaterra, S., Glanz, J., & Binswanger, I. (2013). National trends in pharmaceutical opioid related overdose deaths compared to other substance related overdose deaths: 1999-2009. *Drug and Alcohol Dependence*. 131(3): 263–270.

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EVIDENCE-BASED SOLUTIONS

The opioid epidemic is a multi-dimensional crisis requiring a multi-faceted response. Initiatives must be tightly coordinated across the full stakeholder spectrum including public health officials and researchers, clinicians, public safety organizations, patient and family advocates and legislators. Solutions must be evidence-based, and implemented and sustained across communities. Shatterproof and the cosigners of this report support the following solutions, which are based on the recommendations of federal and state agencies:

PUBLIC HEALTH SURVEILLANCE

Collection and analysis of data to determine design, target and evaluate public health initiatives.

COMMUNITY-BASED DRUG ABUSE PREVENTION PROGRAMS

Local educational initiatives that target families, schools, community venues and houses of worship.

NATIONAL PATIENT AND PUBLIC EDUCATION

Multi-media campaigns and ongoing access to educational materials provided by government institutions and their branches including HHS, FDA, CDC and NIH.

PROVIDER EDUCATION

Government initiatives to improve the training and education of healthcare providers about pain management and substance use disorder. Under HHS, for example, the NIH has developed five curriculum resources focusing on opioid misuse.

PRESCRIBING GUIDELINES

Addressing the need for opioid prescription guidelines, in March, 2016 the CDC issued the CDC Guideline for Prescribing Opioids for Chronic Pain to be used by primary care physicians. Guidelines need to be developed for prescribing opioids for acute pain, and for the use of all physicians and prescribers.

PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

Establishing and maximizing the effectiveness of state-based electronic databases that enable health care providers, pharmacists, health officials and others to confidentially track the dispensing of controlled substance prescriptions in a coordinated fashion to eliminate overprescribing and inadvertent co-prescribing.

REGULATORY OVERSIGHT

Federal, state and local regulatory actions such as FDA oversight of drug approval and post-marketing activities and CMS's oversight of Medicaid and Medicare to impact behavior among patients and providers in terms of access to and use of opioids.

LEGISLATION ON PRESCRIBING

State adoption of rules governing prescribing, for example, specifying the maximum allowable number of days for initial opioid prescriptions.

Massachusetts has recently passed a 7 day maximum, consistent with CDC Guideline on opioid prescribing.

MEDICATION-ASSISTED TREATMENT (MAT)

The use of medications such as methadone, buprenorphine and naltrexone to treat substance use disorder and sustain recovery. Medication with psychosocial support is now considered the optimal evidenced-based approach.

OVERDOSE PREVENTION

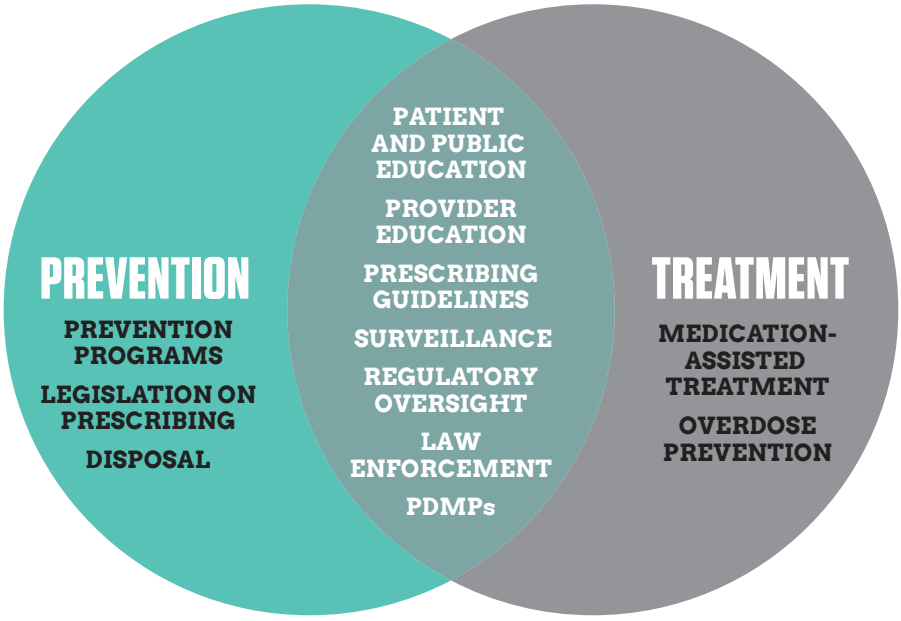
Programs focused on increasing access to naloxone to reverse the effects of overdose in emergency situations and granting immunity from prosecution to encourage people to seek help during an overdose emergency.

SAFE DISPOSAL OF MEDICATIONS AND TAKE-BACK PROGRAMS

The U.S. Drug Enforcement Administration (DEA) and local law enforcement periodically host collection events in communities for safe disposal of prescription drugs.

LAW ENFORCEMENT INVOLVEMENT

Aggressive law enforcement actions including efforts to address doctor shopping and pill mills to enforce compliance with state and national drug laws.



Important Update on Prescribing Guidelines

Improving the way painkillers are prescribed through clinical practice guidelines will ensure patients have access to effective pain treatments while reducing the rates of addiction and overdose.[28] On March 15, 2016, the CDC issued the Guideline for Prescribing Opioids for Chronic Pain, providing recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline includes 12 recommendations addressing 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use.[29] (Appendix D). The use of PDMP data is recommended to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk of an overdose.

In this report, we focus on one of the these evidence-based solutions; optimizing the effectiveness of Prescription Drug Monitoring Programs.

"Kentucky has seen, first-hand, the lifesaving power of legislation mandating physician participation in Prescription Drug Monitoring Programs (PDMPs). In 2012 Kentucky became the first state in the nation to pass legislation requiring doctors to check a patient's drug history before issuing new prescriptions for pain pills. Since that time we have seen a 13.4% decline in prescriptions of opioids dispensed, and a 25% decline in prescription opioid deaths. We still have an epidemic, but we've finally been able to make inroads into stemming the senseless opioid prescription growth that's cost so many lives in our state."

- Van Ingram, Executive Director of Kentucky Office of Drug Control Policy

[28] Prescription drug overdose. US Centers for Disease Control and Prevention. Retrieved from: http://www.cdc.gov/drugoverdose/prescribing/common-elements.html

[29] CDC guideline for prescribing opioids for chronic pain. (2016). US Centers for Disease control and Prevention. Retrieved from: http://www.cdc.gov/drugoverdose/prescribing/guideline.html

PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

Prescription Drug Monitoring Programs (PDMPs) are state-run electronic databases that track the prescribing and dispensing of controlled prescription substances, and are among the most promising clinical tools to curb prescription opioid abuse. A PDMP is not just a monitoring system, but a dynamic, multi-stakeholder tool that has the potential to address the broader issues of prevention, identification, and treatment in real time. PDMPs can provide a prescriber or pharmacist with important information regarding a patient's prescription history, helping to identify patients who may be misusing medications and at risk for overdose due to co-prescribing.[30] PDMP data can help prescribers and pharmacists to identify high-risk patients who would benefit from early interventions and/or referral to treatment.[31] PDMPs also can help federal, state and local officials identify key trends in both legitimate and problematic prescribing and dispensing, critical for tackling this nationwide crisis.

BRIEF HISTORY

The concept of PDMPs was introduced in the 1930s as a paper-based database to track Schedule II drugs so that law enforcement officials could identify diversion. By 1992, 10 states had operational PDMPs.

Reflecting their locations primarily in state agencies concerned with public safety and drug enforcement, these early PDMPs all provided solicited reports and most provided unsolicited reports, to law enforcement personnel and regulatory agencies or professional licensing agencies. None provided reports to prescribers or pharmacists. The reports and, where relevant, PDMP investigations, focused on prescribers selling prescriptions, pharmacies selling controlled substances illegally, and organized doctor shopping rings.

With support from the U.S. Drug Enforcement Administration (DEA), in 1990 the existing PDMP administrators created the Alliance of States with Prescription Monitoring Programs (the "Alliance"). The Alliance was founded to provide a forum for support and information exchange among PDMPs, states where efforts were under way to establish a PDMP, and states where creation of a PDMP was being considered. At this time, PDMPs expanded data collection beyond Schedule II prescriptions. In the context of computer-based information technologies, a second generation of PDMPs came into existence that collected prescription information electronically. Examples included the Oklahoma PDMP in 1990, located in the Department of Public Safety, and the Massachusetts PDMP in 1992, located in the Department of Public Health.

The Nevada PDMP, implemented in 1997, ushered in a new era of PDMPs by providing data directly to prescribers and pharmacists. Initially, Nevada sent unsolicited reports to the health care practitioners who had issued and dispensed prescriptions to possible doctor shoppers—that is, individuals receiving multiple simultaneous prescriptions of commonly abused drugs. This resulted in a rapid demand for solicited reports, i.e. reports upon request.[32] While the reports initially were sent by fax, in 2001 Nevada developed an online system that began issuing

[30] What health care providers need to know about PDMP. (2016) US Centers for Disease Control and Prevention. Retrieved from: http://www.cdc.gov/drugoverdose/pdmp/providers.html

[31] Prescription drug monitoring programs. (2016). US Centers for Disease Control and Prevention. Retrieved from: http://www.cdc.gov/drugoverdose/pdmp/index.html

[32] Using PDMPs to improve medical care: Washington State's data sharing initiative with Medicaid and workers' compensation. Notes from the Field, NF 4.1, April 2013, PDMP Center of Excellence at Brandeis University.

reports based upon users' direct inquiries. Kentucky soon followed Nevada's lead, developing online capabilities within a few years. In 1994, the Alliance initiated a process to help standardize electronic formats for data collection. This resulted in the publication of the American Society for Automation in Pharmacy's (ASAP) first version of guidelines for pharmacies to submit controlled substances prescription data to PDMPs. The standards have been updated frequently to incorporate enhancements in electronic system capabilities, and all PDMPs are now using a version of an ASAP standard.

In 2002 the federal government created the Harold Rogers Prescription Drug Monitoring Program Grant Program in the Department of Justice, Bureau of Justice Assistance (BJA), funded by a specific appropriation. In 2005, Congress passed the National All Schedules Prescription Electronic Reporting (NASPER) Act.

In 2008, in collaboration with the Alliance and the Heller School of Social Policy and Management at Brandeis University, BJA formed the PDMP Training and Technical Assistance Center, charged with assisting PDMPs in planning, implementing, and enhancing their programs. Two years later BJA funded the PDMP Center of Excellence (COE) at the Heller School in order to provide practice-relevant information, evaluation, and expertise to PDMPs and their stakeholders, including the development of best practices. BJA has maintained a focus on developing PDMP best practices and encouraging innovative applications of PDMP data. BJA has given priority funding consideration to states proposing to implement evidence-based practices that contribute to PDMP effectiveness.

Beginning in 2014, the Center for Disease Control and Prevention (CDC) began funding a Prevention Boost State Program to equip states with the resources and scientific assistance to prevent prescription opioid overdoses by addressing the inappropriate prescribing that fuels the epidemic. The funding supports three key areas, including maximizing PDMPs. For this federal fiscal year, BJA has allocated approximately $12 million for PDMPs while the CDC Prevention Boost has allocated approximately $70 million, a significant portion of which will go to PDMPs. With increasing grants in 2015 and 2016, the CDC is becoming the provider of the most funding support for PDMP enhancements and technical assistance.[33]

As a result of increased public and private support and the growing recognition of PDMPs' potential to address the prescription drug abuse epidemic, PDMPs have proliferated rapidly.

PDMPs are well positioned to serve the dual objectives of improving medical care and reducing diversion of these important medications. This is analogous to the collaboration of public health and law enforcement agencies in reducing automobile accidents, injuries, and fatalities.

EFFECTIVENESS

Evidence indicates PDMPs are effective in addressing the opioid epidemic shattering our families.[34] PDMP data are irreplaceable in identifying questionable activity with respect to prescription drugs, such as doctor and pharmacy shopping, prescription fraud, and problematic

[33] CDC-Drug overdose prevention. US Centers for Disease Control and Prevention. Retrieved from: http://www.cdc.gov/injury/pdfs/budget/fy2016_pres_budget_final_drug-overdose-prevention.pdf

[34] Briefing on PDMP effectiveness. (2013, April). PDMP Center of Excellence, Brandeis University. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/briefing_PDMP_effectiveness_april_2013.pdf

prescribing. No other system exists that can compile all controlled substances prescriptions, regardless of who is issued the prescription, which pharmacy dispensed it, or the source of payment. According to surveys of PDMP users and a study of emergency department doctors, PDMPs are an important tool in making sound clinical decisions when prescribing or dispensing controlled substances. [35]

PDMP data can also be used to track emerging trends in legitimate prescribing, to evaluate efforts to improve prescribing practices, such as provider education initiatives, and epidemiological surveillance and early warning systems. Several additional studies further suggest a connection between PDMP utilization or particular PDMP practices and positive outcomes related to improving, prescribing, and reducing prescription drug misuse and substance abuse disorder.[36]

THE TRAGEDY: A VASTLY UNDERUTILIZED CLINICAL TOOL

Although 49 states and the District of Columbia have legislation authorizing the creation and operation of PDMPs, in the vast majority of our states this effective clinical tool is significantly underutilized. A 2015 study of primary care prescribers found that while a majority reported having obtained data from their PDMP at some point in time, prescribers consulted PDMP data in fewer than one-quarter of instances when they prescribed opioids to patients. In a recent review of 2015 prescribing data in a sample of states where prescriber's have discretion of whether to request patient information from their state PDMP prior to considering issuing a prescription for an opioid, prescribers did so only 14% of the time before prescribing an opioid.[37] **These facts clearly indicate that state legislation which mandates that prescribers view PDMP data before making a decision to prescribe is the single most critical success factor for the effectiveness of PDMPs to save lives of citizens.**

> "Having been a public health professional for 46 years and in leadership in preventing prescription drug misuse and abuse for 31 of those years, I am very impressed with the work Shatterproof has done to put together this document and their on-the-ground advocacy in states. This organization understands the vitally important role of PDMPs in helping stop the prescription opioid overdose epidemic and in reversing the role those drugs play in driving new heroin use. This document provides solid recommendations for every state. Governors and state legislatures will be very wise if they adopt all of them."
>
> **- John Eadie, Public Health and PDMP Project Coordinator, National Emerging Threat Initiative of the National High Intensity Drug Trafficking Areas (HIDTA) Assistance Center and former Director, PDMP Center of Excellence at Brandeis University**

[35] ASPMP, 2007; Kentucky Cabinet for Health and Family Services, 2010; Baehren, 2010

[36] Pearson et al., 2006; Pradel et al., 2009; Reisman et al., 2009; Wang & Christo, 2009; Paulozzi & Stier, 2010; Fisher et al. 2011b; LeMire et al., 2012; Reifler et al., 2012

[37] The prescription opioid epidemic: An evidence-based approach. (2015, November) Johns Hopkins Bloomberg School of Public Health. Retrieved from: http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf

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CRITICAL ELEMENTS OF EFFECTIVE STATE LEGISLATION

Shatterproof holds that PDMPs are key tools in the fight against prescription drug misuse and addiction. Their effectiveness is maximized by the adoption of proven best practices, including mandates for prescribers to view PDMP data before making the decision to prescribe all drugs within Schedules II, III and IV of the federal Controlled Substances Act.

The following pages highlight recommendations for legislation that will optimize PDMPs so that their full potential is achieved in saving lives that would otherwise be lost to the opioid epidemic.

OVERARCHING PRINCIPLES:

Shatterproof holds that there are three principals that states need to adopt in order to address the prescription opioid overdose epidemic that transcend the legislative language of specific sections of PDMP authorization. These are:

I. PDMPs require sufficient funding to carry out the functions described in this paper. Each state must assure that its PDMP receives adequate funding. In addition to state funds, federal funds that may be available include funding through the Centers for Disease Control and Prevention and the Harold Rogers PDMP Grant Program administered by the Bureau of Justice Assistance.

II. States need to assure that prescribers, dispensers and other healthcare professionals fully understand the appropriate uses of prescription controlled substances and the risks of misuse, abuse, addiction, overdoses and deaths involving these medications, how to intervene with persons who may be addicted, and how to refer such persons into treatment.

III. The CDC issued the Guideline for prescribing of opioids for treatment of chronic pain. States should assure that healthcare professional licensing boards adopt these guidelines, that prescribers use these guidelines in their practices, and that the guidelines become the standard of care.

1. DISPENSERS REPORT SPECIFIED INFORMATION EXPEDITIOUSLY

RECOMMENDED LEGISLATION

1.1. Dispensers required to input the information listed in Appendix C ("Data Elements") to the PDMP on all controlled substances in Schedules II – V in the federal Controlled Substances Act (Appendix A, B) and any drugs the state has specifically scheduled or designated as drugs of concern.[38]

1.2. Dispensers required to submit prescription information to the PDMP within 10 minutes of dispensing, or at a maximum, no later than within 24 hours of dispensing (or by close of next business day).

1.3. Dispensers required to inspect the photo identification of each person picking up the prescription and, if that person is not the patient for whom the prescription was written, report to the PDMP the name, address, date of birth, gender and the relationship of that person to the patient.[39]

1.4. Dispensers required to report the source of payment for the prescription.

RATIONALE

1.1. Inputting information to the PDMP database on all controlled substances in Schedules II – V in the Controlled Substances Act will allow health care providers to see a more comprehensive list of prescription information and make better informed clinical prescribing decisions.

1.2. Timely data entry ensures health care providers are receiving up-to-date information regarding prescribing information on patients.

1.3. Entering information on the individual who physically obtains the prescription medication will allow for authorized recipients of the data collected (physicians, nurses or law enforcement officials) to detect any potential patterns of misuse or abuse. When a PDMP examined prescriptions for Schedule II drugs, it found that 38% were picked up by someone other than the patient. If the person picking up the medication is not identified, the state is making it easy for persons with substance use disorder to obtain drugs undetected and criminal elements to divert medications into drug trafficking.

1.4. Entering information on the source of payment will allow for authorized recipients of the data collected (physicians, nurses or law enforcement officials) to detect potential problematic patterns such as frequent payments in cash.[40] Persons trying to obtain drugs for illegal use often pay in cash to hide what they are doing from being observed by Medicaid, Medicare and health insurance carriers.

[38] Controlled Substances Act. (2009) US Food and Drug Administration. Retrieved from: http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm#cntlsbb

[39] As of 1/11/2016 the American Society for Automation in Pharmacy standard 4.2 for pharmacies to transmit controlled substances data to PDMPs has fields for information on the person dropping off or picking up the prescription if other than the patient (i.e. data fields AIR03 through AIR08). Included are the person's first and last names, the relationship to the patient, and an ID number. Should state legislation also require, the address, date of birth and gender, the ASAP standard will need to be modified, which can be done.

[40] For a description of PDMP measures indicative of possible at-risk prescribing, see Definitions of Prescription Behavior Surveillance System (PBSS) Measures, Section 5: Pill Mill Measures, pp. 4-7, http://www.pdmpexcellence.org/sites/all/pdfs/Definitions%20of%20PBSS%20Measures%20112113.docx

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2. PRESCRIBERS QUERY PDMP BEFORE PRESCRIBING DRUGS IN SCHEDULES II, III AND IV

RECOMMENDED LEGISLATION

2.1. Prescribers or their delegates required to request and review a patient's previous twelve-month prescription history report prior to prescribing any drug included in Schedules II through IV of the Controlled Substances Act.

Exceptions may be permitted for:

- Terminally ill patients under the supervised care of a hospice program
- Prescriptions of three days or less supply with no refills
- Rare instances when it is impossible to query the PDMP in a timely manner due to an emergency situation or if the program is not operational due to technological or electrical failure or natural disaster
- Patient is in a long-term care facility where medication orders are filled by its own pharmacy or hospital pharmacy
- Patients being administered methadone or buprenorphine for treatment of opioid addiction – if drug is dispensed, cannot be exempted

RATIONALE

2.1 Not all enrolled prescribers regularly use PDMPs. Less than half of states with PDMPs legally mandate prescribers to query the system before writing for controlled substances with recognized potential for abuse or dependence or that pose danger to patients when used concurrently with existing prescriptions. As a result, prescribers are solely reliant on information shared by patients to inform clinical decision-making. This practice is fraught with risk because a patient who is misusing opioid medications or has an opioid use disorder may be motivated to conceal prescription history, or alternatively, a patient's memory or understanding of their own drug intake may be inaccurate or incomplete.

Medications that are classified in Schedule I by the Controlled Substances Act, or drugs that currently have no accepted medical use in the U.S., are not prescribed for or dispensed to patients. Without mandated reporting of medications that are classified in Schedules II through IV, which can be prescribed and dispensed by healthcare providers, the prescribers do not know if a drug can be safely prescribed and how much. Prescribers are unable to detect prescription drug misuse and may unintentionally expose patients to dangerous and sometimes fatal drug quantities or combinations. Controlled substances in Schedules II, III and IV contain opioids, sedatives/tranquilizers, and stimulants which are subject to misuse, substance use disorder, overdose, injury and death. Schedule II and III substances include frequently prescribed painkillers including oxycodone and hydrocodone; Schedule IV prescriptions include central nervous system depressants, including Benzodiazepines like Xanax or Valium, that when mixed with Schedule II and III substances can be fatal. Mandated PDMP-generated intelligence on a patient's current or past Schedule II and III substance history offers health care providers vital, and sometimes life-saving, background information to inform sound clinical and prescribing decisions. It will also deter "doctor shoppers" from asking for medications within Schedules II thru IV, with potentially fatal outcomes.

WHY SCHEDULE IV?

The dangers of opioids are beginning to become well known. And in this regard, policy makers are beginning to legislate that prescribers check a patient's prescribing history before considering prescribing an opioid.

So if most opioids are listed in Schedule's II and III, why do the Shatterproof recommendations include a prescriber checking a patient's history before considering prescribing drugs listed in Schedule's II, III and IV?

The most important reason is that Schedule IV includes benzodiazepines, which if taken concurrently with an opioid can be extremely dangerous. In fact, Guideline #11 in the recently released CDC Guideline for Prescribing Opioids for Chronic Pain states:

"Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible."

FURTHER BACKGROUND IN THE GUIDELINE STATES:

Benzodiazepines and opioids both cause central nervous system depression and can decrease respiratory drive. Concurrent use is likely to put patients at greater risk for potentially fatal overdose. One case-cohort study found concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone. Clinicians should check the PDMP for concurrent controlled medications prescribed by other clinicians and should consider involving pharmacists and pain specialists as part of the management team when opioids are co-prescribed with other central nervous system depressants.

Recent data confirms that both overdoses and deaths involving combinations of opioid analgesics and benzodiazepines are rising:

A 2016 study published in the American Journal of Public Health found that in 2013 22,767 people died of an overdose involving prescription drugs in the United States. Benzodiazepines were involved in 31% of these fatal overdoses.

- A 2015 study published in the British Medical Journal found approximately 50% of the veterans who died from drug overdose between 2004 and 2009 were prescribed opioids and benzodiazepines at the same time. Those at highest risk of death were those receiving the larger quantities of benzodiazepines.[41]
- Beyond benzodiazepines, Schedules II, III and IV controlled substances contain sedatives/tranquilizers, and stimulants which are subject to abuse, addiction and death.
- For further information on drugs that are contained in each of Schedules II, III and IV, see Appendix A, B.

[41] Park, T.W., Saitz, R., Ganoczy, D., Ilgen, M.A., & Bohnert, A.S.B. (2015). Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. *BMJ.* Retrieved from: http://www.bmj.com/content/bmj/350/bmj.h2698.full.pdf

3. LICENSED PRESCRIBERS REGISTER WITH PDMP

RECOMMENDED LEGISLATION

3.1. All prescribers with a U.S. Drug Enforcement Administration (DEA) or state-controlled substance registration number and all state-licensed pharmacists should be required to register with the PDMP upon the initial registration or renewal of the prescriber's professional license or certification. This can be accomplished automatically by the board or agency responsible for licensing, registering, or certifying the prescriber, or can be incorporated into the licensing, registering, or certifying process to be completed by the prescriber at the time s/he applies for initial registration, licensure, certification or renewal.

RATIONALE

3.1 PDMP registration in conjunction with license registration and renewal will ensure prescriber compliance and reinforce the importance of the program. It also makes it possible for these healthcare providers to request data from their state's PDMP.

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4. ENABLE DELEGATION OF PDMP DATA QUERIES

RECOMMENDED LEGISLATION

4.1. Allow prescribers and dispensers to designate individuals to act as an agent of said prescriber or dispenser for the purposes of obtaining data from the PDMP. Delegates must be:

- Licensed or registered health care professionals overseen by a professional licensing board, such as a physician assistant, registered nurse, resident physician or pharmacy technician.
- Other employees who report directly to the prescriber or dispenser

In all cases, each delegate must be directly supervised by the prescriber or dispenser and such prescriber or dispenser must be held accountable for the delegate's actions.

RATIONALE

4.1 Prescribers have reported that the time required to obtain PDMP reports is the major obstacle to using the PDMP.[42] Allowing them to delegate this activity to staff removes this obstacle. Enlisting delegates such as nurses, physician assistants, resident physicians or other individuals among the team of health care providers and pharmacy staff, can not only benefit patient care and safeguard prescribing and dispensing activities, but can also save doctors' time.

[42] Rutkow L, Turner L, Lucas, E, et al. (2015). Most primary care physicians are aware of prescription drug monitoring programs, but many find the data difficult to access. *Health Affairs*. 34(3): 484–492. Retrieved from: http://content.healthaffairs.org/content/34/3/484.full.html

5. AUTHORIZE SPECIFIED RECIPIENTS OF PDMP DATA

RECOMMENDED LEGISLATION

5.1. The individuals or officials given direct access must include:

- Prescribers and their designees, including those practicing in Veterans Affairs (VA), Department of Defense (DOD) and Indian Health Service (IHS) facilities and in other states.
- Dispensers and their designees, including those located in VA, DOD and IHS facilities and in other states.
- The state department of public health for purposes of public health research, education, disease intervention, and evaluation of the quality of healthcare provided by healthcare facilities under its regulatory authority.
- Local public health departments for purposes of public health research, education, and disease intervention.
- Professional licensing or certification boards or agencies for prescribers and dispensers who are specifically designated, trained, and supervised for specific investigations.
- Medical examiners, county coroners or others authorized under law to investigate causes of deaths.
- Licensed healthcare professionals at drug and alcohol addiction treatment programs, including individuals licensed or certified to provide substance abuse treatment services.
- Drug court judges and their designees.
- Representatives from the state Medicaid or other state-administered health insurance program.

5.2. Individuals allowed to request specific data from the PDMP database will include:

- Licensed healthcare professional supervisors from Medicare, health insurers, workers compensation programs/insurers for persons enrolled in or covered by their programs, and prescription benefit managers (PBMs) as agents of the third party payers for whom they manage benefits;[43] the above representatives must be authorized to request and receive data for all of the persons enrolled in or covered by their programs.[44]
- Licensed healthcare professional supervisors of VA, DOD and IHS facilities must be authorized to access data regarding individuals enrolled in their healthcare programs as well as the prescribers and dispensers who work for them; the above representatives must be authorized to request and receive data for their systems' prescribers and dispensers and all persons enrolled in or covered by their programs.[45]

[43] PDMPs and third party payers meeting: Report of proceedings. (2014, April) PDMP Center of Excellence at Brandeis University. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_COE_PDMP_3rd_pty_payer_mtg_rpt.pdf

[44] Using PDMPs to improve medical care: Washington State's data sharing initiative with Medicaid and workers' compensation. Notes from the Field, NF 4.1, April 2013, PDMP Center of Excellence at Brandeis University.

[45] Using PDMPs to improve medical care: Washington State's data sharing initiative with Medicaid and workers' compensation. Notes from the Field, NF 4.1, April 2013, PDMP Center of Excellence at Brandeis University.

- Peer review committees in hospitals and other healthcare facilities so they can assess quality of care being provided by healthcare professionals to patients.
- Patients and parents of patients who are minor children.
- Local, state and federal law enforcement and prosecutorial officials as part of an ongoing investigation.

RATIONALE

5.1 Physicians, health care providers and insurers play a key role in addressing prescription drug abuse, and access to PDMP data is key to an effective response. Insurers, while not direct health care providers, do not have a complete understanding of the scope or type of prescribing actually provided to their enrollees without access to PDMP data.[46] With proper guidelines in place to regulate legitimate use of prescription history information, patient confidentiality, and data security, third party payers can become a strategic partner in preventing and identifying abuse.

5.2. Confidential access to data in the PDMP for third party payers and their prescription benefit managers (PBMs), as agents of the third party payers, can improve clinical decision-making and patient health care and safety. PBMs manage the pharmacy benefits for health plans and large employers and possess members' claims data for prescription drugs, and at times, other healthcare goods and services. PBMs do not have visibility of prescriptions paid with cash or those paid by another insurer. The fact that PBMs lack a comprehensive view of an individual patient's prescription history makes it essential for them to be able to request information in the PDMPs for all of the persons enrolled in or covered by their programs.

Software algorithms can be used to identify individuals, pharmacies and prescribers that are potentially using or dispensing controlled substances fraudulently. In addition, PBMs' prescription claims surveillance and prescriber intervention programs often use retrospective analysis to identify members meeting excessive controlled substance use criteria, such as some combination of the use of multiple prescribers, multiple dispensing pharmacies, exceeding a threshold of morphine milligram equivalent (MME) dose, or multiple controlled substance claims over a period of three-to-six months. Prescriber letter interventions through PBMs have been shown to decrease members' controlled substance score and controlled substance drug claims.[47,48] These programs could be enhanced if the PBM has the complete controlled substance prescription history, including cash claims, through access to states' PDMPs.[49]

[46] PDMPs and third party payers meeting: December 2012. (2014, April). Prescription Drug Monitoring Program Center of Excellence at Brandeis. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_COE_PDMP_3rd_pty_payer_mtg_rpt.pdf

[47] Gonzalez A.M., Kolbasovsky A.(2012) Impact of a managed controlled-opioid prescription monitoring program on care coordination. American Journal of Managed Care. 18(9):516-24.

[48] Daubresse M., Gleason P.P., Peng Y., Shah N.D., Ritter S.T., & Alexander C.G. (2014) Impact of a drug utilization review program on high-risk use of prescription controlled substances. Pharmacoepidemiology Drug Safety. 23:419-427.

[49] The prescription opioid epidemic: An evidence-based approach. (2015, November) Johns Hopkins Bloomberg School of Public Health. Retrieved from: http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf

CASE STUDY

The health insurer Aetna reported in 2014 that its PBM "Pharmacy Misuse, Waste and Abuse" program monitors access to opioids through precertification and reviews of pharmacy and medical claims and quantity limits to find patterns of above-normal use. Further, members who have had frequent emergency room visits are identified. Other signs, and suspicion of developing substance abuse problems or a history of controlled substance abuse, also are noted. The program reduced opioid prescriptions among 4.3 million members by 14 percent between January 2010 and January 2012.[50]

In addition to improving the quality of care, allowing third party payer access can provide significant savings to workers compensation claims. According to predictive data from the California Workers Compensation Institute, expanding PDMP access to third party payers in California would have yielded savings of $57 million (4%) in 2011 in claims alone.[51]

[50] Aetna helps members fight prescription drug abuse. (2014, January). Aetna. http://news.aetna.com/news-releases/aetnahelps-members-fight-prescription-drug-abuse/. (Accessed February 3, 2015).

[51] Briefing on PDMP effectiveness. (2013, April). PDMP Center of Excellence, Brandeis University. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/briefing_PDMP_effectiveness_april_2013.pdf

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6. PROACTIVELY ANALYZE AND DISTRIBUTE PDMP DATA

RECOMMENDED LEGISLATION

6.1. The PDMP should be required to proactively analyze its data to identify persons who may be using, prescribing, or dispensing prescription controlled substances in a manner that puts patients at risk of injury, overdose, or death or that violates laws or practice standards.

Analyses should measure data against criteria indicative of high-risk drug use or illegal activities.[52]

When probable high-risk behavior is identified, the PDMP should distribute unsolicited reports to the party best able to address it.

State statutes should direct PDMPs to analyze data and send out reports regarding:

- Data regarding patients.
- Data regarding prescribers.
- Data regarding dispensers.

For patients, an example is the State of California that launched its rebuilt PDMP system in December 2015. As each prescriber signs into his/her PDMP account, the account dashboard lists his/her patients who:[53]

- Are currently prescribed more than 100 morphine milligram equivalents per day.
- Have obtained prescriptions from six or more prescribers or six or more pharmacies during the last year.
- Are currently prescribed more than 40 milligrams of methadone daily.
- Have been prescribed opioids for more than 90 consecutive days.
- Are prescribed benzodiazepines and opioids concurrently.

For prescribers, examples include:

- Multiple patients who travel long distances to the prescriber and general practitioners prescribing high dosages or high-risk drug combinations to multiple patients.[54,55]

[52] Prescription Behavior Surveillance System (PBSS). Definitions of PBSS Measures. PDMP Center of Excellence at Brandeis University. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/Definitions%20of%20PBSS%20Measures.pdf

[53] CURES 2.0: Prescription Drug Monitoring Program. California Department of Justice. September 2015-power point slide presentation

[54] Kolodny, A, et al. (2015). The prescription opioid and heroin crisis: A public health approach to an epidemic of addiction. Annual Review of Public Health. 36:559-574.

[55] Fulton-Kehoe, D., Sullivan, M.D., Turner, J.A., et. al. (2015). Opioid poisonings in Washington State Medicaid: Trends, dosing, and guidelines. *Medical Care*. 53(8): 679-685.

For dispensers, examples include:

- Quantities of drugs purchased by the pharmacy (as reported to state and DEA) should be equivalent to quantities dispensed.
- Pharmacies that regularly dispense prescriptions issued by prescribers who appear to be engaged in high-risk prescribing or "pill mill" activity.

The parties to whom PDMPs should distribute unsolicited reports when probable high-risk behavior is identified include:

- For patients at risk of addiction, injury, overdose or death, the patients' prescribers and dispensers should be notified so that they may intervene and, if necessary, refer patients to appropriate treatment.
- When a patient's activity appears to be criminal in nature, such as organized doctor shopping to obtain drugs for street sale, law enforcement should receive a report.
- For prescribers and dispensers, if questionable prescribing or possible mis-prescribing, mis-dispensing or self-misuse is identified, the applicable professional licensure board should receive a report.
- If practitioner criminal behavior is identified, such as "pill mill operation," law enforcement should receive a report.

RATIONALE

6.1 Because they collect a constant stream of comprehensive data, PDMPs are uniquely positioned to identify inappropriate prescribing and misuse patterns among physicians and patients, respectively, as those behaviors emerge. PDMP-generated reports can notify prescribers and dispensers that patients may be misusing or diverting medications, and law enforcement agencies and prescriber licensing boards of questionable activity among prescribers and dispensers.

A 2014 study that surveyed more than 300 physicians in Massachusetts after they received unsolicited reports found that only 8 percent were aware of most, all, or nearly all other prescribers. Nearly 44 percent indicated having sufficient knowledge to determine whether the prescriptions were medically necessary after reviewing the reports, of whom nearly 70 percent felt the prescriptions were unwarranted. A majority of the physicians found the report useful to their practice.[56]

Multiple state-level experiences have shown that a minority of prescribers are responsible for problematic behavior, which PDMPs can detect when proactively monitored. In Florida in 2012, 60 percent of opioid prescriptions originated from the top 10 percent of prescribers in the state. While prescribing frequency and dosage alone do not necessarily denote inappropriate prescribing practices, when brought to light by PDMPs, they provide data points for further law enforcement agency or prescriber licensing board investigation.

[56] Thomas, C.P., Kim, M., Nikitin, R.V., et al. (2014). Prescriber response to unsolicited prescription drug monitoring program reports in Massachusetts. *Pharmacoepidemiology and Drug Safety.* DOI: 10.1002/pds

Additionally, proactive PDMP reporting can allow for early identification of intentional misuse practices. Data identifiable in PDMPs is capable of pinpointing possible patient misuse or substance use disorder by alerting authorities to concerning patterns, such as medical practices that attract a high proportion of possible doctor shoppers and pharmacies that dispense a large volume of prescriptions paid for in cash.[57]

Proactive reporting to law enforcement agencies and prescriber licensing boards concerning questionable activity by patients and prescribers, respectively, can also help reduce drug diversion.[58]

[57] Data from the Prescription Behavior Surveillance System (PBSS) as presented by Dr. Len Paulozzi at the 2013 Harold Rogers PDMP National Meeting, see http://www.pdmpassist.org/pdf/PPTs/National2013/26-8-A%20Paulozzi.pdf slide 21.

[58] Guidance on PDMP Best Practices. Options for Unsolicited Reporting. Prescription Drug Monitoring Program Center of Excellence at Brandeis. Published January 2014. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_COE_Guidance_on_Unsolicited_Reporting_final.pdf

7. REQUIRE INTERSTATE SHARING OF PDMP DATA

RECOMMENDED LEGISLATION

7.1 Each state with a PDMP must provide for appropriate interstate sharing of PDMP data with other states' PDMPs by statute, regulation, or interstate agreement.

7.2 Users of PDMP data from the sending state through the receiving state's PDMP must include all users with direct access to PDMP data in the sending state, but at minimum:

- Prescribers & dispensers.
- When part of an ongoing investigation, trained and supervised law enforcement and professional licensing board investigators.
- PDMP officials, or other specified authorities.

7.3 Upon receipt of requests from prescribers and dispensers for patient prescription histories, PDMPs should routinely request data from all adjoining states as well as providing data from within the PDMP's own database.

RATIONALE

7.1. Current PDMPs are limited within state lines and may not be able to detect cases of individuals who filled prescriptions in other states.

7.2. Permitting interstate sharing of information will help providers more quickly identify cases of doctor shopping, where patients may have gone out of state for an opioid prescription. In addition, frequently a college student will have a doctor prescribing medication in his or her home state and then another doctor at college. To protect the health of this student, interstate sharing of information is a must.

7.3. Prescribers and dispensers need the full prescription history for each patient for clinical evaluation prior to issuing or dispensing prescriptions. Yet patients may also obtain prescriptions from others. PDMP data show that while a large majority of prescriptions dispensed in a state were issued by prescribers in that state, 5% or more are issued by prescribers in adjoining states. That leaves about 1% to 2% issued by prescribers in the rest of the US and its territories. Thus, if the PDMP routinely requests data from the adjoining states, they can provide to the requesting prescribers and dispensers all or almost all of the prescriptions they need to see. The requesters are also able to specify the additional state or territory from which they request data, should they be aware of a patient's travel to those locations.

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8. PROVIDE DE-IDENTIFIED INFORMATION

RECOMMENDED LEGISLATION

8.1 PDMP administrator authorized to disclose de-identified data for statistical, public research, public policy, or educational purposes. Prior to disclosure, the PDMP administrator should remove information that identifies, or could reasonably be used to identify, the patient, prescriber, dispenser, or other person who is the subject of the information. For purposes of epidemiological use, the dates of birth and the zip codes should be left unchanged in the data whenever feasible. States may opt to charge for the provision of this information to apply toward the costs associated with sharing this information.

RATIONALE

8.1. Current means of obtaining data do not allow proper assessments of PDMPs and accurate measurement of their success against the growing use and abuse of prescription painkillers. By allowing the use of de-identified data to be shared with researchers and other authorized personnel, patterns and trends may be identified that could aid in the effort to end addiction on a broad scale. In particular, the CDC and the FDA fund a Prescription Behavior Surveillance System (PBSS) at the PDMP Center of Excellence (COE) at Brandeis University. States participate in this system by providing quarterly de-identified data to the PDMP COE. In return, the states receive back reports of analyzed data using 43 trend measures that permit states to understand the level of the epidemic, identify the rates of doctor shopping and other signs of high risk danger in prescription patterns, and evaluate effectiveness of interventions.

9. TAKE A COMMUNITY-BASED APPROACH TO PDMP DATA

RECOMMENDED LEGISLATION

9.1. PDMPs required to work with their states' Departments of Public Health and Substance Abuse Services to utilize their epidemiological capabilities to identify community hot spots, target prevention programs, assign resources for substance abuse treatment, and assist in interventions to address overprescribing, such as sending letters to the top prescribers in each therapeutic category of controlled substances.

9.2. Using de-identified data, PDMPs required to work with law enforcement to track the intersection of prescription opioid overprescribing, misuse and overdoses with heroin trafficking in order to warn communities of increasing heroin risks. Since four out of five heroin users begin using heroin following nonmedical use of prescription opioids,[59] communities where opioids are most used and misused would appear to be at highest risk for increases in heroin use.

To facilitate this type of work, states should consider joining the Prescription Behavior Surveillance System.[60] In addition, technical assistance is available from the PDMP Center of Excellence on using PDMP data for these purposes.

RATIONALE

9.1. PDMPs can serve a wider purpose than data records for prescribers and dispensers. When properly used, PDMPs have the potential to offer additional stakeholders in the fight against the opioid epidemic, essential information which could help assist in prevention and treatment of substance use disorders. Data from PDMPs identify the levels of persons in need of prevention and treatment so states can target limited resources to the communities with the greatest problems. As the number of substance use disorders moves up or down within communities or between communities, states should routinely review the PDMP data to monitor these changes and make adjustments in assignment of resources as needed.

9.2. State governments and law enforcement can and should consider PDMP data an early warning system for communities, and leverage the data to help address the epidemic on a community level.

[59] Volkow, N.D. (2014). America's addiction to opioids: Heroin and prescription drug abuse. Presented May 14, 2014. Retrieved from: https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse

[60] Prescription Behavior Surveillance System (PBSS). Definitions of PBSS Measures. PDMP Center of Excellence at Brandeis University. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/Definitions%20of%20PBSS%20Measures.pdf

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10. LINK PDMP DATA TO PAIN AND ADDICTION TREATMENT

RECOMMENDED LEGISLATION

10.1. PDMPs required to assist prescribers and dispensers in referring patients to pain and substance use disorder treatment.

State statutes should:

- Direct PDMPs to provide prescribers and dispensers links to pain and substance use disorder professionals and treatment centers as well as guidelines for intervening with persons with possible substance use disorders on their web pages.
- Direct PDMP administrators to refer prescribers and dispensers whom the data indicate may be impaired to the appropriate professional licensing or certification agency for investigation and referral to impaired professionals associations, as appropriate.

RATIONALE

10.1 Raw data spotting potential opioid abuse and misuse has limited value if it does not effectively foster intervention. Beyond identifying individuals who may have substance use disorders, PDMPs should assist prescribers in establishing linkages between these individuals and pain and substance use disorder treatment professionals.

Additionally, enabling PDMP administrators to take action and report at-risk prescribers can be an effective action. Kentucky's PDMP sends reports on prescribers to investigators at the state's Drug Enforcement and Professional Practices Branch (DEPPB). From July 2012 (the start of this initiative) to November 2013, DEPPB received 95 cases for review.[61] Actions thus far have resulted in retirements, agreed orders setting out sanctions and terms to be imposed upon the prescriber, and controlled substance license revocations.[62]

[61] Data from DEPPB provided courtesy of KASPER.

[62] Using PDMP Data to Guide Interventions with Possible At-Risk Prescribers. (2014, October). PDMP Center of Excellence at Brandeis University. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/Using_PDMP_Data_Guide_Interventions_at_Risk_Prescribers.pdf

11. INSTITUTE CONFIDENTIALITY PROTECTIONS

RECOMMENDED LEGISLATION

11.1. Requirement that PDMP law or other state law that applies to the PDMP require confidentiality protections from improper use of the system or of information from the PDMP. These are important statutory and programmatic provisions.

- PDMP data should not be subject to public or open records laws, civil subpoena or disclosure or be discoverable, compelled to be produced in any civil proceeding, nor deemed admissible as evidence in any civil proceeding where a prescriber or dispenser is not a named party.
- The enabling statute for the PDMP or other statute applicable to the PDMP should include civil and criminal penalties for knowingly disclosing, using or obtaining information other than as authorized by law.
- The PDMP administering agency should be required to maintain procedures to protect the privacy and confidentiality of patients and to ensure that data collected, recorded, transmitted, and maintained pursuant to the PDMP law is not disclosed or used except as authorized by the law.
- The law should mandate that auditable records are kept of every release of identified data.
- While PDMPs should provide patients and parents access to the data held by the database (as above under item 2), PDMPs should be exempted from state information practices acts that require the PDMP to reveal to an individual his/her prescription records and, when demanded, correct those records. The pharmacy that dispensed each prescription and submitted the information to the PDMP is the only party that should make such correction.

RATIONALE

11.1 Data held by PDMPs is confidential health information that should only be accessed and used by persons and organizations expressly authorized for that purpose by state law and regulation. To assure that the data is restricted to these authorized users and uses, states must provide statutory protections to the data and penalties if someone violates those protections. To ensure consistent use and acceptance of PDMP practices, it is critical that this confidentiality be clearly communicated and uniformly enforced.

12. ESTABLISH BASELINE EVALUATION MEASURES

RECOMMENDED LEGISLATION

12.1 Requirement to report basic measures of PDMP registration, utilization, prescribing, and patient risk measures. Using these data, produce quarterly and annual reports that can be used to track trends in controlled substance use and assess the PDMP's performance and impact. The reports should contain data from prior quarters and/or years to allow trend analysis by comparing the most recent time period to previous time periods. Provide such reports to the Governor, legislature, other key stakeholders and post them on the PDMPs' websites and a website open to the public. Areas that should be described in reports include:

- Registrations with the PDMP, including but not limited to:
  - Number of prescribers, by type of practice, e.g. physician, dentist, nurse practitioner, physician assistant, podiatrist, optometrist, veterinarian, and dispensers who have registered with the PDMP.
  - For each type of prescriber and dispenser, the percentage registered of all in-state practitioners who have a DEA registration.
  - Numbers of law enforcement and professional licensing board investigators registered with the PDMP.
- Use of PDMP Data, including but not limited to:
  - Number of requests for PDMP reports made by prescribers, dispensers, law enforcement, professional licensing boards and other users.
  - The ratio of requests to volume of prescriptions, for each category of user above.
  - At least annually, calculate the ratio of requests by each type of prescriber, i.e., number of requests made by physicians, dentists, nurse practitioners, physician assistants, podiatrists, and others divided by number of prescriptions issued by each group.
  - Number of unsolicited reports/alerts provided, by category of recipient, i.e. prescribers, dispensers, law enforcement, professional licensing boards and other users.
  - At least annually, the ratio of unsolicited reports sent to each category of user divided by the number of users in each category should be calculated, including by each type of prescriber.
  - Comparison of a state's use of data to other states.

- At least annually, prescribers' compliance with mandate to review PDMP data, including but not limited to:
  - Collect audit data on each prescriber's queries to the PDMP.
  - Calculate each prescriber's ratio of data requests to number of prescriptions issued by that prescriber that required pre-check with the PDMP.
  - Prescribers with low ratios can be sent letters by state health departments, professional licensing boards, or the PDMP, encouraging better compliance with the mandate.
  - For prescribers with the very lowest ratios and/or those who previously received letters but made no change in practice, investigations and, if necessary, proceedings should be undertaken by professional licensing boards.
- Changes in prescribing and risk measures over multiple quarters and years, including but not limited to:
  - Total prescriptions by therapeutic category, and by specific drug
  - Geographical distribution of prescribed drugs by county or municipal area, by total and by therapeutic category (can be done by mapping)
  - Number of prescriptions per 100,000 population
  - Number of dosage units per 100,000 population
  - Number of morphine milligram equivalents (for opioids) per 100,000 population
- Changes in patients' risk measures, for example, including but not limited to:
  - Number of individuals meeting threshold for multiple provider episodes.
  - Number of patients being prescribed over 100 morphine milligram equivalents.
  - Number of patients being prescribed opioids and benzodiazepines during the same time period.

RATIONALE

12.1 One of the key uses for PDMPs is the ability to measure success of the programs in order to evolve and improve upon the process. However, there is currently no protocol in place to formally track data to report basic measures of PDMP registration, utilization, prescribing, and patient risk measures. Putting in place a system and reporting structure for evaluating the success of PDMPs will enable more uniform assessment of PDMP success.

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STRONG STATE LEADERSHIP: SAVING THE LIVES OF THEIR RESIDENTS

It requires strong leadership by state elected officials to stop the epidemic of prescription drug overdoses and death. Recognizing that discretionary use of PDMPs is not effective in maximizing the benefits of PDMPs, elected leadership in several states began passing legislation in 2012 requiring various aspects related to utilizing its PDMPs.

Shatterproof applauds the leadership in the following seven states for passing legislation that captures most of the elements in *Shatterproof's Critical Elements of Effective State Legislation:*

Kentucky	New York	Tennessee	Connecticut	Ohio	Wisconsin	Massachusetts
2012	2013	2013	2015	2015	2016	2016

Stories of Success

Three states passed legislation in 2012 and 2013 which included many of the elements in *Shatterproof's Critical Elements of Effective State Legislation.* It is important to note that as a result these states are seeing significant increases in PDMP use simultaneous with decreases in key indicators including doctor shopping, prescriptions for the most misused drugs, co-prescribing of opioids and benzodiazepines, and high risk prescribing of large dose opioids. At the same time, prescribing of buprenorphine, a medication used to help treat OUD, has increased.

Summarized on the following pages are the experiences of these states.

KENTUCKY

THE LEGISLATION

- Enacted April, 2012. Effective July 2012.
- First state in the nation to mandate comprehensive PDMP use.

RECOMMENDATIONS INCLUDED*

1. Dispensers Reporting of Information	24 Hour Reporting
2. Prescriber Query	Schedule II, III and IV – First time, every 3 months in most situations
3. Prescriber Registration	All Shatterproof Recommendations
4. Delegates	All Shatterproof Recommendations
5. Authorized Recipients	Most Shatterproof Recommendations

6. Proactive Analysis	Most Shatterproof Recommendations
7. Interstate Sharing	Most Shatterproof Recommendations
8. De-Identified Information	All Shatterproof Recommendations
11. Confidentiality	Most Shatterproof Recommendations
12. Evaluation	Most Shatterproof Recommendations

THE RESULTS

- 13.4% decline in prescriptions of opioids dispensed (twelve months prior to June 2015 compared to twelve months prior to June 2012). [63]
- 17.7% decline in prescriptions of sedatives dispensed (twelve months prior to June 2015 compared to twelve months prior to June 2012). [63]
- 26% decline in prescription overdose hospitalizations after the program's inception.[64,65]
- 25% decline in prescription opioid deaths, the first decline in a decade.[66]
- Nearly 90% increase in prescriptions for buprenorphine, a medication used to treat opioid addiction.[67]
- 465% increase in prescriber's average requests for reports (2011 to 2013).[68]

Every 1% reduction in opioids prescribed for chronic pain will result in an approximate 1% - 1.2% reduction in overdose deaths.

[63] Kentucky Office of Drug Control Policy.

[64] PDMP Center of Excellence at Brandeis University. Bureau of Justice Assistance Prescription Drug Monitoring Program Performance Measures Report: January 2009 through June 2012. Revised 2014. Available at: http://www.pdmpexcellence.org/sites/all/pdfs/BJA_PDMP_Performance_Measures_1_09_6_12_fdbk.pdf.

[65] The prescription opioid epidemic: An evidence-based approach. (2015, November) Johns Hopkins Bloomberg School of Public Health. Retrieved from: http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf

[66] Ingram V, Kentucky Executive Director, Office of Drug Control Policy. Email correspondence to Eadie, JL. 6 March 2015 and 12 March 2015.

[67] The prescription opioid epidemic: An evidence-based approach. (2015, November) Johns Hopkins Bloomberg School of Public Health. Retrieved from: http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf

[68] Mandating PDMP participation by medical providers: current status and experience in selected states. (2014, February). PDMP Center of Excellence at Brandeis University. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/COE%20briefing%20on%20mandates%20revised_a.pdf

*As two of the twelve recommendations are new to the field, they have been excluded from this analysis

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NEW YORK

THE LEGISLATION

- Enacted June 2013; effective August 2013.
- First state to require prescribers request and review a patient's prescription history prior to prescribing any drug included in Schedules II through IV.

RECOMMENDATIONS INCLUDED*

1. Dispensers Reporting of Information	24 Hour Reporting
2. Prescriber Query	Schedule II, III and IV – Every time
3. Prescriber Registration	Does not require
4. Delegates	All Shatterproof Recommendations
5. Authorized Recipients	Many Shatterproof Recommendations
6. Proactive Analysis	Most Shatterproof Recommendations
7. Interstate Sharing	Most Shatterproof Recommendations
8. De-Identified Information	Most Shatterproof Recommendations
11. Confidentiality	Most Shatterproof protections in place
12. Evaluation	Some Shatterproof Recommendations

THE RESULTS

Between Q4 2012 and Q4 2013:

- 9% decline in the number of opioid painkillers prescribed
- 75% decline in patients' seeing multiple prescribers for the same drugs
- 15% increase in the number of buprenorphine prescriptions (medication used to treat opioid addiction)
- 11,400% increase in requests for PDMP reports[69]

Every 1% reduction in opioids prescribed for chronic pain will result in an approximate 1% - 1.2% reduction in overdose deaths.

[69] Mandating PDMP participation by medical providers: current status and experience in selected states. (2014, February). PDMP Center of Excellence at Brandeis University. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/COE%20briefing%20on%20mandates%20revised_a.pdf

*As two of the twelve recommendations are new to the field, they have been excluded from this analysis

TENNESSEE

THE LEGISLATION

- Effective April 2013.

RECOMMENDATIONS INCLUDED*

1. Dispensers Reporting of Information	24 Hour Reporting
2. Prescriber Query	Opioids, Benzodiazepines. First time, Annually
3. Prescriber Registration	All Shatterproof Recommendations
4. Delegates	All Shatterproof Recommendations
5. Authorized Recipients	Most Shatterproof Recommendations
6. Proactive Analysis	Most Shatterproof Recommendations
7. Interstate Sharing	Most Shatterproof Recommendations
8. De-Identified Information	Area for improvement
11. Confidentiality	Most Shatterproof Recommendations
12. Evaluation	Some Shatterproof Recommendations

THE RESULTS

From 2012 to 2014:

- 7% decline in the number of opioid prescriptions
- 36% decline in persons involved in multiple provider episodes[70]
- 405% increase in requests for PDMP reports in first year[71]

Every 1% reduction in opioids prescribed for chronic pain will result in an approximate 1% - 1.2% reduction in overdose deaths.

[70] PDMP Center of Excellence at Brandeis University. Mandating PDMP participation by medical providers: current status and experience in selected states. Retrieved from: http://www.pdmpexcellence.org/sites/all/pdfs/COE%20briefing%20on%20mandates%20revised_a.pdf

[71] Controlled substance monitoring database: 2015 report to the 109th Tennessee General Assembly. (2015, February). Tennessee Department of Health: Health Licensure & Regulation, Controlled Substance Monitoring Database Committee.

*As two of the twelve recommendations are new to the field, they have been excluded from this analysis

Inspired by this and other compelling evidence of the effectiveness of PDMP legislation, in 2015 and 2016, leadership from the states of Connecticut, Massachusetts, Ohio and Wisconsin each drove enactment of PDMP legislation requiring many of the components of *Shatterproof's Critical Elements of Effective State Legislation*. These states and their leadership are true pioneers in the mission to protect the lives of their residents.

CONCLUSION

Shatterproof, in conjunction with leaders in substance use disorder treatment across the country, believes strongly that PDMPs can and will be a key piece of the puzzle in solving our national health crisis. However, we cannot make this happen alone, and the support of state governors and legislators is required.

Together, we can reduce the number of our loved ones who become addicted to opioids and the tragic shattering of lives caused by this preventable epidemic.

APPENDIX A

FEDERAL CONTROLLED SUBSTANCES ACT

Schedules I-V of Controlled Substances (Federal Controlled Substances Act)

- Schedule I
  - (A) The drug or other substance has a high potential for abuse.
  - (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
  - (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.
- Schedule II
  - (A) The drug or other substance has a high potential for abuse.
  - (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
  - (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.
- Schedule III
  - (A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
  - (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
  - (C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
- Schedule IV
  - (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
  - (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
  - (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

- Schedule V
  - (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.
  - (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
  - (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

APPENDIX B

SCHEDULED CONTROLLED SUBSTANCES: THERAPEUTIC CATEGORIES & EXAMPLES OF EACH WITH GENERIC AND (BRAND) NAMES

Schedules	Opioids	Sedatives & Tranquilizers	Stimulants	Other
II	Fentanyl (Duragesic) Hydrocodone (Lortabs) Morphine (MS Contin) Oxycodone (OxyContin)	Amobarbital (Amytal Sodium) Secobarbital (Seconal)	Dextroamphetamine (Adderall) Methamphetamine (Desoxyn) Methylphenidate (Ritalin)	
III	Buprenorphine (Bupranex) Codeine (Empirin with Codeine)	Butabarbital (Busodium) Butalbital (Fioranol)	Benzpheatmine (Didrex) Phendimetrazine (Phendiet)	Muscle relaxants: Carisoprodol (Soma) Anabolic Steroids: Testosterone (Androderm)
IV	Propoxyphene (Darvon) Tramadol (Ultram)	Benzodiazepines: Alprazolam (Xanax) Diazepam (Valium) Triazolam (Halcion)	Mefenorex (Rondimen) Phentermine (Obenix)	

APPENDIX C

DATA ELEMENTS

List of data elements dispensers should submit to PDMPs for each prescription.

1. (I) Dispenser identification number.
2. (II) Date prescription filled.
3. (III) Prescription number.
4. (IV) Prescription is new or is a refill.
5. (V) NDC code for drug dispensed.
6. (VI) Quantity dispensed.
7. (VII) Days' supply dispensed
8. (VIII) Number of refills ordered
9. (IX) Patient identification number.
10. (X) Patient name.
11. (XI) Patient address.
12. (XII) Patient date of birth.
13. (XIII) Patient gender
14. (XIV) Prescriber identification number.
15. (XV) Date prescription issued by prescriber.
16. (XVI) Person who receives the prescription from the dispenser, if other than the patient, including name, address, date of birth, gender and the relationship of that person to the patient.
17. (XVII) Source of payment for prescription.
18. (XVIII) State issued serial number [if state chooses to establish a serialized prescription system].

APPENDIX D

CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

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GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

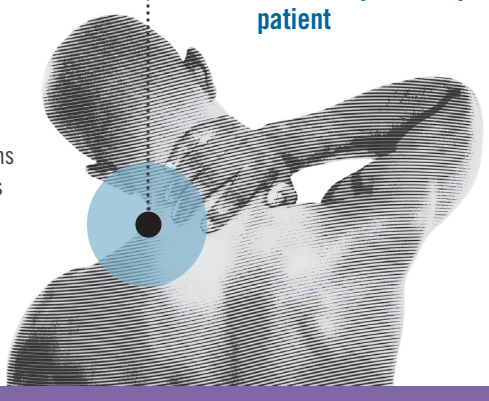
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

CLINICAL REMINDERS

- **Opioids are not first-line or routine therapy for chronic pain**
- **Establish and measure goals for pain and function**
- **Discuss benefits and risks and availability of nonopioid therapies with patient**



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

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OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed

4 When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5 When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

6 Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7 Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

8 Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

9 Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10 When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12 Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

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205 E 42nd Street, 17th Floor New York, NY 10017
www.shatterproof.org