

**JOINT STATE
GOVERNMENT COMMISSION**
General Assembly of the Commonwealth of Pennsylvania

**HOUSE RESOLUTION 659
REPORT OF THE TASK FORCE AND
ADVISORY COMMITTEE ON
OPIOID PRESCRIPTION DRUG
PROLIFERATION**

JUNE 2015



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REPORT

*Report of the Task Force and Advisory Committee
on Opioid Prescription Drug Proliferation*

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The Joint State Government Commission was created in 1937 as the primary and central non-partisan, bicameral research and policy development agency for the General Assembly of Pennsylvania.¹

A fourteen-member Executive Committee comprised of the leadership of both the House of Representatives and the Senate oversees the Commission. The seven Executive Committee members from the House of Representatives are the Speaker, the Majority and Minority Leaders, the Majority and Minority Whips, and the Majority and Minority Caucus Chairs. The seven Executive Committee members from the Senate are the President Pro Tempore, the Majority and Minority Leaders, the Majority and Minority Whips, and the Majority and Minority Caucus Chairs. By statute, the Executive Committee selects a chairman of the Commission from among the members of the General Assembly. Historically, the Executive Committee has also selected a Vice-Chair or Treasurer, or both, for the Commission.

The studies conducted by the Commission are authorized by statute or by a simple or joint resolution. In general, the Commission has the power to conduct investigations, study issues, and gather information as directed by the General Assembly. The Commission provides in-depth research on a variety of topics, crafts recommendations to improve public policy and statutory law, and works closely with legislators and their staff.

A Commission study may involve the appointment of a legislative task force, composed of a specified number of legislators from the House of Representatives or the Senate, or both, as set forth in the enabling statute or resolution. In addition to following the progress of a particular study, the principal role of a task force is to determine whether to authorize the publication of any report resulting from the study and the introduction of any proposed legislation contained in the report. However, task force authorization does not necessarily reflect endorsement of all the findings and recommendations contained in a report.

Some studies involve an appointed advisory committee of professionals or interested parties from across the Commonwealth with expertise in a particular topic; others are managed exclusively by Commission staff with the informal involvement of representatives of those entities that can provide insight and information regarding the particular topic. When a study involves an advisory committee, the Commission seeks consensus among the members.² Although an advisory committee member may represent a particular department, agency, association, or group,

¹ Act of July 1, 1937 (P.L.2460, No.459) (46 P.S. § 65), amended by the act of June 26, 1939 (P.L.1084, No.380); the act of March 8, 1943 (P.L.13, No.4); the act of May 15, 1956 (1955 P.L.1605, No.535); the act of December 8, 1959 (P.L.1740, No.646); and the act of November 20, 1969 (P.L.301, No.128).

² Consensus does not necessarily reflect unanimity among the advisory committee members on each individual policy or legislative recommendation. However, it does, at a minimum, reflect the views of a substantial majority of the advisory committee, gained after lengthy review and discussion.

such representation does not necessarily reflect the endorsement of the department, agency, association, or group of all the findings and recommendations contained in a study report.

Over the years, nearly one thousand individuals from across the Commonwealth have served as members of the Commission's numerous advisory committees or have assisted the Commission with its studies. Members of advisory committees bring a wide range of knowledge and experience to deliberations involving a particular study. Individuals from countless backgrounds have contributed to the work of the Commission, such as attorneys, judges, professors and other educators, state and local officials, physicians and other health care professionals, business and community leaders, service providers, administrators and other professionals, law enforcement personnel, and concerned citizens. In addition, members of advisory committees donate their time to serve the public good; they are not compensated for their service as members. Consequently, the Commonwealth of Pennsylvania receives the financial benefit of such volunteerism, along with the expertise in developing statutory language and public policy recommendations to improve the law in Pennsylvania.

The Commission periodically reports its findings and recommendations, along with any proposed legislation, to the General Assembly. Certain studies have specific timelines for the publication of a report, as in the case of a discrete or timely topic; other studies, given their complex or considerable nature, are ongoing and involve the publication of periodic reports. Completion of a study, or a particular aspect of an ongoing study, generally results in the publication of a report setting forth background material, policy recommendations, and proposed legislation. However, the release of a report by the Commission does not necessarily reflect the endorsement by the members of the Executive Committee, or the Chair or Vice-Chair of the Commission, of all the findings, recommendations, or conclusions contained in the report. A report containing proposed legislation may also contain official comments, which may be used in determining the intent of the General Assembly.³

Since its inception, the Commission has published more than 350 reports on a sweeping range of topics, including administrative law and procedure; agriculture; athletics and sports; banks and banking; commerce and trade; the commercial code; crimes and offenses; decedents, estates, and fiduciaries; detectives and private police; domestic relations; education; elections; eminent domain; environmental resources; escheats; fish; forests, waters, and state parks; game; health and safety; historical sites and museums; insolvency and assignments; insurance; the judiciary and judicial procedure; labor; law and justice; the legislature; liquor; mechanics' liens; mental health; military affairs; mines and mining; municipalities; prisons and parole; procurement; state-licensed professions and occupations; public utilities; public welfare; real and personal property; state government; taxation and fiscal affairs; transportation; vehicles; and workers' compensation.

Following the completion of a report, subsequent action on the part of the Commission may be required, and, as necessary, the Commission will draft legislation and statutory amendments, update research, track legislation through the legislative process, attend hearings, and answer questions from legislators, legislative staff, interest groups, and constituents.

³ 1 Pa.C.S. § 1939 ("The comments or report of the commission . . . which drafted a statute may be consulted in the construction or application of the original provisions of the statute if such comments or report were published or otherwise generally available prior to the consideration of the statute by the General Assembly").



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June 2015

Dear Members of the General Assembly of Pennsylvania:

2014 House Resolution 659 directed the Joint State Government Commission to establish a legislative Task Force and appoint an Advisory Committee to study the problems wrought by the proliferation of prescription opioid medications, and develop recommendations to combat the proliferation, illicit use, and abuse of opioid prescription drugs in Pennsylvania.

The *Report of the Task Force and Advisory Committee on Opioid Prescription Drug Proliferation*, presents a comprehensive review of the problems of illicit use and abuse, and the actions being taken by state agencies, healthcare and addiction service providers, and law enforcement. The report includes the Advisory Committee's recommendations to further curtail the tragic consequences of opioid abuse

It is available on our website, <http://jsg.legis.state.pa.us/>.

Sincerely,

A handwritten signature in blue ink, appearing to read "Glenn Pasewicz".

Glenn Pasewicz
Executive Director

HOUSE RESOLUTION 659

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INTRODUCTION

House Resolution 659 of 2014 directed the Joint State Government Commission to establish a legislative task force and appoint an advisory committee to conduct a one year study opioid addiction in Pennsylvania, opioid medication management practices, ensure that pain management practitioners are sufficiently trained in identifying addiction and referring addicted patients to appropriate care, and help combat the proliferation of misuse and abuse of opioid prescription. HR659 further directed that the Commission, Task Force, and Advisory Committee produce an interim report of guidelines for prescribers within 60 days of the adoption of the resolution.

Prior to the appointment of the Advisory Committee, Commission staff was made aware that the Pennsylvania Department of Drug & Alcohol Programs (DDAP) had organized the Safe and Effective Prescribing Practices and Pain Management Task Force to develop a set of opioid prescribing guidelines for pain management care for non-cancer patients who suffer chronic pain. Commission staff and Representative Doyle Heffley, sponsor of HR659 and chairman of its Task Force, were invited to attend meetings of the DDAP Task Force.

The DDAP Task Force consists of approximately 80 members with knowledge and expertise in the study and clinical use of opioids, and included practitioners and representatives of both medical and addiction treatment services.⁴ This Task Force, after lengthy and comprehensive deliberations that began December 16, 2013, formed a set of guidelines. The final draft, "Prescribing Guidelines on the Use of Opioids to Treat Chronic Noncancer Pain," was released to the public on July 10, 2014.⁵ DDAP received support for the guidelines by several prominent healthcare organizations, including the Pennsylvania Medical Society, the Pennsylvania Psychiatric Society, the Pennsylvania Recovery Organization Alliance, the Pennsylvania Chapter of the American College of Emergency Physicians, the Pennsylvania Academy of Family Physicians, University of Pittsburgh School of Pharmacy, and Geisinger Health System's Enterprise Pharmacy.

The DDAP Task Force has since released, "Prescribing Guidelines for Emergency Departments," and is expected to release "Pennsylvania Guidelines on the Use of Opioids in Dental Practice," in the first half of 2015.⁶

The HR659 Advisory Committee held its first meeting on June 25, 2014. The meeting's primary focus was to discuss the directive that it release a set of guidelines, and to what extent its own document should reflect the DDAP guidelines. There was general agreement that the DDAP guidelines should first be thoroughly reviewed. A number of members cautioned that if the Advisory Committee were to release a different set of guidelines, it may sow confusion among healthcare regulators, providers, insurers, and patients in instances where its guidelines differed from the DDAP guidelines. Further, the DDAP guidelines had been developed and thoroughly

⁴ The DDAP Task Force continues its work with regard to opioid prescribing guidelines at the time of this report.

⁵ DDAP Task Force guidelines are found in Appendix D.

⁶ DDAP website. http://www.ddap.pa.gov/portal/server.pt/community/for_professionals__stakeholders/20936.

vetted by the DDAP Task Force's many participants, several of whom also served on the HR659 Advisory Committee. It was, therefore, established early in the process that the HR659 Advisory Committee would not embark on a wholesale revision of the DDAP guidelines, but would make recommendations toward enhancing future revisions by the DDAP Task Force.

Having released *Interim Report: Guidelines for Prescribing Opioid Analgesics* in December 2014, the Advisory Committee went on to address other areas of the proliferation and illicit use of prescription opioids.⁷ Prescription drug monitoring programs (PDMPs) are the most significant tool deployed against illicit use and abuse, and were discussed at length. Most states have established PDMPs, which are databases of patient, prescriber, and dispenser information. PDMPs allow doctors, pharmacists, public health authorities, law enforcement agents, and sometimes drug addiction counselors, to identify people and situations that may involve illicit use and abuse. Pennsylvania's Act 191 of 2014, "Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP)" created the Commonwealth's PDMP.⁸

This report presents data that describe the problem in the U.S. in general and in Pennsylvania in particular. HR659 directed that the report include information from public hearings where illicit use and abuse of prescription opioids were discussed. Summaries of those hearings are found later in this report.

As with most challenging problems, the key to success lays in the coordination of the problem solvers. They must work together, each contributing the tools and knowledge of his or her specialty. The Advisory Committee endorsed 15 recommendations that make the most of these available resources. The recommendations address guidelines for prescribers, prescriber and dispenser education and licensing, insurance laws, abuse deterrent opioid formulations, and implementation of the Commonwealth's PDMP.

The resolution asked that people who have lost loved ones to drug overdoses have an opportunity to submit their stories. These stories, in their own words as written by them, are included in Appendix B. The HR659 Task Force, Advisory Committee, and the staff of the Joint State Government Commission express our gratitude for their strength and willingness to share these extraordinarily painful experiences.

⁷ *Interim Report: Guidelines for Prescribing Opioid Analgesics*, Joint State Government Commission, (Harrisburg, PA: December 2014), http://jsg.legis.state.pa.us/publications.cfm?JSPU_PUBLN_ID=396.

⁸ Act of October 27, 2014, (P.L. 2911, No. 191), known as "Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP).

ILLICIT USE OF OPIOID ANALGESICS

The opioid class of drugs, that is, substances that are derived from or are pharmacologically similar to opiates, comprise a powerful family of analgesics that carry with them a significant risk of addiction. The wide availability of opioid analgesics has been both a blessing, in that many Pennsylvanians have been able to manage debilitating pain and return to productive lives, and a curse, in that tragic numbers of lives have been destroyed as a consequence of opioid addiction.

Too many people are familiar with stories about family members, friends, or neighbors who have been trapped by addiction. “I knew I was addicted when the first prescription ran out,” one high school athlete told her drug addiction counselor. Anecdotally, opioids are widely available in the construction and roofing industries, “It’s such a physically demanding job, they rely on the pills to work through the day,” according to another drug addiction counselor. In medically underserved areas of Pennsylvania, the lack of medical treatment resources leaves doctors with few alternatives to opioid analgesics. Furthermore, access to pain management treatments may rely as much on a patient’s ability comply with treatment as it does on whether the resources are available at all.

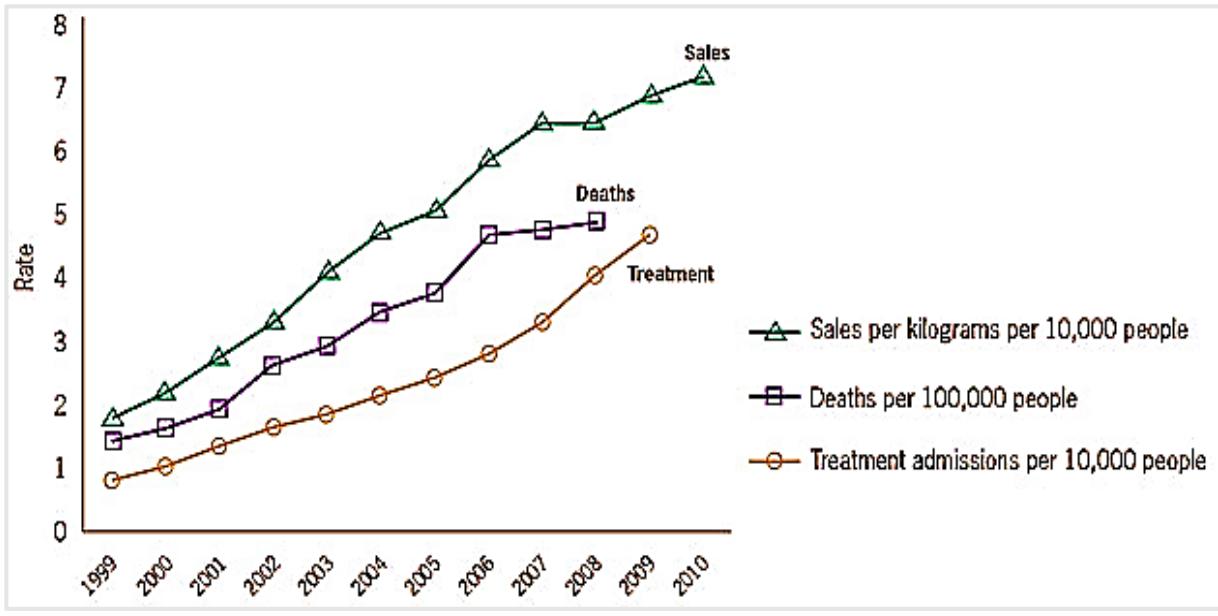
There are perhaps no analgesics that are as effective at killing pain as are the opioids. Opioids can make intolerable pain tolerable. They have long provided a source of blessed relief for terminal cancer patients. Opioids allow people who suffer acute and particularly chronic pain to take control of their lives, a benefit not only to them but to their families. There exists, however, a fine line between using opioid analgesics as a means of controlling one’s life, and having one’s life controlled by opioid addiction.

The United States, despite containing less than 5 percent of the world’s population, consumes approximately 80 percent of the global opioid supply, including 99 percent of the hydrocodone supply.⁹ Though this widespread and growing use of opioids over the past two decades has been able to help some of the estimated 100 million Americans suffering from chronic pain, it has also had tragic side effects.¹⁰ While prescribing rates of opioid analgesics have dramatically risen, so have opioid treatment admissions and opioid overdose deaths. Figure 1 depicts the rates of prescription painkiller sales, deaths, and substance abuse treatment admissions from 1999 to 2010.

⁹ Laxmaiah Manchikanti and Angelie Singh, “Therapeutic Opioids: A Ten-Year Perspective on the Complexities and Complications of the Escalating Use, Abuse, and Nonmedical Use of Opioids,” *Pain Physician Journal*, 2008, accessed March 18, 2015, <http://www.painphysicianjournal.com/2008/march/2008;11:S63-S88.pdf>.

¹⁰ “Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research,” *Institute of Medicine of the National Academies* (June 29, 2011), <https://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx>.

**Figure 1. Rates of Prescription Painkiller Sales, Deaths, and Substance Abuse Treatment Admissions
1999 to 2010**



SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009
<http://www.cdc.gov/vitalsigns/painkilleroverdoses/infographic.html>

In 2012, health care providers in the U.S. wrote 259 million prescriptions for painkillers; enough to medicate every American adult around-the-clock for one month. At the same time, 44 people died each day from an overdose of prescription painkillers.¹¹ This amounted to 16,007 deaths, accounting for nearly 40 percent of all drug-poisoning deaths. Furthermore, deaths from opioid analgesics have more than tripled since 1999, from 1.4 deaths per 100,000 to 5.1 deaths in 2012. There was a decline of 5 percent from 2011 to 2012, the first decrease measured seen in over a decade.¹² As of 2013, the most recent data available show 16,235 deaths involved opioid analgesics in the U.S., an increase of 1 percent from the previous year.¹³

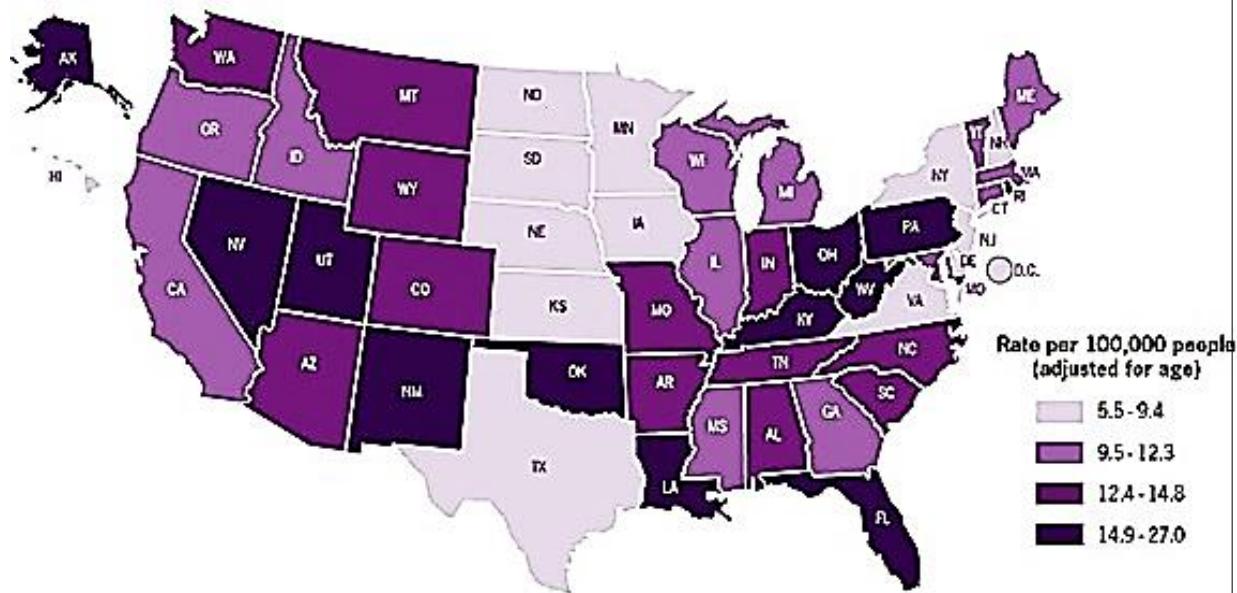
Pennsylvania ranks among the 12 states with the highest death rates from drug overdoses. As of 2008, the death rate in Pennsylvania due to drug overdose was 15.1 per 100,000 persons. Figure 2 shows the overdose drug rates by state.

¹¹ “Opioid Painkiller Prescribing,” Centers for Disease Control and Prevention. Last updated July 1, 2014, accessed January 30, 2015. <http://www.cdc.gov/vitalsigns/opioid-prescribing/>.

¹² Margaret Warner, Holly Hedegaard, and Li-Hui Chen, “Trends in Drug-Poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999-2012,” Centers for Disease Control and Prevention, December 2014, accessed March 18, 2015. http://www.cdc.gov/nchs/data/hestat/drug_poisoning/drug_poisoning_deaths_1999-2012.pdf.

¹³ “Prescription Drug Overdose in the United States: Fact Sheet,” Centers for Disease Control and Prevention, last updated March 2, 2015, accessed March 30, 2015.

Figure 2. Drug overdose death rates per 100,000 people 2008



Source: "Prescription Pain Killer Overdoses in the US" Centers for Disease Control and Prevention. Last updated November 1, 2011. Accessed June 24, 2014.

<http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html>.

According to a recent report, 20 to 30 percent of opioids prescribed for chronic pain are being misused.¹⁴ The rate of addiction was found to be roughly 10 percent among chronic pain patients.¹⁵ Moreover, there are approximately 5 million Americans abusing prescription opioid pain relievers;¹⁶ an estimated 2.1 million of whom are suffering from substance use disorders related to these drugs.¹⁷ Among Pennsylvanians, slightly fewer than 8 percent of residents reported that they had taken illicit prescription pain medication in the previous month; the national average was 8.82 percent.¹⁸

Source of Opioids

According to the U.S. Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health, 53 percent of persons aged 12 or older who used pain relievers nonmedically in the past year obtained them from a friend or relative for free.

¹⁴ Opioid misuse is defined as use contrary to the directed or prescribed pattern of use, regardless of the presence or absence of harm or adverse effects.

¹⁵ C.J. Arlotta, "Opioid Misuse In Chronic Pain Patients Is Around 25%, New Study Shows," *Forbes*, (April 1, 2015), <http://www.forbes.com/sites/cjarlotta/2015/04/01/opioid-misuse-in-chronic-pain-patients-is-around-25-new-study-shows/>.

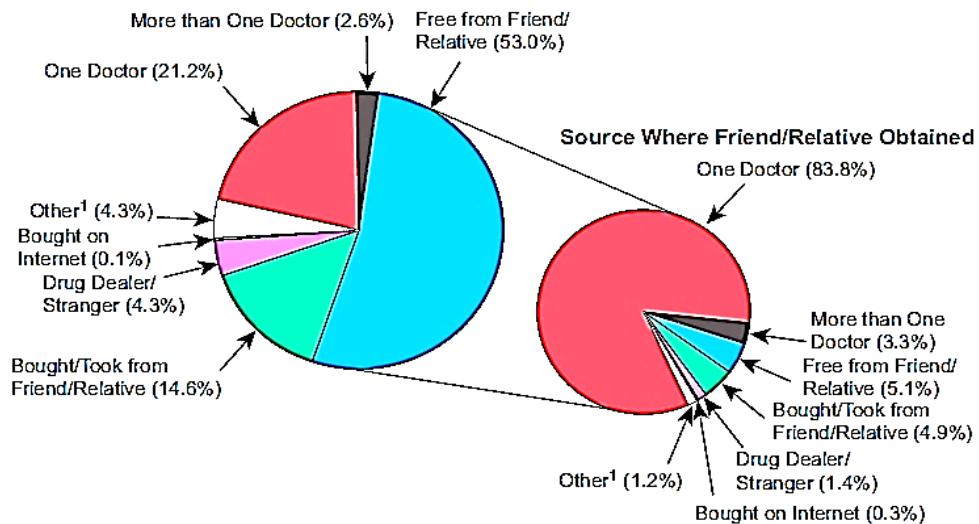
¹⁶ "Topics in Brief: Prescription Drug Abuse," National Institute on Drug Abuse December 2011, www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse.

¹⁷ "Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings," Substance Abuse and Mental Health Services Administration, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795, (Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013).

¹⁸ "National Survey on Drug Use and Health," (NSDUH 2009-2010), <http://www.samhsa.gov/data/NSDUH/2k10State/NSDUHsae2010/Index.aspx>.

Those receiving them through a prescription from a single provider accounted for 21.2 percent, up from 18.1 percent from the previous survey. Figure 3 represents the sources where pain relievers were obtained for their most recent nonmedical use among past year users aged 12 or older from 2012-2013.

**Figure 3. Sources of Pain Relievers
2012 to 2013**



¹The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

Note: The percentages do not add to 100 percent due to rounding.

Source: “Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings,” Substance Abuse and Mental Health Services Administration, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

Though most abusers of opioids receive pills for free from family and friends, startlingly, those with the highest risk of overdose often get prescriptions directly from a doctor.¹⁹ Some data suggest that 60 percent of prescription opioid deaths occur in patients without a history of substance abuse who are taking opioids prescribed by one practitioner.²⁰

From 1998 to 2010 the quantity of prescription pain medications sold to pharmacies, hospitals, and doctor’s offices quadrupled.²¹ Specifically, Pennsylvania ranks 21st in the U.S. with a prescribing rate of 88.2 opioid pain relievers per 100 persons. In comparison, California, ranking

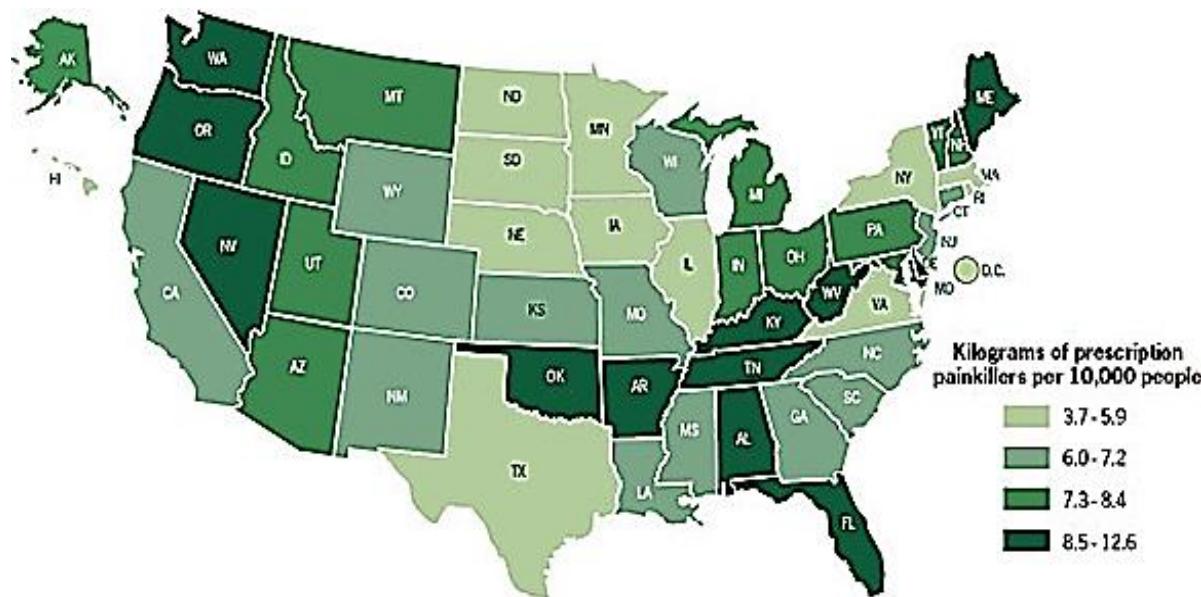
¹⁹ “Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 2010,” (November 1, 2011), accessed August 8, 2014, <http://www.deadiversion.usdoj.gov/arcos/>.

²⁰ Edwards, E. & Read, E., “Prescription Opioid Overdose: Providing a Safeguard for At-Risk Patients,” *Pharmacy Times* (June 26, 2014), <http://www.pharmacytimes.com/publications/issue/2014/June2014/Prescription-Opioid-Overdose-Providing-a-Safeguard-for-At-Risk-Patients#>.

²¹ “Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 2010,” (November 1, 2011), accessed August 8, 2014, <http://www.cdc.gov/vitalsigns/painkilleroverdoses/infographic.html>.

50th, has a prescribing rate of 57.0.²² Figure 4 depicts the amount of prescription painkillers sold by state per 10,000 people as of 2010.

Figure 4. Prescription painkillers sold per 10,000 people 2010



Source: "Prescription Painkiller Overdoses in the U.S.," CDC Vital Signs, (November 2011), <http://www.cdc.gov/vitalsigns/painkilleroverdoses/>. Accessed August 6, 2014

A separate study found that a small number of patients accounted for a relatively large number of prescriptions obtained via doctor shopping. This small number of purchasers, representing 0.7 percent of all purchasers, were presumed to be doctor shoppers, in that they each obtained, on average, 32 opioid prescriptions from 10 different prescribers. Their purchases accounted for 1.9 percent of all opioid prescriptions. In other words, extreme doctor shoppers, as individuals, account for nearly three times as many prescriptions as do other purchasers. The authors did not conclude, however, that doctor shoppers are necessarily making purchases for illicit purposes. More important, to connect doctor shopping exclusively to illicit use would be to ignore potential problems associated with complex healthcare delivery systems.²³ Simply put, some doctor shoppers may be attempting to manage pain that is not being managed by their regular doctor visits.

²² J. Leonard Paulozzi, Karin A. Mack, and Jason M. Hockenberry, "Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines — United States, 2012," Centers for Disease Control and Prevention, July 4, 2014, accessed March 17, 2015, http://www.cdc.gov/mmwrhttp://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s_cid=mm6326a2_w#Tab.

²³ Douglas C. McDonald, Kenneth E. Carlson. "Estimating the Prevalence of Opioid Diversion by "Doctor Shoppers" in the United States." *PLoS ONE*, vol. 8, no. 7, July 17, 2013, accessed September 5, 2014, doi: 10.1371/journal.pone.0069241.

Demographics

Those with the highest risk of an opioid overdose death are between the ages of 25 and 54. However, adults aged 55 to 64 saw an increase more than seven-fold from 1999 to 2013. Fifty-six percent of overdoses are among men, and men are 59 percent more likely to die of an overdose. The gender gap, however, is closing at an astonishing rate. Between 1999 and 2010 overdose deaths from prescription pain medications among women increased more than 400 percent. The incidence of overdose death for men grew as well, by an alarming 265 percent.

The majority of those overdosing on prescription painkillers were non-Hispanic whites. From 1999 to 2013 this population saw an increase from 1.6 to 6.8 deaths per 100,000 persons. Native Americans (including Alaska Natives) also have higher rates of overdose than people identifying as other races or ethnicities; their rates increased from 1.3 to 5.1. Non-Hispanic Black persons also saw a significant increase; from 0.9 to 2.5. The Hispanic population saw minor increases from 1.7 to 2.1 per 100,000. It is estimated that 10 percent of Native Americans, 5 percent of whites, and 3 percent of blacks were using prescription pain medication for nonmedical uses.²⁴

Additionally, people residing in rural counties were twice as likely as those residing in urban areas to suffer an overdose, and some of the nation's most rural states have the highest death by overdose rates.²⁵

Pennsylvania Youth

Illicit prescription opioids have a significant impact on Pennsylvania's youth. According to the most recent Pennsylvania Youth Survey, which surveyed students in 6th, 8th, 10th, and 12th grade across the state, 2.1 percent of students used prescription narcotics that were not prescribed to them in the past month. Use increased for each grade level. Further, 6.8 percent of students said that in their lifetime they had used prescription narcotics that were not prescribed to them. These numbers were relatively stable from the previous survey in 2011. Not surprisingly, the percent of youth using grew with age; while 2.1 percent of 6th graders admitted to taking pills not prescribed to them, the numbers grew to 12.1 percent for 12th graders. Another 14.1 percent of students believed there was little to no risk in using prescription drugs not prescribed to them and 24.3 percent said it would be "sort of easy" or "very easy" to obtain prescription drugs.²⁶ The figures listed in the Appendix A depict the percent of students using non-prescribed narcotic prescription drugs in the past 30 days and their lifetime by county.

²⁴ "Prescription Drug Overdose Data," Centers for Disease Control and Prevention, last updated April 3, 2015, accessed April 6, 2015, <http://www.cdc.gov/drugoverdose/data/overdose.html>.

²⁵ "Prescription Pain Killer Overdoses in the U.S.," Centers for Disease Control and Prevention, last updated November 1, 2011, accessed June 24, 2014, <http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html>.

²⁶ Pennsylvania Youth Survey (PAYS), fall 2013, <http://www.pccd.pa.gov/Juvenile-Justice/Pages/Pennsylvania-Youth-Survey-%28PAYS%29.aspx#.VWxmYUYjdp8>.

Prison Population

It is estimated that 50 percent of America's adult prison population have a substance abuse or dependence issue and between 12 and 15 percent have a history of heroin addiction. Those committing more serious offenses have rates closer to 25 percent. Despite this, just 15 percent of inmates who used drugs 30 days prior to their incarceration receive proper substance abuse treatment.²⁷

In Pennsylvania, it is estimated that 70 to 80 percent of criminal offenders have substance abuse problems. Often this abuse can be directly linked to their criminal behavior. In 2013 the Pennsylvania Office of Attorney General's Bureau of Narcotics Investigations made 522 arrests related to heroin, accounting for 38 percent of drug arrests. In 2014, 748 arrests involving heroin were made, which is almost 50 percent of drug arrests made by the Bureau.²⁸

Health Care and Costs

This mishandling of prescription opioids has led to a dramatic rise in the number of hospital emergency room visits related to the misuse or abuse of pharmaceuticals. From the years 2004 through 2011, the count of visits grew from 626,470 to 1,428,145, a rate of growth of over 100,000 visits per year, a percent rate of change of 16 percent per year. Anti-anxiety and insomnia medications were cited in 501,207 visits, while opioid analgesics accounted for 420,040.²⁹

Figure 6. Drug-Related Emergency Department Visits for Misuse or Abuse of Opioid Analgesics Percent change from 2004 to 2011	
Opioid Analgesics	153%
Oxycodone products	220
Hydrocodone products	96
Methadone	74
Morphine products	144

Source: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. The DAWN Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. Rockville, MD. February 22, 2013. www.samhsa.gov

²⁷ Anna Pecoraro and George E. Woody, "Medication-assisted treatment for opioid dependence: making a difference in prisons," *F1000 Medicine Reports*, January 2011, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3042317>.

²⁸ Alyssa Weinhold e-mail message to Kathleen Wojtowicz, April 9, 2015.

²⁹ "The DAWN Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits." (Rockville, MD: SAMHSA, 2011), <http://www.samhsa.gov/data/2k13/DAWN127/sr127-DAWN-highlights.htm>.

The cost of this abuse and addiction is staggering. Though estimates vary, the costs of illicit use of opioid analgesics has created an enormous drain on the U.S. economy. In 2007 *Pain Medicine* published a study putting societal costs at \$55.7 billion annually. Included among these costs were workplace costs, including premature death, reduced compensation, and lost employment that were estimated at \$25.6 billion. Criminal justice costs, which included corrections and law enforcement, were close to \$5.1 billion. Health care costs consisted primarily of excess medical and prescription costs of about \$23.7 billion.³⁰ The Coalition Against Insurance Fraud estimated in 2007 that public and private insurers' costs related to opioid theft and abuse at \$72.5 billion annually.³¹

Heroin

There is also evidence to suggest that the increase in opioid is correlated with an increase in drug-poisoning deaths involving heroin. About 80 percent of individuals who have progressed to heroin initially abused prescription pain medications.³² One study comparing admission rates for overdoses from prescription opioids and heroin between 1993 and 2009 found that overdose from one strongly predicted an overdose from the other, supporting the evidence that heroin and illicit opioid markets are connected.³³

From 1999 through 2012, heroin deaths increased from 0.7 to 1.9 deaths per 100,000. The most dramatic rise occurred between 2011 and 2012, which saw a 35 percent increase from 1.4 per 100,000 to 1.9. This was the same time period that saw a 5 percent decline in prescription opioid overdose deaths.³⁴ Further, those with the most severe dependency on pharmaceutical opioids were found to be 7.8 times more likely to have used heroin in the past year.³⁵

In Pennsylvania, heroin is the most commonly cited drug among primary drug treatment admissions. In 2010, almost one-third of drug treatment admissions in Pennsylvania were for heroin.³⁶ In April of 2010 the FDA approved a reformulated version of OxyContin designed to be more difficult to misuse or abuse. Figure 5 illustrates the recent increase in heroin use in the U.S., correlating with the downward trend in OxyContin abuse following the introduction of abuse-deterrent formulations.

³⁰ H.G. Birnbaum, et al, "Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States," *Pain Medicine*, vol. 12, issue 4, (April 2011), <http://www.ncbi.nlm.nih.gov/pubmed/21392250>.

³¹ "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," Coalition Against Insurance Fraud, (December 2007), www.insurancefraud.org/downloads/drugDiversion.pdf.

³² P. K. Muhuri, J. C. Gfroerer, and M.C. Davies, "Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States," SAMHSA, August 2013, <http://www.samhsa.gov/data/>.

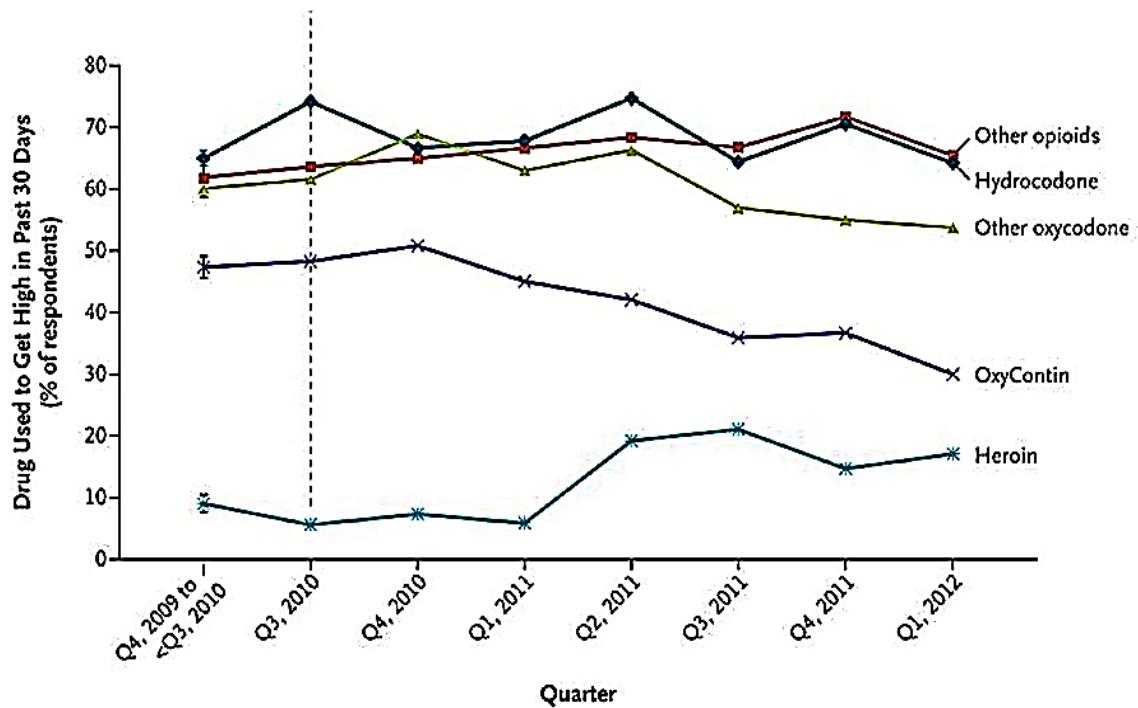
³³ G. J. Unick, et al, "Intertwined Epidemics: National Demographic Trends in Hospitalizations for Heroin-and Opioid-Related Overdoses, 1993-2009," *PLOS ONE*, vol. 8, no. 2, February 6, 2013, doi: 10.1371/journal.pone.0054496.

³⁴ Margaret Warner, Holly Hedegaard, and Li-Hui Chen, "Trends in Drug-Poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999-2012," Centers for Disease Control and Prevention, (December 2014), accessed March 18, 2015. http://www.cdc.gov/nchs/data/hestat/drug_poisoning/drug_poisoning_deaths_1999-2012.pdf.

³⁵ C. M. Jones, "Heroin Use and Heroin Use Risk Behaviors Among Nonmedical Users of Prescription Opioid Pain Relievers — United States, 2002-2004 and 2008-2010," *Drug and Alcohol Dependence*, vol. 132, nos. 1 and 2, pp. 95-100, (September 2013), doi: 10.1016/j.drugalcdep.2013.01.007.

³⁶ "Pennsylvania Drug Control Update," Executive Office of the President of the United States, n.d., <https://www.whitehouse.gov>.

Figure 7. Relationship between Prescription Opioids and Heroin



Source: Volkow, Nora, "Prescription Opioid and Heroin Abuse," *National Institute on Drug Abuse*. Presented to House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, (April 29, 2014).

**PENNSYLVANIA
HOUSE OF REPRESENTATIVES
COMMITTEE HEARINGS**

The broad subject of substance abuse and the consequences it bears for individuals, families, and communities has been a significant concern of the General Assembly for many years. Committee hearings have provided legislators with face-to-face opportunities to listen and learn from experts in substance abuse, from medical doctors to law enforcement agencies, from state health officials to counselors, from survivors of addiction to the families of those who have succumbed. The individuals who address the committees provide information, expertise, and often motivation to continue to pursue solutions to the widespread substance abuse problems in Pennsylvania.

HR659 directed that this report include facts from public hearings that have been held by legislative committees that addressed the illicit use and abuse of opioids. A number of suggestions and recommendations arose from the testimony that the committees received.

***Health and Human Services Committees Joint Hearing
November 16, 2009***

The Health and Human Services Committees held a joint hearing on 2006 House Resolution 585, which had established the Pennsylvania Parent Panel Advisory Committee (PPAC) in the Bureau of Drug and Alcohol Programs in the Pennsylvania Department of Health. PPAC consists of parents from across the state whose children have been or continue to be affected by alcohol and drug abuse.³⁷ The parent panel was directed to convene in Harrisburg at least three times a year and report its findings to the House Health and Human Services Committee and to the Bureau of Drug and Alcohol Programs. The intent of the resolution was to assist people with family members in crisis because they often have difficulty locating alcohol and drug abuse and addiction intervention and treatment services.

According to PPAC testimony, in 2005 expenses related to substance abuse and addiction totaled \$12 billion in Pennsylvania, while only \$188 million was spent on prevention.

Members of PPAC testified about the hardships and heartbreak they face as parents of people whose lives have been devastated by opioid addictions. They told of advising their children to tell psychiatric hospital staffs that they were homeless and suicidal in order to qualify for lifesaving treatment, and that they themselves considered buying illegal drugs to help their children so they could manage the addiction without overdosing during weekends when treatment programs were closed, and that intentionally having their children arrested was considered a viable way of gaining entry to treatment.

³⁷ 2006 House Resolution 585 (P.N. 4032) was adopted June 13, 2006.

PPAC made several recommendations at the hearing, which included establishment of a 2-1-1 emergency telephone system with 24/7 information and referral services. Along with this, the committee recommended establishment of a system that would provide immediate referral to treatment services for ER patients who are in for drug-related care. PPAC recommended that Pennsylvania set up a means of tracking and measuring outcomes data for the prevention continuum of care.

The hearing included testimony from five current and former House members who shared their own stories as parents, relatives, and friends of young people whose lives were crushed by addiction.

Human Services Committee Hearing
June 16, 2011

Ms. Deb Beck, President of Drug and Alcohol Service Providers of Pennsylvania, testified that from 2007 to 2011 there were five times more prescription drug overdoses than heroin overdoses. Unintentional deaths from overdose were four times higher than before. It is the second leading cause of unintentional death in the U.S. She introduced several parents who had lost children to opioid overdoses. A couple of them shared their stories.

Ms. Sherry Green, National Association of Model State Drug Laws, (NAMDL) testified about the significance of prescription drug monitoring programs as a public health tool. PDMPs change prescribers' behaviors and help identify addicted patients to refer them to treatment as early as possible. She cited Kentucky's PDMP as a leading program that has had a positive influence on 80 percent of prescribers who use it. Ms. Green testified that (at the time of the hearing) Pennsylvania was the only state that monitored only Schedule II substances. Forty-four states monitor Schedules I-IV. Those states' expansion beyond Schedule II was a necessity because as each Schedule substance was monitored, abuse of the others followed. State officials realized comprehensive monitoring was necessary because addiction "doesn't know nice legal categories like schedules of class substances."

Ms. Green testified that states were beginning to share PDMP data with each other because people often cross state lines in order to fill prescriptions, and each PDMP wants to have a comprehensive picture of all the prescriptions that are being dispensed to residents of its state.

She highlighted four "statutory safeguards" that are common among the 48 state PDMPs. These are: 1. The PDMP law exempts the data from any kind of public record or Right-to-Know Act. 2. They identify who has access to the data, under what conditions, and for which purposes they have access. 3. They specify that procedures and policies be established to protect confidentiality. 4. They penalize unlawful use, access, and disclosure in violation of the enabling statute.

Ms. Green commended the draft PDMP bill because it had been one of the few she had seen that placed a priority on education and treatment. Education and treatment had long been advocated by the NAMSDL.

Dr. Michael Ashburn, PA Society of Anesthesiologists, testified that about 40 percent of opioids are not administered by specialists but by primary care doctors. His concern is that efforts to interdict diverted medications would result in unintended consequences of further burdening busy doctors and thereby limiting patients' access to health care, particularly in rural areas. More specifically, Dr. Ashburn's concern is that doctors may withdraw from prescribing opioids as part of patient care, and thus shift that 40 percent of pain patients to pain specialists, who are in short supply in Pennsylvania. In other words, these patients would likely be left without adequate pain management care. Rural patients would be hardest hit because of the lack of pain management alternatives in areas where they live.

Dr. Ashburn stated that "opioids, when they are used for the treatment of chronic non-cancer pain, have limitations." Research suggests that approximately 40 percent of chronic non-cancer pain is alleviated by opioids, which subverts physicians' and patients' expectations of 100 percent relief. In response, prescriptions tend to be increased to stronger and stronger dosages. In turn, stronger dosages increase the risk of harm, addiction, and inappropriate use.

Dr. Ashburn discussed statistics describing rates of addiction and overdose. Significantly, drug-induced deaths, he testified, were the leading cause of injury-related death, exceeding automobile accidents.

He made an important recommendation by drawing parallels between opioid analgesics and medication for other conditions.

"We should use medications with a goal of lowering the pain and improving physical and mental functioning. We should institute some way of monitoring the patient to make sure those goals have been accomplished. And, of course, if our therapy doesn't lead to those goals, or it leads to adverse side effects, such as inappropriate use of the medication, then the medication needs to be discontinued."³⁸

Dr. Ashburn considered the reasons for monitoring as side effects of opioid prescribing. These side effects are the inappropriate use, evidence of addiction, and evidence of diversion. He identified five means of monitoring for these side effects. First, doctors must identify patients who may be at high risk. Second, they then institute higher levels of diligence for those patients. Third, doctors use medication agreements that explain the risk, alternatives, potential benefits of opioids, and conditions of complying with the treatment. Fourth, patients are often asked to sign the agreements to communicate that they know, and more important, understand the conditions. Fifth, patient monitoring, including regular urine screens, are a regular part of the pain management plan.

Dr. Ashburn noted that the PDMP could have beneficial financial implications in that the PDMP may allow the identification of people who are using insurance coverage to pay for diverted opioids.

³⁸ Dr. Michael Ashburn testimony before the Human Services Committee, Pennsylvania House of Representatives, June 16, 2011, p. 31 of hearing transcript.

Ms. Patricia Epple, Pennsylvania Pharmacists Association, testified that one of the biggest contributors to opioid diversion are mail order pharmacies located outside of Pennsylvania. They were not included in HB1651, the bill being discussed. She recommended several options. First, that out-of-state pharmacies be required to participate in the PDMP. Second, that they be required to have in-state licenses. Third, that they be prohibited from mailing controlled substances into Pennsylvania.

She pointed out that many independent pharmacies did not have the capability to verify patients' I.D.s, as would be required by the bill. While pharmacies are supportive of PDMPs, compliance would present a high cost to them.

Ms. Epple strongly supported that Pennsylvania join the PMP [Prescription Monitoring Program] Interconnect. At the time of her testimony, eight states belonged to the system that allowed prescription monitoring information sharing across state lines.

She requested that any PDMP legislation include language that provided pharmacies with legal protections from civil liability

Mr. Tom Plaitano, Project Director of MedTech Rehabilitation and Chairman of the Westmoreland County Criminal Justice Advisory Board Jail Diversionary Program, testified that a lot of the diverted drugs are paid for by Workers' Compensation, automobile accident insurance, Medicare, and Medicaid.

Mr. Plaitano further testified that wholesale pharmacies supply medical facilities such as plastic surgery centers, pain centers, and storefront medical centers with thousands of opioid pills, which are stored on site. These medications are not dispensed through pharmacies and are not subject to PDMP laws. Further, they present a safety and security risk to the facility because the number of pills on hand are a high value target for criminals.

Human Services Committee
June 23, 2011

The Pennsylvania House of Representatives Human Services Committee held a public hearing on House Bill 1651 on June 23, 2011. This was the second hearing on HB1651, the purpose of which was to require DDAP to establish the Pharmaceutical Accountability Monitoring System (PAMS). As envisioned, the system was intended to electronically record all prescription pharmaceuticals dispensed to each person who received a prescription for pharmaceuticals on Schedules II, III, IV, and V. Every dispenser and practitioner dispensing pharmaceuticals would be required to register with PAMS. Any dispensation of these drugs would be recorded on this system along with the date of dispensation; name, quantity, and strength of the pharmaceutical dispensed; name of the person receiving the pharmaceutical; type of identification used to confirm the receiving person's identity; recommended dosage and frequency of taking the pharmaceutical; the name of the pharmacy or other entity dispensing the pharmaceutical; the pharmacy's registration numbers; name of the pharmacist; and payment information. This information would be required to be entered into the system within two days of dispensing the pharmaceutical.

DDAP would enable the electronic record system to be able to identify forged, false, or altered prescriptions, as well as to indicate obtaining pharmaceuticals in a manner inconsistent with standard use. DDAP personnel would investigate a possible violation of controlled substance laws.

The system would also be accessible to:

1. Personnel of the department specifically assigned to investigate in regards to controlled substance laws.
2. Personnel of the department specifically assigned to analyze data.
3. Personnel conducting research. In this instance, identifying information will be deleted before it is obtained by such personnel.
4. Licensed practitioners with usernames and PINs.
5. Licensed dispensers with usernames and PINs.
6. Federal or State law enforcement authorities.
7. Personnel responsible for licensing or certifying prescribers and dispensers who are involved in an investigation regarding professional practice.
8. A medical examiner investigating cause of death.
9. A prescription monitoring official.
10. An individual whose information is entered into the database, given the ability to positively prove identity.
11. The Attorney General of Pennsylvania and a similar law enforcement official from another state conducting a bona fide investigation or prosecution of a criminal offense involving the use of controlled substances.

The purpose of the database would be to allow early detection of unusual or unacceptable practices in the prescribing, disbursing, and procurement of these scheduled substances, and possibly for early detection of misuse, abuse, and addiction. DDAP would refer a patient suspected of having an addiction problem to an addiction treatment program. If DDAP believes a prescriber or dispenser has an impairment problem, DDAP could refer the person to a licensing or certification agency. DDAP may also refer such a person to an impaired professionals association for treatment and monitoring. A practitioner prescribing or considering prescribing a controlled substance, or a representative of a practitioner, may access records of the person to whom the pharmaceutical would be prescribed. It would be a third degree felony to illegally access or attempt to access information from this system or to intentionally release information that legally cannot be released. A dispenser failing to properly submit information to this system could have a license revoked, suspended, restricted, non-renewed, be placed on probation, receive a cease and desist order, be reprimanded, and fined \$1,000 or less per prescription not submitted.

PAMS would be monitored and evaluated to determine if its benefits exceeded its expenditures of operation. All costs would be borne by the pharmacy submitting records.

Testimony

Steve Wheeler Deputy Chief of the Bureau of Narcotics Investigations (BNI), Pennsylvania Office of the Attorney General. Mr. Wheeler testified that the Commonwealth had had a form of prescription monitoring for decades. In 2002 the Office of Attorney General transitioned to an electronic database. BNI used the database as a tool in investigating pharmaceutical diversion and cracked a number of cases, some of which involved millions of doses and tens of millions of dollars.

The AG's office supported the expansion into Schedule III, IV, and V drugs, and supported the expanded access to practitioners and professionals. It did, however, express concerns that unethical members of the professions may find ways to use the new database to hide their criminal behavior and circumvent Commonwealth and federal laws and regulations. It recommended that the bill be amended to include local law enforcement agencies among those with access.

Mr. Wheeler stated that recent research had shown that only states where law enforcement maintained oversight of PMP databases experienced reductions in overdose rates and opioid drug consumption. States where the databases were controlled by agencies other than law enforcement did not see similar benefits.

Adam Kegley, Chairman of Legislative Committee for the Pennsylvania Association for the Treatment of Opioid Dependence (PATOD). Mr. Kegley testified that PATOD members operated 40 of the 55 methadone clinics in Pennsylvania and served 15,000 patients. PATOD supported passage of HB1651 because the database would provide its members with useful information to help curtail doctor shopping and other prescription pharmaceutical abuses. PATOD noted three significant expectations of the proposed database.

First, the information would help identify high-risk patients who may be abusing benzodiazepines. Second, it would help identify patients who were abusing other opioid drugs. Third, it would provide information that would help coordinate care with the patients, their physicians, and others.

Moreover, the database was seen as a tool for helping ensure that patients maintain compliance with their treatment plans and would provide vital oversight for take-home doses and similar protocols.

Mr. Kegley expressed PATOD's concern that CFR 42 Part 2 addresses confidentiality of patient information. Narcotic treatment program (NTP) providers are prohibited from sharing patient information unless a crime is committed on the facility's premises. Subpoenas are insufficient; court orders are necessary for NTPs to divulge patient data.

Jeff Kreitman, clinical pharmacy manager for AmeriHealth Mercy Plan. Mr. Kreitman testified that his managed care organization (MCO) supports HB1651. The AmeriHealth Mercy Plan regularly audits its pharmacies for fraud, waste, and abuse. The weak link in the audit and management chain is the fact that unethical pharmacists intentionally evade the system's checks.

The MCO estimated that the PMP envisioned in the bill would help decrease controlled substance dispensing by 5 percent in Pennsylvania. Mr. Kreitman's research found that the Department of Corrections housed 9,000 inmates who were incarcerated because of drug abuse, with 3,000 being incarcerated each year. He estimated that a 5 percent decrease in incarcerations would save \$17 million annually. Further, he stated that each non-medical opioid overdose treated in a hospital emergency room costs \$500,000.

Dr. Danna E. Droz, RPh, D, PMP Administrator, Ohio State Board of Pharmacy. Dr. Droz testified that controlled substances made up 12 percent to 14 percent of prescriptions. She compared the proposal laid out in HB1651 to the system in Ohio and other states and generally stated that the Pennsylvania proposal was a good one. Dr. Droz said that studies showed the monetary costs of doctor shopping. MEDCO found in 2005 that doctor-shoppers cost seven times

more than non-shoppers. WellPoint found that for every dollar in prescription cost to a doctor-shopper, there is an additional cost of \$41 in associated claims such as physician and emergency room visits, lab tests, MRIs, etc. She further stated that an opioid abuser's health costs exceed \$15,000 per year as compared to \$1,800 for a non-abuser.

Dr. Droz cited a University of Toledo study that researched whether or not PMPs change doctor behaviors in treating Emergency Room patients complaining of chronic pain. Doctors developed treatment plans for their patients, then checked the PMP for those patients. In 41 percent of cases, the physician decided, based on the PMP information, to change the original treatment plan. Of the 41 percent, 61 percent prescribed fewer or no opioids. In 39 percent of cases, the patient received more analgesics than the doctor originally planned.

Dr. Ahmad Hameed, Associate Medical Director, Pennsylvania Psychiatric Institute; and Ms. Deborah Shoemaker, Executive Director, Pennsylvania Psychiatric Institute. Dr. Hameed expressed support for HB1651. He expressed the Society's suggestion that the bill be amended in the following ways. Methadone clinics ought to be exempted from reporting to the PMP because they are already heavily regulated and patients are already screened for controlled substance abuse.

Dr. Ahmad highlighted three ways that the PMP would be beneficial. First, it would help prevent accidental overdoses and deaths from interactions of multiple prescriptions. Second, it would help reduce diversion. Third, it would balance patient safety with personal autonomy.

Mr. Phil Bauer, board member of Drugfree.org. Mr. Bauer lost his teenaged son to a lethal mix of Oxycodone, acetaminophen, morphine, and stimulants. He was discovered overdosed on the morning of his last day of high school. Mr. Bauer supported HR1651.

Questions & Answers

Dr. Droz answered questions about how the Ohio PMP works. It processes 4,000 entries per day. 83 percent from prescribers, 16 percent from pharmacists, and 1 percent to 2 percent from law enforcement. Drug manufacturers are involved in the PMP in that they use information and facts about the program as part of their presentations to doctors and prescribers. Also, the manufacturers funded programs such as training for law enforcement and health care groups (no funding for the PMP, which operated on federal grants).

Dr. Droz expressed the opinion that PMPs need not be housed in a law enforcement agency to be effective.

There were several questions that were not answered during the hearing but were deferred for later discussion. Among them was a question as to why it was recommended during the hearing that methadone clinics be excluded from the database, and a question about how medical practices with limited Internet access would manage the availability and expense of utilizing the database.

Human Services Committee Hearing
January 28, 2014

Attorney General Kathleen Kane testified that between 2009 and 2013 there were 280 pharmacy break-ins in Pennsylvania. Automobile accidents were thought to increase so alleged patients could get pain prescriptions to sell on the streets. Further, she testified, patients who are prescribed pain medications are 19 times more likely to be using heroin. In some cases, heroin replaces the opioid medications because it is less expensive.

Attorney General Kane stated that as of 2013, nine of the 25 top pharmaceutical purchases of oxycodone in the United States were located in Pennsylvania. In 2010, there were zero out of the 25 in Pennsylvania. In 2011, there were three out of 25. In 2012, there were five out of the top 25, she said, highlighting the alarming and dramatic increase.

Attorney General Kane testified that the problem is also caused by unscrupulous physicians and pharmacists, who are willing to provide drugs to patients for intentional misuse, and patients fraudulently obtaining prescriptions. The Attorney General's law enforcement and health oversight authority is in the Controlled Substance, Drug, Device and Cosmetic Act.³⁹ The office inspects controlled premises such as hospitals, pharmacies, and long-term care nursing facilities. It operates a forgery alert system to help combat fraudulent prescriptions.

The Office of Attorney General supported expansion of the PMP.

Questions and Answers

Representative Matthew Baker cited a federal report that 70 percent of abusers get their drugs from family members, and 55 percent get them for free. His statement signified the importance that the problem be viewed as being larger than one that is primarily associated with organized crime and cartels.

Attorney General Kane answered that the two missions of her office are to prosecute crimes and to prevent people from becoming victims. To this end, she stressed the importance of education for families, parents, and youngsters.

Attorney General Kane recommended that physicians and other prescribers have guidelines that limit the number of doses per prescription based on what is essential for a patient's well-being.

She further commented on that legal settlements between pharmaceutical manufacturers and states can result in large amounts of money being used to fund treatment and rehabilitation. The Commonwealth of Kentucky received a \$32 million recovery from a settlement with Vioxx and Avandia. The money was directed to treatment and rehabilitation programs. The Pennsylvania Attorney General does not have the authority to direct recovered funds. Rather, the money is awarded to injured parties or deposited into the Commonwealth's General Fund.

³⁹ Act of April 14, 1972, P.L. 233, No. 64, the "Controlled Substance, Drug, Device and Cosmetic Act."

Attorney General Kane recommended increased funding for drug bring-back programs, which provide locations where patients can securely deposit excess and unwanted prescription drugs. The drugs are then collected and properly disposed by qualified handlers.

Committee Chairman Eugene DiGirolamo stated that a proposed Medicaid expansion for Pennsylvania would allow an additional 500,000 to 600,000 people to receive treatment and rehabilitation for addiction.

Drug Courts

Attorney General Kane spoke about drug courts and how they successfully treat people who have been arrested for drug offenses. According to Kane, the accused are:

“...called up as a person. They have the support, they have housing, they have education, they have a bunch of community support systems right in the courtroom for that time. Probation, the D.A.’s office, the public defenders office and the judge are all trained and also the drug and alcohol personnel are there and they are trained in the addiction of drugs and alcohol so they recognize the signs. There’s continuous monitoring. There’s repercussions if they come in with a hot urine. And they really do work because they treat the person and they aren’t just a member of the system.”⁴⁰

Drug courts, according to Attorney General Kane, are proven, effective means of providing treatment for drug offenders who are suffering from addiction in ways that reduce recidivism, reduce expenditures, and fulfill the corrections systems’ obligations to serve the public interest. They are organized on the county level, and have been successful where counties have sufficient resources to establish them.

Deb Beck, president of Drug & Alcohol Service Providers of Pennsylvania. Ms. Beck testified that untreated drug and alcohol addiction in Pennsylvania cost \$14 billion per year, while less than 1 percent of that amount is spent on treatment. She cited CVS as an example of a private sector entity that is taking steps toward fighting prescription drug abuse. The company checks its own pharmacy databases for outliers and contacts the pharmacists and physicians to resolve problems.

Ms. Beck cited a further compelling statistic, stating that more than half of the young people who die from drug overdoses had previous hospital visits for drug problems. In other words, there are many more lives that can be saved if appropriate treatments are made available to the individuals who are known to need them.

Dauphin County Coroner Graham Hetrick. Coroner Hetrick testified that his experience is that the increased rate of prescription drug deaths is staggering. He cited a CDC report from January 12, 2014 that opioid analgesic-related deaths outpaced the combined deaths from cocaine and heroin since 2003. His and others’ research shows that prescription drug overdoses are most common among non-Hispanic white males around 41 years of age.

⁴⁰ Pennsylvania Attorney General Kathleen Kane testimony before the Human Services Committee, PA House of Representatives, January 28, 2014, p. 28 of the hearing transcript.

Dr. George Lloyd, Foundation of the Pennsylvania Medical Society. Dr. Lloyd testified that the medical society supports the establishment of a prescription drug monitoring program, particularly if it were set up to group patients by the amounts of drugs received. The CDC follows this procedure and found that 80 percent of patients were prescribed fewer than 100mg of morphine equivalent doses per day. This cohort accounted for 20 percent of opioid drug overdose deaths. Ten percent of patients are prescribed high doses of greater than 100mg per day. This group accounted for 40 percent of the overdose deaths. Another 10 percent sought medications from more than one prescriber, which accounts for a further 40 percent of deaths. In other words, 20 percent of patients account for 80 percent of opioid overdose deaths.⁴¹

Dr. Lloyd went on to state that there is very little training for doctors and very little monitoring of what is being prescribed, which leads to potentially deadly consequences for patients. He estimated that perhaps 40 percent of overdose deaths result from opioids being prescribed in conjunction with sedatives such as benzodiazepines.

Dr. Lloyd characterized the death rate as “the tip of the iceberg.”

“For every one death, there’s approximately 10 treatment admissions for abuse, 32 emergency department visits for misuse or abuse, 130 people who abuse or are dependent on opioids, and 825 non-medical users. And there’s a tendency to migrate up this pyramid over time to go from non-medical user to dependent and then on to that potentially leading to overdose and death.”

Emphasizing the need for everyone, patients, prescribers, students, and the general public to be informed about opioid analgesics, Dr. Lloyd stated that the Pennsylvania Medical Society launched an educational program for physicians.

In addition to education, Dr. Lloyd supported recommendations made by others: that a PDMP be established, and that drug take-back programs be more available. He cautioned that restraining the availability of opioid pain medications would lead to increases in heroin addiction, and therefore the whole treatment and rehabilitation system needs to be overhauled from the ground up to ensure that they are provided when and where they are needed.

Colleen Caden, pharmacist, testified in support of regulations that were to accompany 2002 amendments to Pennsylvania’s Pharmacy Act that permitted collaborative drug therapy management (CDTM) in institutional settings such as hospitals and long term care facilities.⁴² CDTM is a team approach to healthcare delivery whereby a pharmacist and prescriber establish written guidelines or protocols authorizing the pharmacist to initiate, modify or continue drug

⁴¹ Ibid., p. 57.

⁴² Act of June 29, 2002, P.L. 673, No. 102. Section 9.1.

therapy for a specific patient.⁴³ In 2010 the Pharmacy Act was again amended to allow for the practice of CDTM regardless of setting, thereby including community pharmacists.⁴⁴

Ms. Caden stated that the purpose and benefit of CDTMs is that they allow prescribers and pharmacists to work together to provide comprehensive medication therapy management for patients. By working together to monitor and adjust drug strength, frequency, and other considerations, the teams are able to improve patient compliance with treatment plans and maximize the benefit and safety of the patient.

Ms. Caden stated that she supported physicians' adoption of guidelines to carefully monitor the amount of drugs prescribed, particularly at the start of therapy. Further, she stated that prescribers should not be incentivized to prescribe more opioids than medically necessary. Oftentimes, small supplies of analgesics are sufficient to help patients through crises. In some cases, patients are given more than needed so as to not inconvenience them, or insurance copays incentivize the writing of larger prescriptions.

Mr. Rick Seipp, Vice President of Pharmacy at Weis Markets, representing the Pennsylvania Association of Chain Drug Stores (PACDS). Mr. Seipp testified that PACDS actively supports PDMP legislation as a valuable tool in stemming the dramatic increases in controlled substance abuse. Further, PCADS supports efforts to establish drug disposal programs. To this end, PCADS members have installed 250 secure MedReturn boxes throughout the Commonwealth. PCADS endorsed the federal Drug Enforcement Administration's decision to allow for the electronic submission of controlled substance prescriptions, which improves prescription security and monitoring, and encourages Pennsylvania to adopt regulations that would allow prescribers and patients to benefit from electronic prescribing.

Mr. Julian Phillips, U.S. Pain Foundation, rendered powerful and memorable testimony about his life's experience with crippling and debilitating chronic pain. On behalf of the Pain Foundation, he supported Senate Bill 1180 of 2011, and asked the committee to decide against House Bill 544.⁴⁵ He stated that House Bill 544 would essentially tax patients, the majority of whom are not prescription drug abusers. In his testimony, Mr. Phillips recognized the direness of the prescription drug abuse epidemic, but entreated the legislature to take steps that would not place further burdens on people whose survival depends on a reliable source of pain management.

⁴³ "Collaborative Drug Therapy Management: A Coordinated Approach to Patient Care," American Society of Health-System Pharmacists, n.d.,

http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCQQFjAA&url=http%3A%2F%2Fwww.ashp.org%2FDocLibrary%2FAffiliates%2FCDTM.aspx&ei=42xsVYi_FJesyASYg4PIDw&usg=AFQjCNHLTzwckeSROmNPgVMziS5u-5eWw&sig2=Tq6N9wgm545q58TAn_8vig&bvm=bv.94455598,d.aWw&cad=rja

⁴⁴ Act of June 1, 2010, P.L. 201, No. 29. Section 9.3.

⁴⁵ 2013 Senate Bill 1180 (P.N. 2393) was passed in the Senate on May 6, 2014. The House of Representatives amended then passed SB1180 on October 14, 2014. The Senate concurred in the House amendments and passed the bill finally on October 16, 2014. The bill was approved by Governor Corbett and enacted as the Act of October 27, 2014, P.L. 2911, No. 191.

PENNSYLVANIA DRUG ADDICTION PREVENTION AND REHABILITATION

Department of Drug and Alcohol Programs

In 1972, the General Assembly established a health, education, and rehabilitation program for the prevention and treatment of drug and alcohol abuse through the enactment of the Act of April 14, 1972 (No. 63, P.L. 221), known as the “PA Drug and Alcohol Abuse Control Act.” This law established the Governor’s Council on Drug and Alcohol Abuse. The Council was subsequently transferred through Reorganization Plan 1981-4, which placed its responsibilities and its administrative authorities within the Department of Health. Act 1985-119 amended Act 1972-63, changing the name of the Council to the Pennsylvania Advisory Council on Drug and Alcohol Abuse and designating the Secretary of Health, or his designee, as the chairperson.

Act July 9, 2010 (No. 50, P.L. 348) recognized that substance abuse affects a large segment of Pennsylvania’s population and is a major cost driver in its criminal justice, health care, children and youth, workers’ compensation, and other taxpayer-funded systems. Act 50 amended Section 201 of the Administrative Code of 1929 by creating the Department of Drug and Alcohol Programs (DDAP).

As of July 1, 2012, DDAP, which was created from PADOH’s Bureau of Drug and Alcohol Programs and its Division of Drug and Alcohol Program Licensure, formerly under the Department of Health as the Bureau of Drug and Alcohol Programs and the Division of Drug and Alcohol Program Licensure, became a department in its own right. This change reflected a commitment by the General Assembly and the Commonwealth to provide education, intervention, and treatment programs to reduce the burden of drug and alcohol abuse and dependency. DDAP works to establish relationships with state and community agencies at a level previously unavailable, to work effectively on a problem that devastates individuals and families, destroys communities, and drives many of the costs in the state budget.

DDAP is responsible for:

- Development and implementation of programs designed to reduce substance abuse and dependency through prevention, intervention, rehabilitation, and treatment programs;
- Education for all Pennsylvanians on the effects and dangers drugs and alcohol abuse and dependency, and the threat these pose to public health; and,
- Mitigation of the economic damage substance abuse causes for the residents of Pennsylvania.

In addition, Act 50 requires DDAP to develop a State Plan encompassing the entire state government for the control, prevention, intervention, treatment, rehabilitation, research, education, and training related to drug and alcohol dependence and abuse problems.

The passage of Act 50 and the establishment of DDAP led to increased coordination of efforts between state agencies. The Department has collaborated with the Pennsylvania Department of Human Services (DHS), Commission on Crime and Delinquency (PCCD), Department of Health (DOH), Department of Education (PDE), Board of Probation and Parole (PBPP), and the Department of Corrections (DOC). The Department also collaborates with various county and provider organizations, including the Drug and Alcohol Services Providers Organization of Pennsylvania (DASPOP), the Rehabilitation and Community Providers Association (RCPA), Pennsylvania Association of County Drug and Alcohol Administrators (PACDA), Pennsylvania Recovery Organizations-Alliance (PRO-A), and the Pennsylvania Association for Treatment of Opioid Dependence (PATOD) as well as individual Single County Authorities (SCAs), treatment and prevention providers, and recovery organizations.

DDAP Parent Panel Advisory Council

House Resolution 585 of 2006 asked the Department of Health's Bureau of Drug & Alcohol Programs to establish an ongoing Parent Panel Advisory Council (PPAC) to make recommendations to the department on how to improve access to abuse, addiction, and treatment services information to the public.

PPAC works to provide feedback to DDAP. PPAC and the Pennsylvania Drug and Alcohol Advisory Council (DAAC) established a partnership to improve the substance use service system through the two groups collaborating as a whole, as well as through the formation of a separate collaborative workgroup. The Emergency Room/Healthcare Workgroup, comprised of members from both advisory councils, works to explore the possibilities and approaches for networking with physicians and emergency departments to improve their awareness of substance use disorders and services available, identify areas for improvement where healthcare and issues of substance abuse disorder intersect, and identify possible solutions and action steps to address these needed improvements. It provided feedback and input to the Secretary of DDAP regarding access to care, the need to publicize the SCAs' delivery of services, and the need for cross-systems education regarding substance use.

In addition to participation in PPAC, many of the members are involved in local initiatives or are involved in other state affiliated committees which parallel or support their official recommendations made to the House Health and Human Services Committee. This group of individuals remains very active in providing input to DDAP. Through interdepartmental collaboration between the Department and other state agencies, another priority of PPAC is being addressed through disseminating information on how to access treatment services. By providing this information through various meetings, conferences, and other events, DDAP has improved the knowledge base of both state and local agency personnel on how to access substance abuse treatment. Additionally, through collaboration with other agencies, DDAP is able to explore accessing additional funding sources which may provide opportunities for more individuals to enter treatment.

Substance Abuse and Prevention Plan

The DDAP Substance Abuse and Prevention Plan includes six strategies developed by the federal Substance Abuse and Mental Health Services Administration (SAMHSA). These six strategies address information dissemination, education, alternative activities, problem identification and referral, community based process, and environmental areas which together are likely to be the bases for successful prevention programs.

Information dissemination provides awareness and knowledge on the nature and extent of alcohol, tobacco and drug use, abuse and addiction and the effects on individuals, families and communities.

Education involves two-way communication, which is distinguished from the Information Dissemination category by the fact that interaction between the educator/facilitator and the participants is the basis of its activities.

Alternative activities are constructive and healthful activities that offset the attraction to, or otherwise meet the needs usually filled by alcohol, tobacco, and other drugs, and would, therefore, minimize or eliminate use of them.

Problem identification and referral targets those persons who have experienced first use of illicit/age-inappropriate use of tobacco and those individuals who have indulged in the first use of illicit drugs and alcohol.

Community based process aims directly at building community capacity to enhance the ability of communities to more effectively provide prevention and treatment services for alcohol, tobacco and substance use disorders.

Environmental establishes or changes written and unwritten community standards, codes, ordinances and attitudes, thereby influencing incidence and prevalence of the abuse of alcohol, tobacco and other drugs.

DDAP funds county-based Single County Authorities (SCAs) that develop substance abuse prevention programs that include these six strategies along with the Institute of Medicine's (IOM) three Prevention Classifications, which include:

Universal Preventive Interventions, which are activities targeted to the general public or a whole population group that has not been identified on the basis of individual risk.

Selective Preventive Interventions, which are activities targeted to individuals or a subgroup of the population whose risk of developing a disorder is significantly higher than average.

Indicated Preventive Interventions, which are activities targeted to individuals in high-risk environments identified as having minimal but detectable signs or symptoms foreshadowing a disorder or having biological markers indicating predisposition for a disorder which does not yet meet diagnostic levels.

Currently there are 44 evidence-based and 42 evidence-informed programs in Pennsylvania that meet these criteria. The department works closely with other Commonwealth agencies to deliver services and programming in the interest of preventing substance abuse and in helping people and communities heal from the frequently tragic consequences of substance abuse. Collaborations include the following agencies and programs:

- Department of Human Services, Office of Mental Health and Substance Abuse Services (OMHSAS)
- Pennsylvania Youth Suicide Prevention Monitoring Committee – The Pennsylvania Youth Suicide Prevention initiative is a multi-system collaboration to reduce youth suicide.
- Substance Abuse and Mental Health Services Administration (SAMHSA)
 - Support SAMHSA prevention initiatives such as the National Town Hall Meetings
- Pennsylvania Liquor Control Board (PLCB)
 - Contribute to the mandated Act 85 Legislative Report coordinated by the Pennsylvania Liquor Control Board.
- Pennsylvania Commission on Crime and Delinquency (PCCD)
- Disproportionate Minority Contact Committee
 - Provides technical assistance and information to ensure that individual communities are providing the necessary drug and alcohol prevention supports to disproportionately burdened minorities.
- Balanced and Restorative Justice in Pennsylvania Committee
 - The committee supports the juvenile justice system in working with children that have committed delinquent acts and supports their care and rehabilitation to include, but not limited to, substance abuse issues.
- Department of Health
 - Statewide Injury Prevention & Control Plan Injury Community Planning Group (ICPG)
 - Falls Prevention in Older Adults Workgroup
- Mission is to develop a comprehensive and coordinated plan that focuses on preventing injuries and violence across the lifespan by empowering state and local partners through the collection and analysis of data and the leveraging of resources for injury prevention programs to recapture lost human potential. Workgroups have been formed for three main injury topics: motor vehicle crashes, unintentional falls and unintentional poisonings.
 - Sexual Violence Primary Prevention Planning Committee
- Addresses sexual violence prevention throughout the commonwealth.
- Pennsylvania Coalition Against Domestic Violence
 - Assist in the development of a statewide prevention plan to support communities throughout Pennsylvania to prevent domestic violence before it occurs.
- Department of Education
 - Pennsylvania School Wide Positive Behavior Support State Leadership Team
- Through training and technical assistance, supports schools and their family and community partners to create and sustain comprehensive school based behavioral

health support systems in order to promote the academic, social and emotional well-being of all Pennsylvania's students.

- Youth and Family Training Institute Advisory Board - To achieve quality family and youth driven outcomes by advancing the philosophy, practices and principles of High Fidelity Wraparound through training, coaching, credentialing and ensuring fidelity to the process.
- Safe and Supportive Schools (SAS) Student Interpersonal Skills Development Committee
- To develop social and emotional standards that educators and teachers will utilize for instructions with students Pre-K to 12.
 - Student Assistance Program Commonwealth Interagency Committee
- Provides leadership for developing a safe and drug-free environment and mental health wellness in schools and communities across the commonwealth.
- Department of Transportation
 - Multi Agency Safety Team (MAST)
- Assist in the development and implementation of the Comprehensive Strategic Highway Safety Improvement Plan.
- Commonwealth Prevention Alliance (CPA)
 - Representative to the Board of Directors
 - Conference Planning Committee
- Provide trainers and staff support for the annual conference.
- Pennsylvania Association of County Drug and Alcohol Administrators (PACDAA)
 - Provides information and support for grantees related to adherence to requirements and implementing best practices.
- Pennsylvania Prevention Directors Association (PPDA)
 - Provides informational updates regarding DDAP's prevention initiatives to PPDA members as well as provides meeting space for their quarterly meetings.
- Drug Free Pennsylvania
 - Develops and disseminates media literacy curriculums for middle and high school students; provides training on the curriculums; and, oversees an annual Public Service Announcement contest in schools across the Commonwealth.

Take Backs

Specific to opioid medications, DDAP has placed a priority to increase awareness and prevent the illicit use and abuse of prescription drugs. To reach these objectives, DDAP has been monitoring nationwide trends and providing up-to-date research and analysis. The department has been working with the Pennsylvania Commission on Crime and Delinquency (PCCD) and the Pennsylvania District Attorney's Association to emplace permanent drug take-back repositories around the state. DDAP assisted a grant application that resulted in PCCD's award of \$100,000 to distribute 250 secure take-back boxes. According to the DDAP 2013-2014 progress report, there are 275 collection boxes located throughout the Commonwealth.

DEPARTMENT OF HUMAN SERVICES

The Pennsylvania Department of Human Services (DHS) provides funding, through the Medical Assistance program, for individuals to receive prevention and treatment services. The Medical Assistance program's goal, as stated in the governor's proposed 2015-2016 budget is "To support a health care delivery system that provides comprehensive health care services in appropriate settings for the eligible populations." In DHS the Deputy Secretary for Mental Health and Substance Abuse Services oversees the Office of the Medical Director and the bureaus of Community and Hospital Operations; Policy, Planning and Program Development; Financial Management and Administration; Children's Behavioral Health; and Quality Management and Data Review. Under the deputate's mental health responsibilities, and substance abuse services, the department is responsible for the oversight and administration of Behavioral Health Services Initiative (BHSI) funding. Substance abuse treatment services are provided to individuals with severe addictive disorders (including co-occurring mental health disorders) who are uninsured, who do not have insurance that covers the service needed or who cannot obtain Medical Assistance benefits. Services available include the full continuum of treatment, as well as case management services, to assist this population with access to and retention in treatment to promote recovery.

Enforcement of Health Insurance Laws

Members of the HR659 Advisory Committee emphasized the importance of insurance coverage for people who need addiction services. Existing laws require that insurance providers provide coverage for addiction services. Advisory Committee members, however, pointed out that these laws are not fully enforced and patients often go without necessary financial support from their insurers.

A number of laws have been enacted since the late 1980s that require insurance providers, both public and private, to offer coverage of treatment for alcohol and drug addiction. The addiction treatment provisions of Pennsylvania's group insurance law, Pennsylvania's Medicaid law, the Federal Mental Health Parity & Addiction Equity Act of 2008, the Federal Health Insurance Exchanges, and the Affordable Care Act each requires coverage.

Each law also requires consistent enforcement and the establishment of accountability provisions and reporting on compliance to the General Assembly. Act of December 15, 1988 (P.L. 1239, No. 152) expanded state Medicaid coverage to include licensed non-hospital residential detoxification, non-hospital residential rehabilitation, and halfway house services to the types already covered to treat alcohol and drug addictions. Prior to the enactment of Act 152, state Medicaid only covered limited outpatient and limited hospital services.

Act of December 22, 1989 (P.L. 755, No. 106) requires all group health plans, HMOs, some self-insured plans, and the Children's Health Insurance Program (CHIP) to provide comprehensive treatment for alcohol and other drug addictions.

The federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) requires insurers to cover the treatment of drug and alcohol addiction and mental illness in parity with medical and surgical problems.⁴⁶ States are required to be the first line of enforcement of the MHPAEA.

The Patient Protection and Affordable Care Act of 2010 (ACA) included substance abuse treatment as one of the required benefit categories.⁴⁷ Furthermore, the ACA requires applicable plans to comply with MHPAEA.⁴⁸ The U.S. Department of Health and Human Services (HHS) estimates that the consequences of the MHPAEA and ACA will eventually allow 32.1 million Americans access to coverage that includes mental health and substance use disorder benefits that comply with federal parity requirements and an additional 30.4 million who currently have some mental health and substance abuse benefits will benefit from the federal parity protections.⁴⁹ When properly utilized, the federal law should work hand-in-hand with the Commonwealth's drug and alcohol services insurance laws (Act 152 of 1988 and Act 106 of 1989) to ensure and enhance appropriate care for people in need of treatment.⁵⁰

In 2014, HHS selected a default benchmark plan for a health insurance exchange for Pennsylvania, determined to be the small group health plan with the largest enrollment in the state.⁵¹ This group health plan falls under the requirements of Act 106 of 1989. As of early 2015, drug and alcohol service providers began to see admissions to addiction treatment through the federal exchange.⁵²

⁴⁶ Act of 2008, Pub. L. No. 110–343, Div. C, Title V, Subtitle B, 122 Stat. 3881, known as “The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act.”

⁴⁷ Pub. L. No. 111-148, 124 Stat. 119 (2010), known as “The Patient Protection and Affordable Care Act.”

⁴⁸ Carnevale Associates, LLC, “The Affordable Care Act: Shaping Substance Abuse Treatment,” <http://www.carnevaleassociates.com/aca>.

⁴⁹ Kirsten Beronio, Rosa Po, Laura Skopec and Sherry Glied, “Affordable Care Act Will Expand Mental Health and Substance Use Disorder Benefits and Parity Protections for 62 Million Americans,” *ASPE Research Brief*, U.S. HHS, (February 2013), http://aspe.hhs.gov/health/reports/2013/mental/rb_mental.pdf.

⁵⁰ Act of December 15, 1988, P.L. 1239, No. 152; Act of December 22, 1989, P.L.755, No. 106.

⁵¹ “State Exchange Profiles: Pennsylvania,” The Henry J. Kaiser Family Foundation, <http://kff.org/health-reform/state-profile/state-exchange-profiles-pennsylvania/>.

⁵² Deb Beck, president of Drug & Alcohol Service Providers Organization of Pennsylvania, “Enforcement of Health Care Laws,” email to Commission staff, May 8, 2015.

PREScription DRUG MONITORING PROGRAMS

Prescription Drug Monitoring Programs (PDMPs) are primarily state-sanctioned databases that record data on the prescribed and dispensed controlled substances within their state. These programs allow healthcare providers to help prevent the over prescribing and dispensing of controlled substances, and to identify individuals who may be involved in the misuse and diversion of controlled substances. Identifying these individuals can help ensure adequate treatment is being provided to those with legitimate medical needs. PDMPs are also used by health authorities and law enforcement agencies to interdict the diversion of Schedule II substances to unauthorized or criminal users. Patient, prescription, prescriber, and dispenser information is entered into the databases, where it is held in strict confidentiality and accessible only to prescribers, dispensers, health and law enforcement authorities, and the patients themselves. Further, cost-benefit analyses show that PDMPs may save millions of dollars by reducing illicit use, abuse, and diversion. Appendix A presents a list of state PDMPs' successful outcomes that were analyzed by The Heller School PDMP Center for Excellence at Brandeis University.⁵³

Among The Heller School's findings are that PDMPs:

- Improve clinical decision-making and patient care
- Identify and reduce doctor shopping
- Have beneficial effects on controlled substance availability and prescribing
- Are associated with improved health outcomes
- Can reduce drug and medical costs related to inappropriate prescribing
- Reduce diversion and drug investigation times
- Assist in monitoring compliance and abstinence
- Assist substance abuse treatment and medical examiner practice
- Assist drug abuse prevention and surveillance efforts
- Have support of physicians
- Are valued by investigators⁵⁴

At present, 49 states, Washington, D.C., and Guam have active PDMPs. A variety of agencies oversee the operation and management of the PDMPs, including those connected to law enforcement, health, substance abuse, pharmacy, professional licensing, and others. See Table 1.

⁵³ "Briefing on PDMP Effectiveness," Prescription Drug Monitoring Program Center of Excellence at Brandeis, The Heller School for Social Policy and Management, Brandeis University, (2014), www.pdmpexcellence.org.

⁵⁴ Ibid.

Table 1
 Agencies that Administer State PDMPs
 As of March 2015

<i>Agency Type</i>	<i>Number</i>
Boards of Pharmacy	20
Consumer Protection	1
Departments of Health	13
Law Enforcement	7
Other	1
Professional Licensing	6
Substance Abuse	3
Total	51

Source: PDMPT TTAC, The Heller School for Social Policy and Management, Brandeis University, (2015), www.pdmpassisst.org.

PDMPs provide those individuals and agencies whose responsibilities include protecting patients' and the public's health with information that would be all but impossible to obtain through individual patient records spread across any number of healthcare providers.

Despite the high value and utility of PDMP information, prescribers and dispensers may be constrained by busy schedules and stringent limits on time spent with individual patients. A physician member of the HR659 Advisory Committee expressed his concerns that extra time spent entering and accessing information from a Pennsylvania PDMP would cut into doctors' direct contact time with patients.

The PDMP Center for Excellence (COE) at Brandeis University released a brief in February 2015 that highlighted the potential costs and benefits of authorizing opioid addiction treatment programs to access PDMPs.⁵⁵ The COE report discussed the opioid treatment programs' (OTP) and office-based treatment programs' (OBTP) cautious approach to PDMPs. Fourteen PDMPs allow OTPs and OBTPs access to PDMP patient information. A survey of OTPs and OBTPs in states that allow them access showed that approximately 25 percent of patients in treatment were prescribed controlled substances that had not been disclosed to their treatment programs.⁵⁶ Undisclosed use of controlled substances is, of course, of paramount concern to treatment providers because the treatment programs may include the use of prescribed medications part of a medication assisted treatment program (MAT). Non-disclosure entails severe consequences when methadone is prescribed, for example, as the drug may interact with other controlled substances in particularly hazardous and potentially fatal ways.⁵⁷

⁵⁵ "Use of PDMP Data by Opioid Addiction Treatment Programs," PDMP Center of Excellence, The Heller School for Social Policy and Management, Brandeis University, (February 2015), www.pdmplexcellence.org.

⁵⁶ Ibid., 3.

⁵⁷ *Methadone Use and Abuse: Reducing the Incidence of Methadone Overdoses and Deaths.* Joint State Government Commission. June 2011. <http://jsg.legis.state.pa.us>.

Treatment providers and patients are concerned that the inclusion of patients' OTP and OBTP information in PDMPs may breach the confidentiality typically afforded addiction treatment. Substance abuse and addiction are stigmatized and stigmatizing; because of this stigma, patients in treatment programs often prefer that their other healthcare providers not be made aware that they are receiving addiction treatment services. Also, fear of prosecution is an impediment to seeking addiction treatment.⁵⁸ Everyone surveyed for the COE report endorsed this "privacy rationale" for not allowing outside providers to know an OTP patient's status. Some patients, they reasoned, may avoid addiction treatment entirely out of fear that their other healthcare providers could learn of their addiction through a PDMP.⁵⁹ It is possible, however, to set up OTP providers' access to PDMP data in a way that cloak the OTP's access from a patient's other healthcare providers. In this way, OTP providers will know which, if any, dangerously interactive drugs have been prescribed to their patients.

Regardless of how OTP and OBTP providers and patients are considering PDMP access, the issue may be moot. Federal regulations prohibit OTPs from reporting any information that would identify a patient as one receiving addiction services, with narrow exceptions.⁶⁰

Overall, the COE report concluded that the use of PDMPs as a component of OTP and OBTP should be included among the providers' best practices.⁶¹

The U.S. Office of the National Coordinator for Health Information Technology (ONC) at the Substance Abuse and Mental Health Services Administration (SAMHSA) in the U.S. Department of Health and Human Services (HHS) sponsored a project to find ways to improve timely access to, and the use of PDMP information through the use of health information exchanges (HIEs). ONC reported in 2013 that results from several states' pilot projects demonstrated that:

The 2013 implementations successfully increased access to patient prescription drug history information in PDMPs, and providers and dispensers reported value in having this information available when caring for patients. Prescribers and dispensers overwhelmingly reported increased satisfaction with their workflows when pre-queried PDMP data was automatically presented within the context of the patient's full medical history in the EHR. Providing the PDMP data as a part of the patient's HIE-based community health record was considered especially beneficial as it enabled the review of PDMP data in the broadest patient context.⁶²

⁵⁸ Susan Awad, "Confused by Confidentiality? A Primer on 42 CFR Part 2" *ASAM Magazine*, (August 15, 2013), www.asam.org/magazine.

⁵⁹ Supra note 55 at 9.

⁶⁰ Title 42, Chapter I, Subchapter A, Part 2. Electronic Code of Federal Regulations. www.ecfr.gov.

⁶¹ Supra note 55 at 10.

⁶² "Connecting for Impact: Integrating Health IT and PDMPs to Improve Patient Care," SAMHSA, (2013), www.healthit.gov.

Although regional healthcare providers are developing and deploying proprietary systems to distribute patients' electronic health records (EHRs) across their subsidiaries, at present Pennsylvania does not have a comprehensive statewide HIE. The Pennsylvania eHealth Partnership Authority was established in July 2012 by the enactment of the Act of July 5, 2012 (No. 121, P.L. 1042), the "Pennsylvania EHealth Information Technology Act," for the purpose of developing and maintaining a statewide HIE.⁶³ The Authority is an independent Commonwealth agency that is overseen by public-private board of directors; it continues the work of its predecessor, the Pennsylvania eHealth Collaborative. Both the Authority and the Collaborative worked under a strategic and operational plan approved and primarily funded by the Office of the National Coordinator for Health Information Technology.⁶⁴ The Authority's primary goals are fourfold:

- increase the speed and accuracy of diagnosis for individuals and populations
- reduce the occurrence of readmissions and redundant tests
- increase patients' satisfaction by reducing their time spent in the healthcare system
- eliminate frustrating duplication.⁶⁵

A further objective is to "yield the more robust healthcare data that is essential to continuous improvement in healthcare quality."⁶⁶ As SAMHSA found with its project to integrate HIT and PDMPs, HIEs may provide a valuable resource in the implementation and improvement of PDMPs. From an infrastructural and technological standpoint an HIE is an asset; it functions as an existing platform for PDMPs. Similarly, previous public and private financial investments in HIEs can offset the expense of building and deploying PDMP infrastructure. In October 2012, SAMHSA awarded nine grants to states to support PDMP and EHR integration.⁶⁷ Four of the nine grants were used in the several states that initiated pilot projects in conjunction with SAMHSA.

These pilot projects utilized HIEs effectively but in different ways. In Indiana, an HIE delivered PDMP data to hospitals through EHRs. An Oklahoma HIE was also used as a means of data transfer; however, the Oklahoma Bureau of Narcotics maintained authentication and security for the PDMP. Nebraska's pilot was a public private partnership, wherein the PDMP data were stored in a pharmacy health information network.⁶⁸ The pilot projects found three significant improvements to existing PDMP systems led to improvements in prescribers' and dispensers confidence and satisfaction in using PDMPs in clinical and pharmacy settings.

⁶³ Act of July 5, 2012 (No. 121, P.L. 1042).

⁶⁴ "Pennsylvania eHealth Partnership Authority 2014–2017 Strategic and Operational Plan for Electronic Health Information Exchange," PA eHealth Partnership Authority, (September 5, 2014), www.paehealth.org.

⁶⁵ Ibid.

⁶⁶ Ibid.

⁶⁷ Supra note 62 at 8.

⁶⁸ Supra note 62 at 7.

Clinical Decision Making: Presenting PDMP information within the context of the patient's full medical history (within an electronic health record (EHR) system) resulted in increased value and improved clinical decision-making for prescribers and dispensers over presentation of this same data in isolation.

Automation: Using patient data to generate automatic PDMP queries increased the speed and efficiency of accessing controlled substance history data within an EHR, health information exchange (HIE), ePrescribing solution, etc.

Integration: Integrating PDMP data as a resource of HIEs or pharmacy benefits management switches provided a mechanism for improving access to a more complete medical picture through a single resource.⁶⁹

The National Alliance for Model State Drug Laws' (NAMSDL) listed ten *Components of a Strong Prescription Monitoring Program* that ought to be a part of a state's statute that establishes a PDMP. These ten are:⁷⁰

1. **Drugs Monitored.** Drugs monitored should include federal controlled substances along with state regulated substances and others that, while not scheduled, are known to law enforcement and addiction counselors to be highly abused and dangerous.
2. **Unsolicited and Proactive Disclosure.** The PMP should provide data to prescribers, dispensers, law enforcement and occupational licensing individuals, as appropriate, without their having to query the system. In some jurisdictions, HIT systems auto-populate patient EHRs with PDMP data.
3. **Disclosure of De-Identified Information.** De-identified data for statistical, public research, public policy or educational purposes should be made available through the PDMP administrator.
4. **Authorized Users.** The individuals or officials allowed to request specific data from the program should include prescribers, dispensers, law enforcement and prosecutorial officials, health licensing agencies or boards for prescribers and dispensers, and patients. Additionally, state officials should include as authorized users those individuals whose use of the information will enhance patient safety and patient care. Such users include medical examiners, county coroners and designated representatives of drug and alcohol addiction treatment programs.

⁶⁹ Supra note 62 at 3.

⁷⁰ "Components of a Strong Prescription Drug Monitoring (PMP) Statute, Revised June 2012," National Alliance for Model State Drug Laws, (June 2012), www.namsdl.org, 2-4.

5. Education, Training or Instruction for Authorized Users. Authorization to request information should be limited to those individuals who have relevant education, training or instruction.
6. Standards and Procedures for Access to and Use of PMP. Health licensing agencies or boards for prescribers and dispensers, by statute, regulation, rule or policy should establish standards and procedures for their licensees regarding access to and use of PMP data.
7. Linkage to Addiction Treatment Professionals. State officials, by statute, regulation, rule or policy, or in practice, should establish an appropriate linkage from the PMP to addiction treatment professionals to help individuals identified through the PMP as potentially impaired or potentially addicted to a substance monitored by the PMP. An example of such linkage is a PMP Administrator referring prescribers and dispensers she has reason to believe may be impaired to the appropriate professional licensing or certification agency and to the appropriate impaired professionals associations.
8. Interstate Sharing of PMP Data. Interstate misuse and abuse of prescription drugs is a major problem facing all states. Each state with a PMP should provide for appropriate interstate sharing of PMP data by statute, regulation or interstate agreement. Recipients of PMP data from other states may include prescribers, dispensers, law enforcement representatives, PMP officials or other specified authorities.
9. Confidentiality Protections. Confidentiality protections from improper use of the system or of information from the PMP are important statutory and programmatic provisions. PMP data should not be subject to public or open records laws. Also, the enabling statute for the PMP should include penalties for knowingly disclosing, using or obtaining information other than as authorized by law. The PMP administering agency should maintain procedures to protect the privacy and confidentiality of patients and to ensure that data collected, recorded, transmitted, and maintained pursuant to the PMP law is not disclosed or used except as authorized by the law.
10. Evaluation Component. An evaluation component is critical to identifying cost benefits of the PMP, impacts of the use of PMP data on the practices of authorized users, any recommended operational improvements and other information relevant to policy, research and education involving controlled substances and drugs of concern monitored by the PMP. As part of the ongoing assessment process, an advisory committee or designated individuals should provide advice and input regarding the development and operation of the PMP.

Prescription Monitoring Plan (PMP) Interconnect

The Prescription Monitoring Plan (PMP) Interconnect is a prescription drug monitoring system that provides an electronic network for member states to access each other's controlled substance prescription databases. The Interconnect itself is maintained by the National Association of Boards of Pharmacy (NABP). The NABP states,

“The lack of interoperability between current systems and difficulty of data sharing among states makes it easier for doctor shoppers to avoid detection. The program's connected web of information allows appropriate intervention and aid in the prevention of substance abuse and diversion of controlled substances.”

NAPB developed the Interconnect after being approached by the PMP administrators of several states in 2010 about creating an “effective, easy to implement, and highly enhanced solution” for sharing PMP data between states that could be implemented in less than one year.

Development began in January 2011 and was launched for nationwide use in July 2011. The Interconnect is governed by a steering committee comprised of the PMP administrators and authorities from member states.

Another factor in a state's decision of whether or not to join an interconnect should be the question of integration of PMP data into the electronic health records (EHR) or pharmacy dispensing systems of prescribers and pharmacists. Although PMPs have been shown to have value to providers, the process of obtaining the data is not seamless. Therefore, there is great pressure for PMPs to create mechanisms to automate the delivery of patient specific reports into the EHRs or pharmacy software. There is currently a CDC grant opportunity for health departments to apply for funding to (1) enhance and maximize their PMP and (2) implement interventions to prevent prescription drug overdose and abuse. Integration of PMP data into providers' software is one way to meet both of these required strategies.

States that wish to join the Interconnect may do so via memorandum-of-understanding (MOU) with the NABP. Interconnect administrators work with state authorities and PMP service vendors to integrate each state's system into the Interconnect. Each state's MOU is with the Interconnect; states do not join in MOUs with each other. State membership lasts indefinitely, and a thirty day notice is required to sever the MOU. For the time being, NABP is funding the Interconnect through its own resources, revenue it derives from NABP programming.

Currently 28 states are members of the PMP Interconnect. Plans to join are pending in another five, including Washington, D.C. Pennsylvania is not yet a member, and no plans are pending at the time of this report. However, Pennsylvania's Act 191 of 2014 includes directives for the new PDMP executive board to facilitate the development and maintain technologies that would allow the Commonwealth to join the PMP Interconnect.

A second PMP interconnect system, known as RxCheck, has been built to join Maine and Alabama. These two are the only members of that particular PMP interstate system. Kentucky is dually connected to both the PMP Interconnect and RxCheck. All states contiguous to Pennsylvania are members of the PMP Interconnect, with the exception of New York, where a connection to the PMP Interconnect is pending. States can access data only from the interconnects to which they belong.

The inability to access prescription information from other states has put Pennsylvania at a disadvantage in the fight against the proliferation of illicitly obtained opioids. According to HR659 Advisory Committee members who are knowledgeable of controlled substances enforcement, Pennsylvania is a state with a strong presence of diversion crime because it accepts other states' prescriptions. Surrounding states do not accept Pennsylvania prescriptions because the Commonwealth does not have an operational PDMP that they can access states through the Interconnect. In other words, it is easier for criminal doctor shoppers to obtain illicit prescription opioids in Pennsylvania than it is in the surrounding states.

PENNSYLVANIA'S PDMP: ABC-MAP

Research shows that states with comprehensive PDMPs experience lower rates of opioid medication diversion and the consequent problems associated with diversion. There are fewer cases of addiction, fewer overdoses, and fewer overdose deaths.

On October 27, 2014 then-Governor Tom Corbett signed Act 191, the “Achieving Better Care by Monitoring All Prescriptions Program,” (ABC-MAP).⁷¹ The act establishes in Pennsylvania’s Department of Health a new PDMP that expands the categories of professions that are required to report information about Schedule II drug prescriptions, expands the professions that are authorized to retrieve information from it, and provides for patients’ access to their personal prescription records. According to Act 191, the PDMP is to be operational by June 30, 2015.⁷²

A significant part of the PDMP that is being established is that it is overseen by an ABC-MAP executive board within the PADOH that consists of the Secretaries of PADOH, Human Services, DDAP, State, and Aging. The Insurance Commissioner, State Police Commissioner, Attorney General, and Physician General are also included. Among the board’s duties are to contract a vendor to develop, implement, and service the PDMP system, to appoint an advisory group, provide necessary notice to prescribers, dispensers, and patients, and to phase in an enforcement process.

The ABC-MAP board is directed to develop policies and procedures that will not only mandate action by prescribers and dispensers, but will also provide education and support for those who use the PDMP. The primary purpose of the PDMP is to gather comprehensive data about opioid prescriptions for the purpose of compiling statistics, research, educational materials, and outreach to reduce as much as possible addiction, misuse, and diversion of controlled substances. The ABC-MAP board will direct PADOH to operate and maintain the program on a daily basis to allow for authorized PADOH personnel to review, analyze, and interpret data in the system. Further, the ABC-MAP board will develop policies that provide the means for the PDMP to keep pace with technological advances. To ensure the privacy and confidentiality of patients and their information, the ABC-MAP board will set policies to safeguard the database so that only authorized users and PADOH personnel may access it.

The ABC-MAP board will also develop policies to train, educate, and instruct prescribers and dispensers on the use of the ABC-MAP system. Further, the ABC-MAP board will assist professional organizations whose members prescribe, monitor or treat patients or dispense controlled substances to patients in the development of educational programs. Importantly, the ABC-MAP board will establish policies that aid prescribers in identifying at-risk individuals and referring them to drug treatment professionals and programs. The ABC-MAP board will establish professionally developed criteria that generates referrals of prescription monitoring information to

⁷¹ Act of October 27, 2014, P.L. 2911, No.191.

⁷² As of the writing of this report, the Commonwealth is in the process of finding a vendor to build and maintain the PDMP’s IT infrastructure.

the appropriate licensing board in the Department of State for instances when the system identifies a pattern of irregular data that deviates from the clinical standard.

The ABC-MAP board will evaluate the costs and benefits of the program. It will also convene the advisory group at least annually.

The new PDMP places new responsibilities on prescribers and dispensers, and also provides them with certain legal immunities.

Dispensers. The ABC-MAP board will establish a format for dispensers to submit the following information to the PDMP within 72 hours of dispensing a controlled substance:

- Full name of the prescriber
- Prescriber's Drug Enforcement Agency (DEA) registration number
- Date prescription was written
- Date prescription was dispensed
- The National Drug Code
- Full name, date of birth, sex, and address of the person for whom the prescription was written and dispensed
- Quantity and days' supply
- DEA registration number and National Provider Identifier of the dispenser or pharmacy
- Method of payment for the prescription

Prescribers. Prescribers must query the database for each patient the first time the prescriber prescribes a controlled substance for the patient. The prescriber must also query the database if using sound clinical judgment he or she believes or has reason to believe that a patient may be abusing or diverting drugs.

A prescriber will have to include in the patient's medical record the information obtained from the system if the individual is a new patient. The patient's medical record should also note if the prescriber determines a drug should not be prescribed or furnished to a patient based upon information in the database.

Both dispensers and prescribers have certain immunities under the PDMP. If they submit or receive information from the database and maintain confidentiality, they shall not be held civilly liable or disciplined in a licensing board action for submitting information or neither seeking nor obtaining information from the database prior to prescribing or dispensing the controlled substance.

There is a comprehensive listing of those who are authorized to access the database. All designees of the dispensers, prescribers, and the Attorney General's office must have their own unique identifiers to access the system. Prescribers may query the system for an existing patient or for prescriptions written using the prescriber's DEA number. Dispensers may query the system for a current patient to whom the dispenser is dispensing or considering dispensing any controlled substance. The Office of Attorney General shall query the system on behalf of all law enforcement agencies, including the Office of Attorney General and federal, state, and local law enforcement agencies for Schedule II controlled substances, and all other schedules upon receipt of a court order

obtained by the requesting law enforcement agency. The Office of Attorney General shall query the system on behalf of a grand jury investigating a criminal violation of a law governing controlled substances.

Medical examiners and coroners may query to investigate the death of an individual being queried.

Patients who are recipients of a prescription for a controlled substance, or the parent or guardian if the patient is under 18, or are an agent for the patient operating under a valid power-of-attorney may request access to the database on a quarterly basis at no charge. Their access is limited during times of an active investigation.

PADOH staff may access the database when they are conducting internal reviews related to controlled substance laws, or are engaging in the analysis of controlled substance prescription information as part of the assigned duties and responsibilities of employment.

Licensing Boards and Agencies

Access will also be granted to representatives from Pennsylvania and from other states' agencies and boards responsible for licensing or certifying prescribers or dispensers whose professional practice was or is regulated by that agency or board for the purpose of conducting administrative investigations or proceedings.

Commonwealth personnel who are responsible for the development and evaluation of quality improvement strategies, program integrity initiatives, or for conducting internal compliance reviews and data reporting for Medical Assistance, CHIP, PACE or PACENET will be granted access. Access will be granted to DDAP personnel engaged in the administration of the Methadone Death and Incident Review Team.

Prescription drug monitoring officials, dispensers or prescribers from a state with which Pennsylvania has a PDMP interoperability agreement may be granted access.

Funding

The PDMP will be funded by PADOH, which has been authorized to direct money from its General Fund appropriation to operate the PDMP. All costs associated with recording and submitting data shall be assumed by the submitting dispenser. Dispensers and prescribers shall not be required to pay a fee or tax specifically dedicated to the establishment, operation or maintenance of the program; and no fees shall be assessed to patients by dispensers/prescribers citing the need to submit information to the system.

Annual Report

The ABC-MAP board is required to submit annual reports to the General Assembly and to make them available on the PADOH website. The report will include:

- the number of times the ABC-MAP data system has been accessed legally and illegally;
- the rate at which prescribers are utilizing the system;
- any impact on prescribing controlled substances;
- the cost effectiveness of the frequency of data submission;
- the effectiveness of the interoperability with other states and electronic medical records;
- the number of inquiries by law enforcement and the number of search warrants issued as a result of law enforcement queries; and
- other information as determined by the ABC-MAP Board.

The Office of Attorney General must also provide an annual report to the General Assembly beginning two years after the effective date of the act.

The board was to have been organized within 90 days of Act 191's enactment; the remainder of the act will take effect June 30, 2015. The act will sunset on June 30, 2022.

Act 191 includes the provision of \$1,000,000 to create and establish Pennsylvania's PDMP. As of April 6, 2015 the appropriation was not included in Governor Wolf's budget proposal for the 2015-2016 fiscal year.

PDMP Grant

On April 2, 2015, the U.S. Department of Justice (DOJ), Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA) announced that it is seeking applications for funding under the Harold Rogers Prescription Drug Monitoring Program.⁷³ The grants are intended to provide resources to plan, implement, and enhance prescription drug monitoring programs to prevent and reduce misuse and abuse of prescription drugs and aid in investigations of pharmaceutical crime. The grant deadline was May 28, 2015.⁷⁴

The primary purpose of the Harold Rogers Prescription Drug Monitoring Program (PDMP) is to enhance the capacity of regulatory and law enforcement agencies and public health officials to collect and analyze controlled substance prescription data and other scheduled chemical products through a centralized database administered by an authorized state agency. The program was created by the fiscal year 2002 U.S. Department of Justice Appropriations Act (Public Law 107-77) and has received funding under each subsequent year's federal appropriations act.⁷⁵ The current project period will begin October 15, 2015. The BJA estimates that 15 grants will be awarded for a total of \$7 million.

⁷³ "Prescription Drug Monitoring Program (PDMP)," <https://www.bja.gov>.

⁷⁴ Ibid.

⁷⁵ Ibid.

Under the BJA grant program, 15 site-based awards were made in fiscal year 2014 for states to implement or enhance a PDMP program or strategy to address prescription drug abuse, misuse, and diversion within their communities. Since inception of the grant program in fiscal year 2002, grants have been awarded to 49 states and one U.S. territory to support their efforts to plan, implement or enhance a PDMP.⁷⁶

The Harold Rogers Prescription Drug Monitoring Program allows for state discretion to plan, implement, or enhance a PDMP to accommodate local decision making based on state laws and preferences, while encouraging the replication of promising practices. In recent years, the program expanded to support states and localities in assembling responsive, collaborative efforts between public health and public safety authorities to develop innovative ways to use PDMP and other data to inform prevention, treatment, and enforcement efforts. This year's solicitation introduces a new funding category to enable more rigorous, in-depth study of monitoring strategies designed to contribute to the growing body of knowledge of best practice tools and techniques, and spur innovation among state and local drug abuse programs.⁷⁷

⁷⁶ Ibid.

⁷⁷ Ibid.

PREVENTION OF PRESCRIPTION DRUG OVERDOSE AND ABUSE

In 2011, the White House released the paper, *Epidemic: Responding to America's Prescription Drug Abuse Crisis*.⁷⁸ Considered as its expansion of the National Drug Control Strategy, the White House report identified four actionable areas, education, PDMPs, drug disposal programs, and law enforcement, where steps could be taken to reduce prescription drug abuse. The report identifies the importance of raising awareness of the problem by educating healthcare providers, patients, parents, and youth. The report repeats what is commonly reported about opioid medications:

“There is a common misperception among many parents and youth that prescription drugs are less dangerous when abused than illegal drugs because they are FDA-approved.”⁷⁹

Despite parents’ intentions, the report highlights that many do not understand the risks associated with opioid analgesics, and treat them with less concern than they would alcohol.

In terms of healthcare provider education, national studies show that there have been improvements in medical education. A report published in 2000 found 56 percent of medical residency programs required training in substance abuse disorders, with a variation between 3 and 12 hours of training required.⁸⁰ The study concluded:

Consistent training for all residents in the initial diagnosis and management of substance use disorders has not been achieved. New strategies that integrate into existing residency structures are needed to improve substance use disorders training. Faculty development in substance use disorders and review of current substance use disorders training as part of the residency review process should facilitate this endeavor.⁸¹

Researchers had found by 2008 that awareness had grown enough such that substance abuse fellowships had been established, specialty organizations had been founded, and medical education had improved.⁸²

⁷⁸ *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, Office of National Drug Control Policy, The White House, n.d., <https://www.whitehouse.gov/ondcp/prescription-drug-abuse>.

⁷⁹ Ibid.

⁸⁰ J.H. Isaacson, M. Fleming, R. Kraus, and M. Mundt, “A National Survey of Training in Substance Use Disorders in Residency Programs,” *Journal of Studies on Alcohol*, vol. 61, no. 6, (November 2000), <http://www.ncbi.nlm.nih.gov/pubmed/11188498>, pp. 912-15.

⁸¹ Ibid.

⁸² S. Polydorou, E.W. Gunderson, and F.R. Levin, “Training Physicians to Treat Substance Use Disorders,” *Current Psychiatry Reports*, vol. 10, no. 5, (October 2008), <http://www.ncbi.nlm.nih.gov>, pp. 399-404.

The Pennsylvania Patient Safety Authority's (PPSA) March 2013 report, "Results of the Opioid Knowledge Assessment from the PA Hospital Engagement Network Adverse Drug Event Collaboration," summarized findings of the Pennsylvania Hospital Engagement Network's (HEN) analysis of its participating hospitals' practitioners when it comes to prescribing opioids and knowledge of potential consequential problematic issues.

The Institute of Safe Medication Practices' (ISMP) List of High-Risk Medications in Acute Care Settings includes opioids on its list of medications. "High-alert medications are drugs that bear a heightened risk of causing significant patient harm when used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. Use these lists to determine which medications require special safeguards at your practice site to reduce the risk of errors."

HEN sought to develop an assessment tool to determine its participating hospitals' knowledge base regarding opioids. The United States Pharmacopeia MEDMARX database indicates that bad reactions to opioids, which can range from failure to control pain to respiratory arrest to death, are among the most frequently cited adverse events. A 2004 study of data from the PPSA Pennsylvania Patient Safety Reporting System (PA-PSRS) showed that 25 percent of medication error events involved high alert medications. Of these events, 44 percent involved opioids.

The Pennsylvania Medical Society collaborated with the PPSA to develop an assessment survey for prescribers', pharmacists', and nurses' knowledge of opioids. The three areas of knowledge that were most lacking among respondents included:

- Identifying the most important predictor of respiratory depression in patients receiving IV opioids
- Defining what constitutes an opioid tolerant patient
- Choosing which medication could potentiate the effects of HYDROmorphe on ventilation. The assessment corroborated the PPSA's belief that practitioners may have a knowledge deficit that is potentially more dangerous than previously realized. The agency recommended that healthcare providers consider assessing and educating their practitioners in the following topic areas:
 - Potential effect of opioid therapy on sedation and respiratory depression
 - Differences between opioid-naïve and opioid-tolerant patients, and what constitutes or makes a patient opioid tolerant
 - Indications for long-acting opioids (who and/or when should they be prescribed)
 - Equianalgesic dosing between opioids, IV to PO as well as between two different opioids
 - Patient-specific conditions that require a lower starting dose of opioids. The ISMP also set a list of High-Alert Medications in Community/Ambulatory Healthcare.

The list includes all formulations of opioids. The authors identified characteristics of effective substance abuse training for physicians.

- Brief, skills-based curricula can improve physician knowledge, attitudes, and practices
- Combined interactive, experiential, and didactic curricula are preferable to didactics alone
- Expert faculty in addiction are needed to serve as role models and provide support
- Feedback to trainees should be integrated into training programs
- Reinforcement of training improves outcomes⁸³

The White House report listed many “action items” to have been taken “to improve educational efforts and to increase research and development.”⁸⁴ Among the recommendations for healthcare provider education, the White House recommended that federal law be amended to require practitioners who request DEA registration to prescribe opioids to be training on responsible prescribing practices and to recognize, assess, and address signs of abuse and dependence.

This recommendation was to be carried out through the Opioid Risk Evaluation and Mitigation Strategy (REMS).⁸⁵ The strategy is a multi-agency federal effort to address the growing problem of prescription drug abuse and misuse. One of its primary objectives is to reduce risks and improve safety without interfering with access to opioid medications for pain management.

Among other recommendations made in the White House report were to expedite research by continuing to provide grants and build partnerships with academia, and for the FDA to give high priority to New Drug Applications for abuse-deterrent formulations and alternatives for pain management medications that have no potential for abuse. The report goes on to state that direct-to-consumer advertising has increased demand for the opioids, which creates an even greater need for education and awareness.

The White House report recommended that REMS establish a requirement that manufacturers develop education and training materials for practitioners on the appropriate use of opioids. The report also sought REMS to require manufacturers to develop educational materials for patients on the appropriate use and disposal of opioid medications.

⁸³ S. Polydorou, E.W. Gunderson, and F.R. Levin, “Training Physicians to Treat Substance Use Disorders,” *Current Psychiatry Reports*, vol. 10, no. 5, (October 2008), <http://www.ncbi.nlm.nih.gov>, pp. 399-404.

⁸⁴ Supra note 78.

⁸⁵ “Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids,” U.S. Food and Drug Administration, (July 9, 2012), <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>.

Marketing

The marketing of opioid analgesics was a notable topic of discussion at HR659 Advisory Committee meetings. In 2007, drug manufacturer Purdue settled litigation with federal prosecutors, resulting in \$634 million in fines.⁸⁶ A portion of the fines was set aside to reimburse federal and state governments for damages suffered by Medicaid programs as a result of the improper promotion of OxyContin.⁸⁷ As part of its discussion about industry marketing practices, the Advisory Committee discussed three current lawsuits involving opioid medication manufacturers.

California. Alleging deceptive marketing practices, two California counties filed suit against five manufacturers of opioid medications. The plaintiffs, Orange and Santa Clara Counties, allege that the manufacturers engaged in dishonest and manipulative marketing and unfair business practices, in violation of the California's False Advertising Law (Bus. & Prof. Code §17500), Unfair Competition Law (Bus. & Prof. Code §17200), and Public Nuisance Law (Cal. Civ. Code §§3479 and 3480).⁸⁸ The case is pending as of the writing of this report.

Kentucky. The Kentucky Attorney General filed a civil suit against opioid medication manufacturers in 2007. As part of the federal government's 2007 settlement, Kentucky was offered \$500,000, but refused the money; Kentucky was the only state to do so.⁸⁹ A comprehensive review of the lawsuit is in Appendix C. The suit is ongoing as of the writing of this report.

Chicago. The City of Chicago filed suit in federal court against five manufacturers in November 2014. Similar to the other two lawsuits, the Chicago plaintiffs allege that drug makers, ". . . engaged in fraudulent, unfair, and deceptive acts and practices. . ."⁹⁰ The lawsuit lists 11 counts of violations against the Chicago municipal code.⁹¹ In May 2015, the federal judge hearing the case dismissed four of the defendants, stating that Chicago officials failed to "provide enough specific information to demonstrate [that the four companies] had made misrepresentations to doctors and patients."⁹² The lawsuit is pending as of the writing of this report.

Manufacturers are required by the federal Food, Drug, and Cosmetics Act to present information that balances the risks with the benefits of medications.⁹³ A 2013 report in *Pharmacoepidemiology and Drug Safety* titled "Communicating Quantitative Risks and Benefits in Promotional Prescription Drug Labeling or Print Advertising," presented research on the question as to whether or not quantitative risk and benefit information in advertising and labeling

⁸⁶ David Armstrong, "Purdue Says Kentucky Suit Over OxyContin Could Be Painful," *Bloomberg.com*, (October 20, 2014), <http://www.bloomberg.com/news/articles/2014-10-20/purdue-says-kentucky-suit-over-oxycontin-could-be-painful>.

⁸⁷ Ibid.

⁸⁸ Superior Court of the State of California in and for the County of Orange.

⁸⁹ Supra note 86.

⁹⁰ Case: 1:14-cv-04361 Document #: 186 Filed: 11/10/14 Page 1 of 196 PageID #:5059

⁹¹ Ibid.

⁹² Ed Silverman, "J&J and Other Drug Makers Tossed From Lawsuit Over Opioid Marketing," *The Wall Street Journal*, (May 11, 2015), www.wsj.com.

⁹³ Douglas C. Throckmorton, MD, Deputy Director for Regulator Programs, CDER, FDA, "Opioid Prescribing Practices and Pain Management: Role of FDA," U.S. Food and Drug Administration, (October 2013), www.fda.gov.

affect how people process, learn, and behave with regard to prescription medications.⁹⁴ The authors reviewed 52 studies published between 1990 and early 2011 of providers' and consumers' knowledge, comprehension, and behaviors after being presented with information in different formats. As with most data and information presentations, simple is best. No single format was superior; a simple mix of numeric and non-numeric information appears to be the most effective means of communicating risks and benefits.⁹⁵

Many Advisory Committee members hold a strong opinion that aggressive marketing of opioid medications led to the tremendous increases in the prescribing and availability of opioid medications. The abundance of the drugs, they assert, was the primary cause of the extraordinary growth in illicit use and abuse of the drugs beginning in the early 2000s. Advisory Committee members familiar with current marketing practices emphasized that rigorous oversight by federal authorities, working in concert with manufacturers' self-imposed policies, are maintaining ethical and responsible marketing practices.

Abuse Deterrent Formulations

Frequently, those seeking a "high" from these prescription painkillers will crush the pills and either snort, smoke, or inject the new altered formulation. This process allows the user to achieve a quicker, more intense high. One group of opioids that has been especially worrisome are extended-release (ER) formulations. ER formulations can be more attractive to abusers because they have a higher drug concentration per dosage unit than immediate-release formulations. This not only allows for a rapid high, but greater euphoria.⁹⁶

However, abuse-deterrent formulations have, and continue to be developed to prevent this from happening. These formulations possess qualities that help to deter abuse, but typically cannot prevent all abuse. Generally, abuse-deterrent formulations are categorized as follows:⁹⁷

1. *Physical/ Chemical barriers:* Physical barriers can prevent chewing, crushing, cutting, grating, or grinding. Chemical barriers can resist extraction of the opioid using solvents. Physical and chemical barriers can change the form of an oral drug making it less likely to be abused.

⁹⁴ S.L. West, et al, "Communicating Quantitative Risks and Benefits in Promotional Prescription Drug Labeling or Print Advertising," *Pharmacoepidemiology and Drug Safety*, vol. 22, no. 5, (May 2013), <http://www.ncbi.nlm.nih.gov/pubmed/23440924>, pp. 447-58.

⁹⁵ Ibid.

⁹⁶ Robin Moorman-Li, et al, "A Review of Abuse-Deterrent Opioids for Chronic Nonmalignant Pain," *Pharmacy and Therapeutics*, (July 2012), 37(7), pp. 412-418.

⁹⁷ "Abuse-Deterrent Opioids-Evaluations and Labeling Guidance for Industry," U.S. Food and Drug Administration, Center for Drug Evaluation and Research, (April 2015), <http://www.fda.gov>.

2. *Agonist/Antagonist combinations*: An opioid antagonist can be added to interfere with, reduce, or defeat the euphoria associated with abuse. The antagonist can be sequestered and released only upon manipulation of the product. For example, a drug product may be formulated such that the substance that acts as an antagonist is not clinically active when swallowed but becomes active if the product is snorted or injected.
3. *Aversion*: Substances can be combined to produce an unpleasant side effect if the dosage form is manipulated prior to ingestion or a higher dosage than directed is used. For example, the active ingredient can be manipulated that, when crushed, will form chunks causing irritation if snorted.
4. *Delivery System* (including depot injectable formulations and implants): Certain drug release designs or the method of drug delivery can offer resistance to abuse. For example, sustained-release depot injectable formulation or a subcutaneous implant may be difficult to manipulate.
5. *New molecular entities and prodrugs*: The properties of a new molecular entity (NME) or prodrug could include the need for enzymatic activation, different receptor binding profiles, slower penetration into the central nervous system, or other novel effects.
6. *Combination*: Two or more of the above methods could be combined to deter abuse.
7. *Novel approaches*: This category encompasses novel approaches or technologies that are not captured in the previous categories.

Currently, there are three products available that are FDA-approved for an abuse-deterrent label indication, OxyContin® and Embeda®, and Hysingla®. There are other products that have been reformulated, but do not yet have FDA-approved label indication. When, for example, the abuse-deterrent formulation of OxyContin was approved in April 2010 there was a significant decline in use of the drug to get high. However, many users often switched to other opioids, which typically included heroin, as shown on Figure 7 on page 11. Furthermore, the deterrent effect plateaued after two years of implementation.⁹⁸

One issue at the forefront of abuse-deterrent formulations is getting doctors to prescribe them. Often these formulation are released under brand names and are not yet available in generic form. This can be worrisome since state law allows pharmacists to dispense generic prescriptions to all patients without notification, unless the doctor specifically directs otherwise. Further, name brands often have a significantly higher price tag than their generic forms.

⁹⁸ Theodore J. Cicero and Mathew S. Ellis, “Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States,” *JAMA Psychiatry*, (May 1, 2015), doi:10.1001/jamapsychiatry.2014.3043.

CDC Menu of Laws

The CDC developed a website that keeps track of “State Laws on Prescription Drug Misuse and Abuse.”⁹⁹ The laws are categorized into what the CDC refers to as menus. The menus include:

- Prescription Drug Time and Dosage Limit Laws
- Physical Examination Requirements
- Doctor Shopping Laws
- Tamper-Resistant Prescription Form Requirements
- State Prescription Drug Identification Laws
- Pain Management Clinic Regulation
- State Laws Related to Prescription Drug Overdose Emergencies

The CDC recognizes that the effectiveness of state laws that related to injury prevention is well documented, while the effectiveness of those designed to prevent prescription drug abuse and diversion are less well documented. Two agencies of the CDC, the National Center for Injury Prevention and Control and the Public Health Law Program collaborated to summarize the statutory and regulatory strategies used by states with regard to prevention of abuse, misuse, and diversion.¹⁰⁰

Prescription Drug Time and Dosage Limit Laws

In all, 47 states and Washington, D.C. have laws that set time or dosage limits for controlled substances. This meant that the laws set limits on the prescribed quantity of drug per time period or amount.

Time limitations. Some states put time limits on all prescriptions or on all controlled substances. Most of the states that place time limits on prescriptions apply them to specific schedules of drugs. Pennsylvania law, for example, states that prescriptions for Schedule III or IV drugs

“shall not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by a practitioner.”¹⁰¹

Schedule III drugs are those specified by the DEA as having a potential for abuse that is lower than the risk for drugs on Schedules I and II, and may lead to moderate or low physical dependence, such as Tylenol with Codeine.¹⁰² Schedule IV drugs are those that have a low risk of abuse relative to Schedule III, such as Xanax, Valium, and Ativan.¹⁰³

⁹⁹ “Prescription Drugs: State Laws on Prescription Drug Misuse and Abuse,” CDC, <http://cdc.gov>.

¹⁰⁰ Ibid.

¹⁰¹ Act of April 14, 1972, P.L. 233, No. 64. 35 P.S. 780-11(b), known as “The Controlled Substance, Drug, Device, and Cosmetic Act.”

¹⁰² “Controlled Substance Schedules,” Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice, <http://www.deadiversion.usdoj.gov>.

¹⁰³ Ibid.

Dosage limits. Further, Pennsylvania is among a number of states that place time limitations on prescription drug benefit plans' applicability. Act of Nov. 21, 1996, P.L. 741, No. 134 states that recipients of the PACE program, which provides pharmaceutical benefits for the elderly, limits the supply to either 30 days or 100 units. In the case of acute conditions the benefit is limited to a 15 days' supply.

Some states allow for pharmacists to dispense drugs, in emergency situations, prior to receiving authorization from a prescriber. Typically, these states allow for a 72 hour supply to be dispensed; Schedule II drugs, however, are not permitted to be dispensed under these conditions.¹⁰⁴ Opioid analgesics are included on Schedule II.

Prescription Drug Overdose Emergencies

Immunity. Nine states have enacted laws to provide for immunity from prosecution or mitigating circumstances at sentencing for people who call 9-1-1 during overdose emergencies.¹⁰⁵ The laws are intended to encourage individuals to seek immediate medical attention for people who are suffering overdoses without having to worry about criminal consequences of their actions. The laws cover both the person suffering the overdose and those who call for help. Connecticut's law states:

[The penalties] shall not apply to any person (1) who in good faith, seeks medical assistance for another person who such person reasonably believes is experiencing an overdose from the ingestion, inhalation or injection of . . . any drug or substance, (2) for whom another person, in good faith, seeks medical assistance, reasonably believing such person is experiencing an overdose from the ingestion, inhalation or injection of . . . any drug or substance, or (3) who reasonably believes he or she is experiencing an overdose from the ingestion, inhalation or injection of . . . any drug or substance and, in good faith, seeks medical assistance for himself or herself, if evidence of the possession or control of a controlled substance in violation of . . . this section was obtained as a result of the seeking of such medical assistance.¹⁰⁶

Four of the nine states' laws do, however, not extend immunity or mitigating circumstances to other criminal charges that may be filed. Massachusetts' law states:

[n]othing contained in this section shall prevent anyone from being charged with trafficking, distribution or possession of a controlled substance with intent to distribute . . .¹⁰⁷

Mitigation. In an effort to provide some incentive for people to call for medical attention during overdose events, some states provide for mitigation at sentencing. Five of the eight states that provide mitigation do so from within the framework of controlled substances acts, either their own or the federal. For example, Massachusetts law cites the federal Controlled Substances Act in stating:

¹⁰⁴ "Public Health Law Program, Prescription Drugs, State Laws on Prescription Drug Misuse and Abuse, Menu of Prescription Drug Time and Dosage Limit Laws," CDC, <http://cdc.gov>.

¹⁰⁵ Ibid.

¹⁰⁶ Conn. Gen. Stat. Ann. § 21a-279.

¹⁰⁷ Mass. Gen. Laws Ann. ch. 94C, § 34A.

The act of seeking medical assistance for someone who is experiencing a drug-related overdose may be used as a mitigating factor in a criminal prosecution under the Controlled Substances Act...¹⁰⁸

Three of the states extend mitigation beyond controlled substances statutes. Maryland, for example, allows mitigating circumstances in as a General Provision of the Maryland Criminal Procedure Code:

[t]he act of seeking medical assistance for another person who is experiencing a medical emergency after ingesting . . . drugs may be used as a mitigating factor in a criminal prosecution.¹⁰⁹

Physical Examination Requirements

Forty-one states and Washington, D.C. have laws that require, before they may prescribe or dispense a medication, a prescriber or dispenser (typically a physician or pharmacist) to conduct a physical examination of the patient for whom they would prescribe or dispense. Some of these states prohibit the prescribing or dispensing if the physician or doctor has doubts that a physical examination took place.¹¹⁰

Types of Examination Required. Some states' laws require that a physical examination take place, while other states require that an "appropriate" or "sufficient" examination take place, without specifying that it be physical. Some states are even less specific, and require only that an examination be performed, without applying qualifiers such as appropriate or specific.

Applicability of Examination Requirement. Thirty-six states and Washington, D.C. have examination requirements that apply to all medications prescribed and dispensed. Some states require examinations only when controlled substances are prescribed and dispensed for pain management. For example, in Washington a nurse practitioner must,

[o]btain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for chronic noncancer pain.¹¹¹

Application with Reference to a Patient-Practitioner Relationship. Many states require that there be a relationship between the patient and prescriber (either practitioner or physician).¹¹² In Hawaii, for example,

"It shall be unlawful for any person . . . [to] prescribe . . . any controlled substance without a bona fide physician-patient relationship," and the definition of bona fide physician-patient relationship may be found in the definition section of the statute, including reference to a physical examination.¹¹³

¹⁰⁸ Mass. Gen. Laws Ann. ch. 94C, § 34A.

¹⁰⁹ Md. Code Ann., Crim. Proc. § 1-210.

¹¹⁰ "Public Health Law Program, Prescription Drugs, State Laws on Prescription Drug Misuse and Abuse, Menu of Physical Examination Requirements," CDC, <http://www.cdc.gov>.

¹¹¹ Wash. Admin. Code § 246-840-467 (eff. 2011).

¹¹² Ibid.

¹¹³ Haw. Rev. Stat. § 329-41; Haw. Rev. Stat. § 329-1.

Electronic Questionnaires. Many states prohibit writing prescriptions based solely on electronic questionnaires.¹¹⁴ These laws may be linked to a requirement for physical examinations. Connecticut's law is linked to the requirement for a physical examination, and states that a prescription

[i]ssued solely on the results of answers to an electronic questionnaire shall be considered to be issued outside the context of a valid practitioner-patient relationship and not be a valid prescription.¹¹⁵

Doctor Shopping Laws

General Doctor Shopping Laws. All 50 states and Washington, D.C. have laws that prohibit doctor shopping.¹¹⁶ Each either quotes verbatim or closely parallels either the Uniform Narcotic Drug Act of 1932 or the Uniform Controlled Substances Act of 1970.^{117, 118} The Uniform Narcotic Drug Act states that

[n]o person shall obtain or attempt to obtain a narcotic drug, or procure or attempt to procure the administration of a narcotic drug . . . by fraud, deceit, misrepresentation, or subterfuge[] or . . . by the concealment of a material fact ...¹¹⁹

Specific Doctor Shopping Laws. Some states have more specificity in their laws, making it illegal for patients to withhold information from practitioners that applies to any controlled substance they have been prescribed or if they have been prescribed the same or a similar controlled substance. Some of these laws refer to disclosure timeframes, types of drugs, and detailed disclosure requirements.¹²⁰ In terms of time frames, some laws specify that patients reveal prescriptions dispensed within the previous 30 days, although some states require disclosure if prescriptions are concurrent.¹²¹ Connecticut prohibits non-disclosure only if there is intent to obtain drugs for purposes of abusing it.¹²²

Doctor Shopping and Privileged Communications. About half of the states have laws that specify that communications between a practitioner and patient that is intended to obtain drugs through fraud are not privileged and are not subject to privacy and confidentiality statutes. For example, Alaska's law states that

[i]nformation communicated to a physician or other licensed practitioner in an effort to unlawfully procure a controlled substance or to unlawfully procure the administration of a controlled substance is not a privileged communication.¹²³

¹¹⁴ Supra note 110.

¹¹⁵ Conn. Gen. Stat. Ann. § 20-613a (eff. 2005).

¹¹⁶ "Public Health Law Program, Prescription Drugs, State Laws on Prescription Drug Misuse and Abuse, Menu of Doctor Shopping Laws," CDC, <http://www.cdc.gov>.

¹¹⁷ Unified Narcotic Drug Act (1932).

¹¹⁸ Unified Controlled Substances Act (1970).

¹¹⁹ Unified Narcotic Drug Act (1932), §17.

¹²⁰ Supra note 116.

¹²¹ Supra note 116.

¹²² Supra note 116.

¹²³ Alaska Stat. § 11.71.360 (eff. 1982).

Tamper Resistant Prescription Form Requirements

Tamper-Resistant Prescription Forms and the Federal Social Security Act. Five states require tamper resistant prescription forms that tie into the federal Social Security Act.¹²⁴ Section 1903 of the Act states:

...[w]ith respect to amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(k)(2)) for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad...¹²⁵

Circumstances Requiring Tamper-Resistant Prescription Forms and Exemptions. States vary in their treatment of the circumstances under which tamper-resistant forms are required. Some require tamper-resistant forms for all prescriptions, while others require them for Schedule II substances.¹²⁶ In 23 states and Washington, D.C. prescriptions that are not written on tamper resistant paper are not reimbursable through Medicaid.¹²⁷ There are certain circumstances when tamper-resistant paper is not required. For example, certain facilities, institutions, and emergency situations are exemptions in 18 states. A common thread among these laws is that exemptions are granted when the patient does not have the opportunity to handle the prescription. In Alaska, the law states:

(1) prescription for which retroactive Medicaid eligibility has been determined under 7 AAC 100.072, except for refills that are filled after the retroactive eligibility determination date; or (2) prescription prepared in an institutional pharmacy, if the prescriber writes the prescription into the medical record, the medical staff gives the order directly to the institutional pharmacy, and the patient does not handle or have the opportunity to handle the prescription...¹²⁸

Pain Management Clinic Regulation

States have enacted or promulgated statutes or regulations that require state oversight and other requirements regarding ownership and operation of pain management clinics, facilities, or practice locations to control the proliferation of so-called “pill mills,” which are pain management clinics that are sources of large quantities of prescriptions.¹²⁹ Laws may specify requirements for how the clinics are operated and qualifications for personnel. There may be laws regarding inspections, complaint investigations, licensing, health and safety, standards of care, or billing procedures.

¹²⁴ “Public Health Law Program, Prescription Drugs, State Laws on Prescription Drug Misuse and Abuse, Menu of Tamper-Resistant Prescription Form Requirements,” CDC, <http://www.cdc.gov>.

¹²⁵ “Compilation of the Social Security Laws: Payments to States, Sec. 1903,” U.S. Social Security Administration, http://www.ssa.gov/OP_Home/ssact/title19/1903.htm.

¹²⁶ Supra note 124.

¹²⁷ Supra note 124.

¹²⁸ Alaska. Admin. Code tit. 7, § 120.110 (eff. date unclear, 2010-2011).

¹²⁹ “Public Health Law Program, Prescription Drugs, State Laws on Prescription Drug Misuse and Abuse, Menu of Pain Management Clinic Regulation,” CDC, <http://www.cdc.gov>.

Definitions of Pain Management Clinics. Approximately 11 states have pain management clinic laws wherein clinics are defined similarly to Louisiana's:

'Pain management clinic' means a publicly or privately owned facility which primarily engages in the treatment of pain by prescribing narcotic medications.¹³⁰

Other states define a clinic based on the drugs that are prescribed for pain treatment, such as in Texas:

[p]ain management clinic means a publicly or privately owned facility for which a majority of patients are issued on a monthly basis a prescription for opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone.¹³¹

State Oversight of Pain Management Clinics. All states that govern the oversight of clinics require licensing or certification of the clinics operating within their borders. Some laws include language referring to inspections of the clinics and the investigation of complaints.

Ownership and Operation Requirements for Pain Management Clinics. Ownership and operation are addressed in the laws of most states that have statutes specific to pain management clinics. Some states require that the owner or medical director be a physician who has completed training in pain management, and the physician owner or medical director to have an unrestricted license to practice in the state.¹³² Moreover, many of the states' statutes prohibit convicted felons from owning and operating clinics, and may prohibit "non-law abiding" licensees from being employees of pain management clinics.¹³³

Identification Laws

To combat illicit use, abuse, and diversion, a number of states have laws that require patients to show personal identification before being dispensed drugs they had been prescribed. Twenty five states have laws that either require or permit pharmacists to ask for identification from patients.¹³⁴ Those with mandatory laws may specify circumstances under which identification is required, or certain drugs for which identification must be shown, the type of identification that is accepted, and whether the pharmacist shall record the information.¹³⁵ Delaware is the only state with a universal identification law, stating:

The pharmacist and/or an employee under his/her direct supervision must verify the identification of the receiver of the controlled substance prescription by reference to valid photographic identification.¹³⁶

¹³⁰ La. Rev. Stat. Ann. § 40:2198.11(3) (eff. 2005).

¹³¹ 22 Tex. Admin. Code § 195.1(2) (eff. 2010); Tex. Occ. Code Ann. § 168.001 (eff. 2009).

¹³² Supra note 129.

¹³³ Supra note 129.

¹³⁴ "Public Health Law Program, Prescription Drugs, State Laws on Prescription Drug Misuse and Abuse, Menu of State Prescription Drug Identification Laws," CDC, <http://www.cdc.gov>.

¹³⁵ Ibid.

¹³⁶ 24 Del. Admin. Code § 4.0 (eff. 2009).

Idaho's law, by contrast, permits the pharmacist to dispense the prescription without seeing a form of identification if he or she positively and personally knows the patient.¹³⁷

There are discretionary laws, wherein the pharmacist exercises his or her judgment of whether or not identification needs to be presented. In Florida, a pharmacist is required to see identification if certain factors lead him or her to question if the prescription was written for a legitimate medical purpose. Minnesota law requires that identification be presented if the prescription is not covered by an insurer. Other states' laws require identification if the prescription is paid for by an insurer.¹³⁸

Types of Identification Required. States differ in how they specify the types of identification that is required of patients. Some mandate the type, referring to, for example, photo identification or government issued identification. Other states specify that the identification be "appropriate," while others use simply the word "identification," without qualifying it.¹³⁹

Exceptions to Identification Requirements. Some states allow exceptions to identification requirements. For example, some states' laws allow pharmacists to dispense medications without having seen identification from the patient if, in the pharmacist's judgment, dispensing the drug would not be a detriment to the patient. Massachusetts law states a pharmacist may dispense without seeing identification if:

[t]he pharmacy has reason to believe that the failure to dispense the controlled substance would result in a serious hardship for the ultimate user or agent of the ultimate user . . .¹⁴⁰

One study estimated the prevalence of doctor shopping in the U.S. by analyzing data from 76 percent of the U.S. retail pharmacies for 146.1 million opioid prescriptions dispensed in 2008.¹⁴¹ The researchers found that a small number of patients accounted for a relatively large number of prescriptions obtained via doctor shopping. This small number of purchasers, representing 0.7 percent of all purchasers, were presumed to be doctor shoppers, in that they obtained, on average, 32 opioid prescriptions from 10 different prescribers. Their purchases accounted for 1.9 percent of all opioid prescriptions. In other words, extreme doctor shoppers account for nearly three times as many prescriptions as do other purchasers. The authors did not conclude, however, that doctor shoppers are necessarily making purchases for illicit purposes. More important, to connect doctor shopping exclusively to illicit use would be to ignore potential problems associated with complex healthcare delivery systems.

Very few of these patients can be classified with certainty as diverting drugs for nonmedical purposes. However, even patients with legitimate medical need for opioids who use large numbers of prescribers may signal dangerously uncoordinated care.¹⁴²

¹³⁷ Idaho Admin. Code r. 27.01.01.200.

¹³⁸ Supra note 129.

¹³⁹ Supra note 129.

¹⁴⁰ 105 Mass. Code Regs. 701.004 (eff. 2010).

¹⁴¹ Douglas C. McDonald and Kenneth E. Carlson, "Estimating the Prevalence of Opioid Diversion by "Doctor Shoppers" in the United States," *PLoS ONE*, vol. 8, no. 7, (July 17, 2013), doi: 10.1371/journal.pone.0069241.

¹⁴² Ibid.

Along with the concerns that data may capture legitimate medical needs along with illicit users, among healthcare providers there is the professional opinion that overprescribing may lead to doctor shopping and addiction. In other words, people who are in legitimate need of pain management may find themselves drawn into addiction as a consequence of being prescribed more than is prudent. Health care providers generally agree that a lack of training on how to properly prescribe opioids for pain and how to identify abuse contributes to the problem. In 2000 only 56 percent of medical residency programs required substance use disorder training; of those that did, as few as 3-12 credit hours were required. A follow-up study conducted in 2008 showed improvements in requirements, although they were not uniformly applied across schools surveyed.

The study's authors identified a number of recommendations to reduce the incidence of doctor shopping in particular, and the impact of illicit use in general. These recommendations include:

Prescription Drug Monitoring Plans (PDMPs)

- Enhance data collection in PDMPs, Medicaid, and workers' compensation plans to identify improper prescribing of painkillers.
- Set up programs for Medicaid, workers' compensation programs, and state-run health plans that identify and address improper patient use of painkillers.
- Pass, enforce, and evaluate pill mill, doctor shopping, and other laws to reduce prescription painkiller abuse.
- Encourage professional licensing boards to take action against inappropriate prescribing.
- Increase access to substance abuse treatment programs.

Health Insurers

- Set up prescription claims review programs to identify and address improper prescribing and use of painkillers.
- Increase coverage for other treatments to reduce pain, such as physical therapy, and for substance abuse treatment.

Health Care Providers

- Follow guidelines for responsible prescribing, including screening and monitoring for substance abuse and mental health problems.
- Prescribe opioid analgesics only when other treatments have not been effective.
- Prescribe only the quantity of opioid analgesics needed based on the expected length of pain.
- Use patient-provider agreements combined with urine drug tests for patients' long-term use of opioid analgesics.
- Teach patients about safe use, storage and disposal of prescription painkillers.
- Use PDMPs to identify patients who are improperly using prescription painkillers.

In light of the prescription drug abuse problem and lack of guidelines to effectively monitor patients, doctors at the University of Pennsylvania Division of General Internal Medicine developed an electronic health record (EHR) based protocol and educational intervention to standardize documentation and management of patients prescribed opioids by primary care physicians.¹⁴³ Their objective was to evaluate provider adherence to this protocol, attitudes toward the management of these patients, and knowledge of opioid prescribing.

The researchers trained providers at three practices to utilize the following sequence of steps when prescribing opioid analgesics:

1. Select patients who are taking opioids for chronic non-cancer pain (CNCP), (i.e., receiving >2 opioid prescriptions in the 6 months prior to the intervention for a non-limited pain condition).
2. Risk stratify these patients using the Opioid Risk Tool.
3. Follow high-risk patients monthly; low to moderate-risk patients every 3 to 6 months.
4. Use a standard diagnosis (chronic pain, ICD-9 code 338.29A) in the electronic health record (EHR) problem list.
5. Complete a standardized EHR “smart set” documenting evaluation and management in the overview section of the EHR’s chronic pain diagnosis module.
6. Complete a controlled medication agreement (CMA).
7. Order a urine drug screen (UDS) at regular intervals (at least one per year; every 1-3 months in high-risk patients).
8. Designate one provider (in the EHR) to be responsible for opioid prescribing. Medical residents were encouraged to specify a “Continuity Attending” to maintain continuity of care when they were not in clinic.

Four training sessions were conducted during the course of the study. A monetary incentive was awarded to physicians who achieved adherence to the following measures with at least 80 percent of their chronic pain patients: at least one (UDS) in the past year, an office visit at least every six months, and a chronic pain diagnosis that could be indexed to a list preselected by the researchers.

The study’s results showed that participating doctors increased orders for UDSs by 145 percent. Documentation of chronic pain, as specified on the study’s list, increased by 424 percent. In all 3 practices studied, the total number of patients who were prescribed more than two opioid medications decreased. The study’s authors did not address the question of whether the patients may have sought other sources of opioid analgesics, i.e. doctor shopped.

¹⁴³ Robin E. Canada, M.D., Danae DiRocco, MPH, and Susan Day, M.D., MPH, “A better approach to opioid prescribing in primary care,” *The Journal of Family Practice*, (June 2014), <http://www.jfponline.com>.

Further, the researchers recorded statistically significant improvement in the attitudes of the providers, their belief that they had knowledgeable staff that could assist them, their confidence in helping patients on opioids, and documentation of their cases.

Other States' Guidelines

Other states have begun to develop and implement guidelines for prescribing opioid analgesics as one means of curbing the overdose epidemic.

Florida

In 2010, in response to a massive increase in prescription opioid overdoses, Florida began highly regulating pain clinics. At the time, 98 of the top 100 U.S. physicians who dispensed the highest quantities of oxycodone directly from their offices were located in Florida.

The new regulations began by requiring all pain clinics to register with the state by the beginning of January 2010. By February of 2011 law enforcement began conducting raids, often resulting in multiple arrests, seizures, and closure of clinics. In July of that year physicians were prohibited from dispensing Schedule II or III prescription drugs directly from their offices. By September, dispensers were required to report to the new prescription drug monitoring program.

These swift measures resulted in a 52 percent decrease in oxycodone overdose deaths by 2012. Death rates from prescription drugs as a whole also saw a decline of about 23 percent. These declines can be attributed to the actions taken by the Florida State legislature resulting in a 24 percent drop in oxycodone prescriptions. Further, by 2013, over 250 pain clinics had been shut down and zero of the top 100 high prescribers of oxycodone reside in Florida.¹⁴⁴

Ohio

Ohio, for example, experienced a 366 percent increase in drug overdoses between 2000 and 2012, most of which were attributed to opioid analgesics.¹⁴⁵ In response, the state created the Governor's Cabinet Opiate Action Team (GCOAT) to create a set of prescribing guidelines to supplement prescribers' clinical judgment. The guidelines were promulgated in October 2013.¹⁴⁶

The guidelines are intended for prescribers who are caring for patients with chronic, non-terminal pain. Chronic pain is defined in the document persistent pain that lasts longer than three continuous months and continues even after "reasonable" medical efforts have been made to relieve it.

According to the guidelines, providers should avoid long-term opioid therapy as the first step when treating chronic pain. Alternatives to opioid analgesics that may be considered ahead of opioids include non-pharmacologic and non-opioid therapies. When evaluating a patient as a candidate for opioid therapy, providers should consider the risks associated with the patient and

¹⁴⁴ Johnson, Hal, et al, "Decline in Drug Overdose Deaths After State Policy Changes- Florida," *Morbidity and Mortality Weekly Report*, CDC, (July 4, 2012), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm>, pp. 569-574.

¹⁴⁵ "Healthy Ohio," Ohio Department of Health, <http://www.healthy.ohio.gov/en/vipp/drug/dpoison.aspx>.

¹⁴⁶ "Ohio's Opioid Prescribing Guidelines," Opiate Action Team, Ohio, http://www.opioidprescribing.ohio.gov/OOAT_RX_Guidelines.html.

his environment, particularly with regard to the possibility of nontherapeutic use and the possibility that the drugs may be distributed illicitly to other persons. Further, providers should not prescribe benzodiazepines along with opioids.

At initial and subsequent evaluations, providers should establish (or reestablish) informed consent, review the patient's functional status and documentation. Providers should regularly review the therapy's progress toward established treatment objections. An important evaluation tool is the "4 A's of chronic pain treatment," which include monitoring of the patient's:

- Activities of daily living;
- Adverse effects;
- Analgesia; and
- Aberrant behavior.

The GCOAT determined that an 80mg morphine equivalency dose (MED) is a "trigger threshold," meaning that an opioid analgesic prescribed at an 80 mg MED or higher carries a risk of overdose. When patients are near or at the 80mg MED threshold, providers should re-evaluate opioid therapy and consider the adverse effects of long term use of opioid analgesics. If a patient has received opioids equal or greater than the 80mg for more than three months, it is recommended that the provider decrease the risks of adverse outcomes by exploring other treatment options, scheduling the patient for more frequent office visits, increasing drug screenings, and ensuring that the patient is using one pharmacy and one provider. If a patient is not complying with the treatment agreement, the guidelines suggest that consequences include directing the patient to be evaluated by other providers who specialize in the treatment of the pain source.

Tennessee

In June 2013 the Tennessee Medical Authority (TMA) submitted a set of guidelines to the Tennessee Department of Health. In the fall of 2013, the state enacted several bills related to the guidelines, and in summer 2014 the guidelines were included in a comprehensive strategic plan to address the drug overdose epidemic in Tennessee.¹⁴⁷

The guidelines' intent is to assist prescribers on appropriate prescribing patterns for individuals needing opioid pain relievers, including management of acute pain, having a long-term plan, understanding opioid's morphine equivalent, and what is the best and maximum use.¹⁴⁸ It is

¹⁴⁷ William Swiggart, M.S.,L.P.C./MHSP, Charlene M. Dewey, M.D., M.Ed., FACP, and Alex Scarbrough, J.D., "Tennessee's New Prescribing Laws and Old Habits: Effectively Caring for Patients Using Controlled Substances," Vanderbilt University Medical Center, (January 2, 2014), <https://www.mc.vanderbilt.edu>. The 2012 Prescription Safety Act (T.C.A. §53-10-300). The 2011-12 pain clinic regulations (T.C.A. § 63-1-300). Beginning in April 2013, Tennessee law required health care professionals to check the Controlled Substance Monitoring Database (CSMD) before prescribing a controlled substance to a patient in a majority of cases and as a routine for those on chronic CPD management. Effective April 1, 2013, all practitioners in Tennessee were required to use tamper-resistant paper for all prescriptions written or printed (T.C.A. § 53-10-400). Effective July 1, 2013, physicians supervising physician assistants must follow additional specific guidelines for prescribing Schedule II substances (T.C.A. § 63-19-107). Effective July 1, 2013, dispensing of controlled substances by pain management clinics is prohibited (T.C.A. § 63-1-313). Pharmacists are required to use their professional judgment to make every reasonable effort to prevent abuse of drugs he or she dispenses (T.C.A. § 53-10-112).

¹⁴⁸ "Statewide Strategies to Prevent and Treat the Prescription Drug Abuse Epidemic in Tennessee," (2014): 5-62. Tn.gov. Tennessee Department of Mental Health and Substance Abuse Services.

expected that an added benefit is that the guidelines will improve the dialogue between the medical community and law enforcement.

Revisions and improvements to the guidelines are envisioned to include smartphone applications technological enhancements that may provide prescribers automatic updates on MEDs. GCOATS plans to work to develop additional specific guidelines for acute care facilities prescribing opioid analgesics.

Utah

The Utah Department of Health promulgated guidelines several years before Ohio and Tennessee, when it approved the release of a document in November 2008. Utah House Bill 137 of 2007 appropriated funding to the department and directed that it develop guidelines for the proper prescribing of opioids.¹⁴⁹ Similar to the other states' guidelines, Utah's place a priority on consideration of alternatives to opioid therapy. The guidelines direct that alternates to opioid treatment should be tried, or previous failures documented before initiating opioid treatment for chronic pain, and conclude that long-acting opioids should not be used to treat acute pain. To help ensure patient safety, providers should screen for risk of abuse or addiction before initiating opioid treatment. Patient education is a priority of the guidelines, which direct that the patient should be informed of the risks and benefits of opioid treatment.

In addressing the use of methadone, it is recommended that the medication should only be prescribed by clinicians who are familiar with its risks and appropriate uses, and who are prepared to conduct necessary careful monitoring of patients.

The department also created a program to decrease deaths and other harm from prescription medications that aimed to educate the public, providers, and patients on prescription safety. A media campaign, titled "Use Only as Directed," was launched in coordination with the guidelines. Campaign contacts with the public included television, radio, posters, brochure for patients, and bookmarks.

The campaign lasted from May 2008-May 2009, and targeted adults between the ages of 25-54. The campaign presented key messages to the public:

- Never take prescription pain medication that is not prescribed to you;
- Never adjust your own doses;
- Never mix with alcohol;
- Taking opioid analgesics with other depressants such as sleep aids or anti-anxiety medications can be dangerous;
- Always keep your medications locked in a safe place; and
- Always dispose of any unused or expired medications.

The results were positive. In 2008 Utah recorded a 14 percent reduction in unintentional opioid-related drug overdose deaths.

¹⁴⁹ Erin M. Johnson, MPH, et al, "State-Level Strategies for Reducing Prescription Drug Overdose Deaths: Utah's Prescription Safety Program," *Pain Medicine*, (June 2, 2011), doi: 10.1111/j.1526-4637.2011.01126.x.

DRUG TESTING OF HIGH SCHOOL STUDENTS

*“You're living the life of a drug addict...It was a full-time job.
I would pray every day: God give me the strength to quit.”
-Former high school athlete*

Members of the HR659 Task Force expressed concerns about the risk that opioid analgesics present to children and teenagers. Of particular concern are high school students who engage in sports and as a result are therefore somewhat more likely than their peers to suffer physical injuries. Common wisdom had long held that young people who participate in sports were less likely than their peers to engage in illicit activities such as drug use. While it is incontrovertible that sports participation has been associated with positive health behaviors, unrealistic expectations associated with sports participation have been shown to lead to deficits in self-esteem and classroom performance, while raising conflicts over gender ideals.¹⁵⁰ Research has shown that high school athletes are, in fact, more likely than their peers to involve themselves in substance abuse. Ironically, sports participation builds self-esteem, but self-induced and outside pressures to succeed at sports and pressure to conform with tight knit peer groups may lead teenagers, particularly females, to self-medicate with illicit substances.

Researchers have identified several core factors that provide both risks for substance abuse behaviors and protection from substance abuse behaviors among high school athletes. Recognizing that these factors are experienced by both athletes and non-athletes alike, the study's authors believe that athletes are likely to experience them with more intensity:

Identity formation

Athletic ability correlates with peer acceptance and peer admiration. However, the emphasis on athletic skills can come at the expense of developing other vocational and social skills. In turn, the “over identification” with athletics can lead to social isolation, particularly from non-athletic peers: “This strong emphasis on the athlete role may lead to maladaptive thinking and behavior.”¹⁵¹

Athletic injury

A career-ending injury that erodes a high schooler’s identity and that further may end hopes of earning college scholarships can lead to “severe adjustment problems and depression,” as the teenager is forced to transition out of his or her sports and school based culture.¹⁵²

¹⁵⁰ Bryan E. Denham, “High School Sports Participation and Substance Use: Differences by Sport, Race, and Gender,” *Journal of Child & Adolescent Substance Abuse*, 23:3, (2014), doi: 10.1080/1067828X.2012.750974, pp. 145-154.

¹⁵¹ Robert J. Pandina, Valerie L. Johnson, Leah M. Lagos, and Helene R. White, “Substance Use Among High School Athletes: Implications for Prevention Interventions,” *School Sport Psychology: Perspectives, Programs, and Procedures*, Center of Alcohol Studies. Rutgers University, (2005), doi: 10.1300/J008v21n02_07.

¹⁵² Ibid.

Coping with performance stress

Having one's self-esteem built on a foundation of athletic performance carries with it difficult stresses from coaches, peers, parents, and the community. Combined with self-imposed demands, these stressors can lead to weakened self-esteem and increased risk of substance abuse.¹⁵³

The magazine *District Administration* noted in its September 2014 issue, "Football players were the worst offenders, using alcohol, marijuana and prescription drugs more frequently than other athletes did."¹⁵⁴ A paper published in the *Journal of Child & Adolescent Substance Abuse* hypothesized:

[t]his may be because football is an aggressive team sport and players may use substances due to bravado and peer pressure. Because football is a contact sport, players might use Vicodin to continue playing after an injury.¹⁵⁵

With respect to illicit use of opioid analgesics generally, study author Bryan Denham further stated:

Regarding prescription analgesics, male and female athletes tend to sustain injuries such as ankle sprains, ruptured anterior cruciate ligaments, shoulder separations, and torn rotator cuffs, each of which may necessitate the use of pain relievers and, in some instances, require surgery. Adolescents may receive prescriptions for analgesics following injuries and/or surgery, and they may or may not use the medicines prescribed. In some cases, they may retain substances such as Vicodin and Percocet for recreational use. These substances tend to create a sense of well-being, and to the extent that athletes share analgesics with one another, they risk becoming dependent on the drugs not only for athletic injuries but for euphoric effects.¹⁵⁶

Analyses of the data show that female adolescents with low self-esteem, regardless of sports participation, are at risk of both marijuana and prescription drug abuse.¹⁵⁷

At present, the governing body of scholastic sports in Pennsylvania, the Pennsylvania Interscholastic Athletic Association (PIAA) does not directly address illicit use or abuse of opioid medications by high school athletes. Further, neither the Pennsylvania Athletic Trainers' Society nor the National Association of High School Athletic Trainers have policy statements regarding the illicit use or abuse of prescription medications.

¹⁵³ Ibid.

¹⁵⁴ Alison DeNisco, "Prescription Painkiller Use Up Among High School Athletes," *District Administration*, (September 2014), <http://www.districtadministration.com/article/prescription-painkiller-use-among-high-school-athletes>.

¹⁵⁵ Ibid.

¹⁵⁶ Bryan E. Denham, "High School Sports Participation and Substance Use: Differences by Sport, Race, and Gender," *Journal of Child & Adolescent Substance Abuse*, 23:3. (2014), doi: 10.1080/1067828X.2012.750974, pp. 145-154.

¹⁵⁷ Ibid.

The often tragic consequences of teenagers' abuse of controlled substances has prompted schools districts' efforts to prevent and intervene wherever possible. Drug testing of youngsters, despite the urge to do something to help, has been controversial from the outset and frequently met with legal challenges. The U.S. Supreme Court ruled in 1995 and in 2002 that school drug testing could be permissible under the U.S. Constitution. Consequently, the constitutionality of public school drug testing policies has been argued in both state and federal courts. Some Pennsylvania school districts, in establishing drug testing policies, found favor with the courts, while others' policies have not met the courts' tests of constitutionality.

There are several salient court decisions that address drug testing policies. Two decisions by the U.S. Supreme Court upheld school district drug testing policies. In *Vernonia School District 47J v. Acton*, 515 U.S. 646 (1995), the held that suspicionless drug testing of student-athletes was constitutional under the Fourth Amendment. In *Board of Education of Independent School District No. 92 of Pottawatomie County v. Earls*, 536 U.S. 822 (2002), the Court upheld as constitutional a school district policy requiring urinalysis drug testing of students involved in any type of extracurricular activity on the grounds that such testing furthered the school district's significant interest in preventing and deterring drug use.¹⁵⁸

Courts' rulings regarding school district policies in Pennsylvania have been varied. In *Theodore v. Delaware Valley School District*, 836 A.2d 75 (Pa. 2003), the Pennsylvania Supreme Court invalidated the district's policy, stating that a randomized drug testing program will "pass [Pennsylvania] constitutional scrutiny only if the District makes some actual showing of the specific need for the policy and an explanation of its basis for believing that the policy would address that need."¹⁵⁹ The court found that the district had not demonstrated this need.

Following the Theodore decision, the attempts of several school districts to enact randomized drug-testing policies were also invalidated by Pennsylvania trial courts. In *M.T. v. Panther Valley School District* (Court of Common Pleas of Carbon County, May 5, 2011), the court concluded that the school district did not demonstrate any identifiable need to test the students targeted by the policy.¹⁶⁰ In particular,

[t]he court critically observed that the school district did not adduce evidence or specific historical data to show that students participating in extra-curricular activities or athletics were more likely to use drugs than the general student population or to show that the policy would provide an effective deterrent of student drug usage.¹⁶¹

Conversely, the Loyalsock Township School District adopted a policy in 2011 that allows the random and suspicionless testing of students as a condition to participate in extra-curricular activities or to receive a school parking permit.¹⁶² The Loyalsock policy was contested in court in 2013, and the Lycoming County Court of Common Pleas found the district's policy to have satisfied the requirements set forth in the Pennsylvania constitution.¹⁶³ The district, in developing

¹⁵⁸ "Education Law Report," Tucker Arensberg Attorneys, vol. XXIV, no. 3, (2013), <http://www.tuckerlaw.com>.

¹⁵⁹ Ibid.

¹⁶⁰ Ibid.

¹⁶¹ Ibid.

¹⁶² Ibid.

¹⁶³ Ibid.

the policy, had documented drug and alcohol incidents involving students and had conducted surveys of the student population over time that showed drug and alcohol abuse was a continuing problem. A year-long study that included meetings of students, parents, administrators, and school board members led to the development of the district's drug testing policy.¹⁶⁴

The Loyalsock test includes, but is not limited to, the following drugs:

- Alcohol
- Amphetamines/Methamphetamines, MDMA (ecstasy), MDA
- Barbiturates
- Benzodiazepines
- Cannabinoids (Marijuana)
- Cocaine
- Opiates
- Phencyclidine (PCP)
- Methadone
- Propoxyphene

A drug test is regarded as having a positive result if the urinalysis indicates the presence of drugs, if the urinalysis is altered, or if a student refuses to be tested. There are three ranks of offense. Consequences of a first offense are a thirty day suspension from participating in extra-curricular activities, required participation in the district's student assistance program, a meeting with parents and the principal, and a negative retest. Penalties for a second positive test include those levied for a first offense and are extended to include suspension from attending before or after-school events, and revocation of privileges of driving to or from school for 180 days. Conditions for having all privileges restored include random drug testing over the ensuing 180 days, and enrollment in a rehabilitation program, in addition to those set for a first offense. A third positive test result will incur the aforementioned penalties, along with a permanent suspension of driving privileges, permanent suspension from extra-curricular and before and after-school events. Students with a third positive are "strongly" encouraged to enroll in a rehabilitation program.¹⁶⁵

The Loyalsock policy specifies actions that are deterrent, and failing that retributive, but are also restorative and rehabilitative. Students are aware that drug and alcohol infractions will cost them dearly and separate them from significantly beneficial aspects of their young lives: extra-curricular and parking privileges. Those students that violate the policy and suffer the consequences of positive drug tests are a clear example to their peers of what can happen.

More important, however, are the restorative and rehabilitative aspects of the policy. The policy provides means and mechanisms by which students can re-enter the high school's community. In a sense, their good standing may be restored provided that they comply with and hold to their responsibility to re-enter. The rehabilitative aspect is probably the most beneficial and important part of the policy.

¹⁶⁴ Ibid.

¹⁶⁵ Loyalsock School District, Policy 227.1, "Random Drug Testing," (2011), <http://www.ltsd.k12.pa.us/Page/797/>.

Students who test positive are either “strongly” urged or required (language is inconsistent in the policy itself) to enroll in a rehabilitation program. Professional drug and alcohol interventions at a young age may be necessary and yet without enforced prompting the young person and his or her family may not seek help.

In a study of substance abuse by high school athletes, the authors concluded,

[W]e believe that drug testing, as a stand-alone intervention, is unlikely to provide a satisfactory prevention experience for either coaches or student athletes. We believe that drug testing, when employed, should be included as one element of a more comprehensive program that employs one or more of the many strategies we discuss. . .¹⁶⁶

Other research has led to similar conclusions. While not specifically addressing opioids, researchers stated about random drug testing:

Results to date have been at best equivocal with assessments both providing modest support for efficacy and indicating no effects. . . [A] policy of random drug testing surveillance significantly reduced self-reports of recent performance enhancing substances and, to a lesser extent, common drugs of abuse but did not produce long-term changes in substance use and associated high-risk behaviors use among adolescent athletes. . . [W]e believe that drug testing, as a stand-alone intervention, is unlikely to provide a satisfactory prevention experience for either coaches or student athletes.¹⁶⁷

The recommendations shared by researchers is that programs that are intended to reduce and eliminate substance abuse among teenagers, particularly athletes, must be comprehensive. The efforts must reach beyond isolated drug testing and include the involvement of coaches, teachers, and the students themselves. Such programs should include education about drug use and consequences, training in how to resist pressure for illicit use, development of realistic understanding about social norms and behaviors outside of the immediate peer group, and mentoring to help develop strong self-esteem that is not reliant on athletic performance and peer acceptance.

The American Academy of Pediatrics’ Committee on Psychosocial Aspects of Child and Family Health and the American Pain Society’s Task Force on Pain in Infants, Children, and Adolescents issued a joint paper, “The Assessment and Management of Acute Pain in Infants, Children, and Adolescents,” in the September 2001 issue of the journal *Pediatrics*.¹⁶⁸ The organizations recognized that opioid analgesics are useful for the management of moderate to severe pain in pediatric patients:

¹⁶⁶ Supra note 153.

¹⁶⁷ Supra note 153.

¹⁶⁸ Committee on Psychosocial Aspects of Child and Family Health, American Academy of Pediatrics and Task Force on Pain in Infants, Children, and Adolescents, American Pain Society, “The Assessment and Management of Acute Pain in Infants, Children, and Adolescents,” *Pediatrics*, vol. 108, no. 3, (September 2001), <http://pediatrics.aappublications.org>, p. 795.

Prolonged pain may require use of opioids for an extended duration. Dosages should be adjusted to compensate for the development of physical tolerance, and weaning strategies should be used to minimize or obviate withdrawal symptoms.

The American Academy of Pediatric Dentistry (AAPD) promulgated in 2012 a policy on pediatric pain management that includes considerations for the use of opioids.¹⁶⁹ The AAPD recognized that “practitioners can be hesitant to prescribe opioid analgesics for pediatric patients for fear of addiction,” but added, “Because opioid use for dental pain should be of short duration, physical dependence is unlikely and its use should be considered.”¹⁷⁰

The AAPD recommends that dental practitioners recognize opioids’ risks of potential side effects, such as respiratory depression and that some patients may prove to be “ultra-fast” metabolizers of the opioid codeine, which is a potentially serious condition.¹⁷¹

The AAPD policy encourages health care professionals to:

- Recognize and assess pain, documenting it in the patient’s chart.
- Use non-pharmacologic and pharmacologic strategies to reduce pain experience pre-operatively.
- Be familiar with the patient’s medical history to avoid prescribing a drug that would be otherwise contraindicated.
- Comprehend the consequences, morbidities, and toxicities associated with the use of specific therapeutics.
- Consider non-opioid analgesics as first line agents for post-operative pain management.
- Utilize drug formularies in order to accurately prescribe medications for the management of postoperative pain.
- Consider combining NSAIDs with acetaminophen to provide a greater analgesic effect than the single agent alone.
- Combine opioid analgesics with NSAIDs for post-operative treatment of moderate to severe pain in children and adolescents.¹⁷²

Medical professionals and prescribers must be aware of any special considerations surrounding pediatric care involving opioids. Public officials, whether working in law enforcement or education, need to maintain a focus on rehabilitation and restoration when young people are found to have fallen into illicit use, abuse, and addiction. Opioids must be kept secure in people’s houses, and opioids must be properly disposed in all situations but it is particularly important that these guidelines be followed when children and teenagers are present in the house. Efforts to curtail substance abuse by children and teenagers are vital to meeting the responsibility shared by the community as a whole.

¹⁶⁹ Council on Clinical Affairs. American Academy of Pediatric Dentistry, “Policy on Pediatric Pain Management.” *Reference Manual*, vol. 36, no. 6, <http://www.aapd.org>, p. 78.

¹⁷⁰ Ibid., at 79.

¹⁷¹ Ibid.

¹⁷² Ibid.

RECOMMENDATIONS

The HR659 Advisory Committee recommended a list of critical actions that will require the support and commitment of a number of people if the fight against opioid addiction and overdose is to be successful. Some recommendations require action by the General Assembly. Other recommendations require that action be taken by healthcare providers, doctors, pharmacists, and insurers. Still others require actions be taken by mothers, fathers, families, and friends. In full, just as the opioid addiction and overdose epidemic lays like a pall stretched across all walks of life, these recommendations require action from all walks of life to lift and throw aside that pall.

Recommended Opioid Prescribing Guidelines for Pennsylvania

Of the many challenges pressing healthcare systems over the past two decades, few have been more important than the challenge to reduce medical errors and iatrogenic effects.¹⁷³ Strong data show that standard processes, in reducing variability of care, can and do reduce errors and improve patient outcomes. High quality healthcare, however, is necessarily stitched together by practitioners' judgment when treating individual patients' needs. The Advisory Committee recognizes this tension between guidelines and judgment.

DDAP Secretary Gary Tennis asked the HR659 Advisory Committee to endorse the guidelines set forth by DDAP's Safe and Effective Prescribing Practices and Pain Management Task Force. Advisory Committee members agreed that the guidelines capture most of the important points, although there were a few areas where the HR659 Advisory Committee felt that the DDAP Task Force Guidelines could be improved. The Advisory Committee, however, was hesitant to produce a set of guidelines that may compete with DDAP's and lead to confusion. Therefore, the Advisory Committee agreed to accept the DDAP Guidelines as written, and make recommendations for future revisions.

The Advisory Committee was concerned that scientific findings may develop more rapidly than can be addressed by legislative and regulatory actions, and recommends that guidelines such as these, where quick implementation may be life-saving, remain within the purview of the medical community. Further, because of ongoing scientific and medical advances, some members recommend that the guidelines be reviewed after the first year of implementation. Although most clinical practice guidelines are reviewed every three years, it may be advantageous to evaluate these guidelines in the near term on an every-other-year schedule. Other members of the Advisory Committee expressed concern that reviews should be spaced further apart; frequent changes may frustrate practitioners and discourage them from using the guidelines.

¹⁷³ Iatrogenic effects are those induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedures. <https://www.merriam-webster.com>.

The Advisory Committee discussed the effects of both mandated and non-mandated guidelines. Though Ohio has seen a positive impact with voluntary guidelines, New York's guidelines are mandated and have also had a significant impact. The Advisory Committee recommended that the medical and treatment communities maintain the lead in developing and promulgating guidelines.

In an overview assessment of the DDAP guidelines, the Advisory Committee suggested several modifications that could enhance the guidelines' applicability and effectiveness. Current guidelines draw a distinction between cancer and non-cancer pain. The Advisory Committee discussed the extents to which the distinction affects patients and influences prescribers. Some members counseled that future revisions should consider removing this distinction, because many of the same cautions, such as effectiveness of the therapy, pain management, appropriate use, and secure storage and disposal apply to both cancer and non-cancer patients. Other members stated that the distinction is justified because cancer patients' pain management needs may not be sufficiently addressed by the DDAP guidelines. Particularly in the case of end of life pain, the demands of palliative care might reasonably trump guidelines intended for the overall population of patients who require opioid analgesics.

Among Advisory Committee members there is concern that the word "chronic" is generally associated with negative connotations when coupled with opioid use; they would prefer to substitute "long-term" in place of chronic. Members recommended changing the guidelines' reference from cognitive behavioral therapy (CBT), to a more inclusive term, such as "psychological therapy" or "psychotherapy."

Key Considerations

Comorbidity. The present guidelines address screening for sleep apnea as a comorbid risk factor for bad outcomes, while seeming not to include other comorbid risks. Revised guidelines should include screening for all known comorbid risk factors.

Dosage. Guidelines should direct healthcare providers to resources on how to select and manage non-opioid treatments before opioid therapy is prescribed. In agreement with multiple existing guidelines on the treatment of chronic pain conditions and on the use of opioid medications for chronic pain, healthcare providers should reserve opioid medications for those patients with chronic pain who cannot obtain adequate pain relief with appropriate non-opioid first line treatments that are available for the management of chronic pain, or if such non-opioid treatments are contraindicated.

Information. The Advisory Committee recognized the importance of keeping the guidelines brief and actionable to encourage providers to read and use them. At the same time, however, it is important that the guidelines reflect the large scope of opioid analgesic recommendations, and address a wide array of issues. To balance these two needs, the Advisory Committee recommended that online resources be provided for information and support for the guidelines.

Secure Storage. The Advisory Committee discussed secure storage education for patients, and secure storage protocols and procedures for prescribers, patients, and dispensers. Members recognize the importance of keeping patients well-informed about secure storage but differed in

where the responsibility for patient education lay. Some members pressed for prescribers to take the lead on such matters as providing patients with information on secure storage and where they can obtain storage devices. Others felt that the dispensers are in a better position to inform patients about secure storage. Overall, members recommended the development of a robust Internet site that provides such information for both prescribers and the public, although some cautioned that adding the information to the guidelines themselves would unnecessarily lengthen them.

Provider Education. An ongoing problem with opioid medications, and which includes both legitimate therapies and illicit use, is that prescribers are generally under-educated on topics related to the particulars of opioids as a class of medication and in the areas of addiction and addiction treatment.¹⁷⁴ The Advisory Committee recommends that guidelines exhort prescribers to study and maintain current knowledge of opioids, therapies, addiction, and addiction treatment.

Before, During, and After Opioid Therapy

The Advisory Committee made several recommendations that address how guidelines ought to direct providers with regard to several situations, and how healthcare providers ought to work when managing opioid therapies.

Different Disciplines. Importantly, the Advisory Committee discussed how there are many opioid medication prescribers who are not medical doctors and whose disciplines are not addressed by the present DDAP guidelines. For example, some members feel that dental protocols for prescribing opioid analgesics are too liberal in the amounts and duration prescribed. Similarly, other acute care specialties may have specific protocols that are not addressed in the DDAP guidelines. DDAP has begun work to include medical specialty and dental care as it develops prescribing guidelines for other disciplines.

Evaluation. Providers must conduct a thorough evaluation of each patient's case, and ensure that each patient has had an adequate trial of non-opioid treatment prior to starting opioid therapy. Providers must remain cognizant of how patients are progressing toward therapeutic goals and how they are tolerating the medications after they are prescribed opioid analgesics. The Advisory Committee recommends that the guidelines direct that opioid therapy be managed through the use of the most effective and appropriate drug screens, including urine screens. Future revisions should be based, in part, on research into different methods of monitoring long-term opioid therapy. In conjunction, there must be a strong emphasis that providers are taught how to address suspicious behavior.

Research. Opioid prescribers must maintain up to date knowledge of the elements of the appropriate management of chronic pain, including the understanding of chronic pain mechanisms and pathophysiology, available non-opioid treatments recommended by guidelines as the first line treatments for different types of pain, as well as availability of alternative opioid formulations such as abuse deterrent formulations (ADFs), which can help provide both patients and society at large with some degree of protection from the most serious health consequences of opioid misuse – death and overdose.

¹⁷⁴ *Methadone Use and Abuse: Reducing the Incidence of Methadone Overdoses and Deaths*, Joint State Government Commission, (Harrisburg, Penna.: June 2011), http://jsg.legis.state.pa.us/publications.cfm?JSPU_PUBLN_ID=202.

Tapering. Revised guidelines, the Advisory Committee recommends, must emphasize the importance of following proper protocols when opioid therapy is ending. Patients must be provided with information on drug take-back programs for safe disposal of unused opioids when therapy is discontinued.

General Recommendations

- 1. The Commonwealth must fully fund Pennsylvania's prescription drug monitoring program.¹⁷⁵**

Pennsylvania is a state with a strong presence of diversion crime because it accepts other states' prescriptions, while other states do not accept Pennsylvania prescriptions because the Commonwealth does not have an operational PDMP that is connected through the Interconnect. The Commonwealth has yet to identify a private vendor to provide the ABC-MAP infrastructure. Those familiar with the process say a stumbling block is the issue surrounding data standards and how Pennsylvania's data will integrate with other states' through the Interconnect.

- 2. Prescribers should comply with guidelines developed by the Department of Drug & Alcohol Programs and established by their professions.**

Thus far, DDAP and its task force established prescribing guidelines for general prescribing, hospital emergency department, and dental practice. The sets of guidelines were developed through numerous meetings that included experts from across disciplines

- 3. The Advisory Committee recommends that DDAP hyperlink guidelines webpages so viewers can find more information if they need it.**

- 4. The Advisory Committee recommends that medical education provide comprehensive training on addiction.**

It is critical that prescriber and dispenser education include adequate training in pain management, training to recognize and assess patients' risk factors, training to understand addiction treatment, and training on how to refer to treatment patients who suffer from addiction.

The Advisory Committee recommends that the primary training modalities be interdisciplinary, and include both prescribers and dispensers. Interdisciplinary training is commonly and effectively used for other topics in healthcare.

The Advisory Committee discussed different means of achieving these education goals. First, the General Assembly could consider adopting the Model Health Professionals Training Act drafted by the National Alliance for Model State Drug Laws (NAMSDL). The model act is part

¹⁷⁵ Act of October 27, 2014, P.L. 2911, No.191, known as "Achieving Better Care by Monitoring All Prescriptions," (ABC-MAP).

of *The President's Commission on Model State Drug Laws*, published in December 1993.¹⁷⁶ Under the model act, addiction curriculum is mandated to be included in accreditation and curriculum statutes for medical schools, nursing schools, paramedic schools, and other health professional training schools. Further, the act mandates CME credits in drug abuse and addiction for relicensure.

Second, the General Assembly could consider legislation drafted to require the Department of State to direct its relevant licensing boards to set regulations that would ensure that licensed and certificated prescribers and dispensers received appropriate addiction education as a condition of licensure. A deadline for promulgating the regulations should be included in the legislation. Licensees of the following boards can prescribe and in some cases dispense medications from the office:

- Medicine – Medical Doctors, Physician Assistants and Certified Nurse Midwives
- Osteopathic Medicine – Osteopathic Physicians and Physician Assistants
- Podiatry – Podiatrists
- Optometry – Optometrists (some choose to take on prescriptive authority, some do not)
- Nursing – CRNP's can prescribe (LPNs and RNs administer only)
- Dentistry – Dentists
- Pharmacy – No prescribing, only dispensing. Through collaborative agreements with physicians a pharmacist can manage levels of a medication previously prescribed by a physician (these medication management agreements should not involve scheduled/controlled substances).
- Veterinary – Veterinarians hold DEA controlled substance registrations and can prescribe and dispense medications meant for animals. The Department of State is aware of diversion of commonly abused prescription drugs, including opioids, to human drug users.¹⁷⁷

CRNP's, Certified Nurse Midwives and Optometrists who choose to have prescriptive authority are required by statute or regulation to take CME classes specific to pharmacology and prescribing practices. No other licensed prescribers have that specific requirement in their CME statutes or regulations at this time.

Third, the General Assembly could consider legislation to require that the Department of State and relevant state boards mandate addiction education, particularly in pain management and prescribing, be mandated as part of the requisite annual 30 hours of Continuing Medical Education (CME) credits that licensees are required to take. A deadline for promulgating the regulations should be included in the legislation.

¹⁷⁶ "Final Report: The President's Commission on Model State Drug Laws," National Association of Model State Drug Laws, (December 1993), <http://www.namsdl.org/final-report-the-presidents-commission-on-model-state-drug-laws.cfm>.

¹⁷⁷ Ray Michalowski, Senior Prosecutor in Charge, PA Department of State, Office of General Counsel email from to Commission staff, May 18, 2015.

The U.S. Department of Health and Human Services (HHS) recently released the National Action Plan for Adverse Drug Event Prevention (ADE Action Plan), which targets opioids as a significant contributor to ADEs. The new, interactive training, “Pathways to Safer Opioid Use,” teaches healthcare providers how to implement opioid-related recommendations from the ADE Action Plan, and patient-centered strategies to communicate the safe use of opioids in managing chronic pain. Continuing medical education (CME) is available to participants who complete the course.

The Department of State should consider accepting the HHS training modules as appropriate training for new licensure regulations that it may promulgate.

5. **The Advisory Committee recommends that DDAP select specific training modules that can be used online, particularly for risk, treatment, and referral, and that the department collaborate with the Department of State so that the selected modules will be accepted for CME credits.**
6. **The Advisory Committee recommends that the Pennsylvania Department of Human Services continue its efforts to develop a multi-agency approach to substance abuse disorder services through participation in the Centers for Medicare and Medicaid Services (CMS) Medicaid Innovation Accelerator Program (IAP).**

Medicaid’s IAP goals are to “accelerate new payment and service delivery reforms” and will provide technical assistance and other resources.¹⁷⁸

7. **The Advisory Committee recommends that larger health systems provide training in pain management, opioid prescribing, risk, treatment, and referrals.**
8. **The Advisory Committee supports passage of House Bill 854 of 2015, (P.N. 1554). This bill would require pharmacy technicians to register with the Pennsylvania Board of Pharmacy.**

Pennsylvania is one of 16 states that do not license or certify pharmacy technicians and have no oversight reporting for pharmacy technicians. Both Maryland and New Jersey require registration of pharmacy technicians working in their states. Currently, there is no information system in Pennsylvania that can alert pharmacies if a technician had gotten into trouble with prescription fraud or abuse. The Advisory Committee supports passage of HB 854, which establishes certification and oversight for pharmacy techs.

9. **The Advisory Committee supports passage of House Bill 75 of 2015 (P.N. 66), which would require nonresident (out-of-state) pharmacies to register biennially with the State Board of Pharmacy to be permitted to fill prescription orders for Pennsylvania residents.**

¹⁷⁸ Medicaid Innovation Accelerator Program (IAP), <http://www.medicaid.gov>.

Currently, nonresident pharmacies are not required to register to do business in the Commonwealth. This lack of oversight opens loopholes for prescription drug diversion.

- 10. The Advisory Committee recommends that the Pennsylvania Insurance Department vigorously enforce statutes that require parity of coverage for behavioral health services, which include addiction treatment and rehabilitation.¹⁷⁹**
- 11. Prescription “take-back” programs must be sustained and expanded to help reduce the sheer amount of excess prescription opioids in people’s homes.**
- 12. The Advisory Committee recommends that health insurance systems reevaluate “Pay for Performance” (P4P) algorithms.**

P4P systems that set prescribers’ pay through use of algorithms that include patient satisfaction as a metric may have unintended negative consequences for patient care. Members of the Advisory Committee caution that prescribers who responsibly refuse to prescribe opioid medications might receive complaints from dissatisfied patients, and therefore might suffer financial consequences for their diligence.

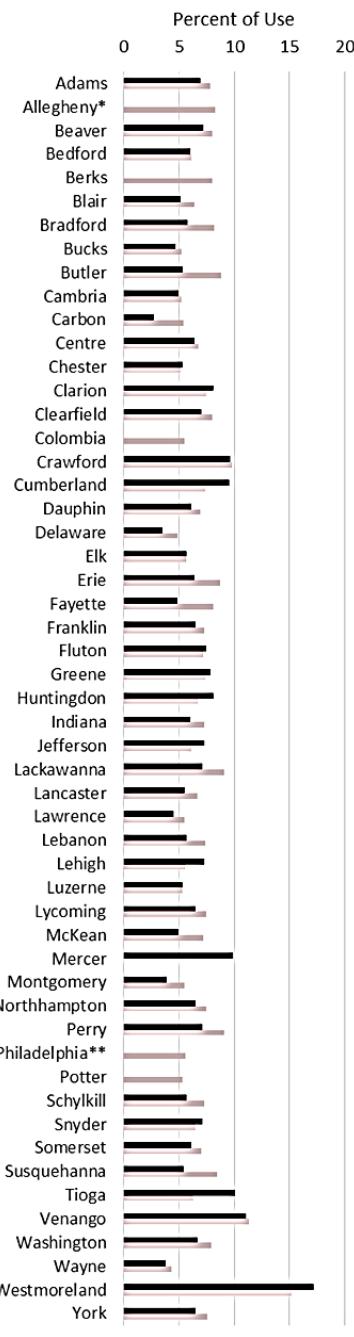
- 13. The Advisory Committee recommends that the General Assembly consider legislation that would support parity of health insurance coverage to encourage the use of alternatives to opioid medications. Three alternatives to include are non-pharmaceutical options, non-opioid products, and abuse deterrent formulations.**
- 14. The Advisory Committee recommends development of a clinical practice guideline that leads to consideration of abuse deterrent formulations as a discussion between prescriber and patient.**
- 15. The Advisory Committee recommends that DDAP provide guidance on how prescribers can refer patients to SCAs and local service providers.**

¹⁷⁹ Relevant statutes include Act of December 15, 1988, P.L. 1239, No. 152; Act of December 22, 1989, P.L. 755, No. 106; the federal Mental Health Parity and Addiction Equity Act of 2008, and the federal Affordable Care Act of 2010.

APPENDIX A

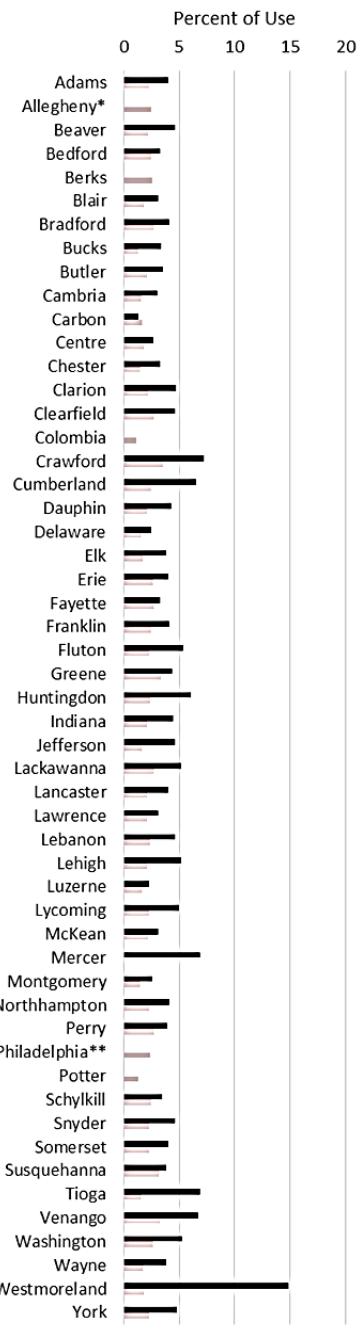
Students Using Non-Prescribed Narcotic Prescription Drugs, 2011 & 2013

**Non-Prescribed Narcotic
Prescription Drug Use:
Lifetime**



■ 2011 ■ 2013

**Non-Prescribed Narcotic
Prescription Drug Use:
Past 30-Days**



■ 2011 ■ 2013

* City of Pittsburgh School District did not participate.

** Charter and parochial schools only. Philadelphia School District did not participate.

Reports for the following eight (8) counties are not available to protect identification of individual students as these counties did not have two public school districts participate or have only one school district: Cameron, Clinton, Forest, Juniata, Mifflin, Monroe, Northumberland, and Warren.

APPENDIX B

In Their Own Words

HR659 directed the Commission to provide an opportunity for parents, siblings, and family members who have lost loved ones to the devastating consequences of prescription opioid abuse to share their stories. Commission staff contacted a number of families who had suffered such losses. Understandably, many were hesitant.

The experiences included here describe lives shattered by opioid addiction. Some stories were transcribed from testimony given at House committee hearings, some were written by members of the PPAC, and others were submitted especially for this report.

Jennifer

A mother of two, Jennifer suffered from scoliosis. Every two weeks she was prescribed 120 Vicodin and Percocet pills in an attempt to control her pain. It was not long before Jennifer became addicted, and she started down the harrowing path well worn by the too many who had gone before her. A red flag was finally raised when Jennifer changed the date on a prescription and was caught by the pharmacist. She received a letter from her physician informing her she was thereafter cut off from her medication and that she needed help.

Jennifer entered a Suboxone rehab program; however, she was dismissed from the program after missing an appointment due to work, despite the fact that working was one of the program requirements. After the dismissal Jennifer's addiction worsened. She visited various hospital emergency rooms to obtain prescriptions for pain medicine from numerous prescribers. With no monitoring program in place, Jennifer's doctor shopping habits went unnoticed. The addiction grew.

Jennifer went so far as to subject herself to surgeries to appease the addiction's relentless drive to obtain opioid prescriptions.

On August 17, 2010, Jennifer's addiction took her life with an overdose of Vicodin and Percocet. It was her 32nd birthday.

B.

Twenty year old B. was an active young man who loved sports and enjoyed outdoor activities. At a young age Brett developed a passion for wrestling. He would spend much of his free time exercising and training to be the very best he could be. His hard work paid off as he not only became a successful wrestler in high school, but went on to be a student athlete at Lycoming College, one of the many colleges he was accepted to.

B. not only excelled in the gym, but in the classroom as well. At Lycoming College Brett was pursuing a degree in criminal justice, another dream of his. He was even considering a double major as his interest in psychology grew.

As with most college students, B. was looking forward to spending his Easter break at home with family and friends. On Good Friday he went out with some friends where they shared drinks together, and, by all accounts, were having a good time.

The night took a dramatic turn when one of the people at the party offered B. a pill; he accepted, taking half. Though B. was told the pill was a Percocet, it was actually Opana, a time-release formulation that is more potent than morphine.

The next day, April 23, 2011, B. was found unresponsive in his bedroom. He was pronounced dead on the scene.

Mark Bauer

Eighteen year old Mark Bauer could be described as introverted, funny, and strong. He enjoyed lifting weights and playing basketball; he could often be found on his driveway basketball court playing a no-foul game with his dad. Although the games were very competitive, and sometimes resulted in injury, his father, Phil, described it as “their way of hugging.”

Though Mark had never exhibited signs of drug addiction, on a May morning in 2004, one week before his high school graduation, Mark’s mother found him unresponsive in his bedroom. Next to his lifeless body was a bag of loose pills containing multiple prescription opioids. A toxicology report later showed amounts of oxycodone, acetaminophen, morphine, and amphetamines. Not a single illegal drug was among them.

MY STORY by Fredrica H.

I stood on the steps watching my son trying to focus his eyes on me; fear is gripping my heart. As a nurse, I know that he is under the influence of something powerful, but my mother's heart screams, "No!" I have this sense of unreality—this can't be happening, what do I do, who do I call, who knows what to do? My husband was teaching computer classes at a state correctional facility a couple hours away, and I knew that he did not take his cell phone into the jail for obvious reasons. The protocol for going "behind the wire" requires that he leave virtually everything of value in his car. My friends are good Christian people whose children attend church and Sunday school; they certainly wouldn't know what to do.

I called the local hospital asking to be put through to the rehab floor. I don't give my name; the man on the other end doesn't ask. He kindly offers advice without questions: call the police, take him in to the ER to have him tested. I wrestle with the options, fear in my heart. What if I just let him sleep it off and try to talk to him later? What if I let him fall asleep and he dies under the influence of whatever substance he has taken? I cast out a desperate prayer, my heart strangled with my fears. After a moment, I have the cold calm I need to call the police. I am filled with a deep sense of shame as I answer questions: he was out all night bowling; he came home; he can't finish sentences; he can't focus or walk straight. An officer will be out.

There is something truly intimidating about a police officer. He stands in my hallway, dressed in black. He has a heavy leather belt with a tommy stick, a gun, handcuffs, and mace, tools of the trade for this man. He is holding a pad of paper and a pencil. He is kind and polite, and agrees that my son is definitely under the influence of something. He can't be charged with anything since there is no sign of criminal activity. He recommends that I take him to the ER. He leaves.

I look my son in his unfocused eyes and state that we are going to the ER. He snarls that he is going to bed. He staggers up the stairs and stumbles into bed. I stand in the hallway thinking about my choices. I was involved in a serious car accident in which I broke both legs. Although I am able to walk, I am uncertain of my balance, and too weak to take the chance to wrestle with my teenager and win. I opt for the coward's way out and decide to wait for my husband to get home.

This is the beginning of a journey on which I would not have set out. The valleys are deep and dark; there are moments when the light of day shines down and just barely touches the valley floor. Mostly the pathways are narrow and tricky, strewn with rocks. It is only as I went deeper into the valleys that I discovered that others were traveling through there, too. Each of us was walking a different path, getting lost in darker valleys and getting found in little patches of sunlight. This fellowship of the journey was my lifeline.

Unfortunately, I didn't find that fellowship of travelers for a long time. In fact, for a very long time my husband and I thought we were alone, and we were ashamed and filled with despair.

When our youngest son finished kindergarten, we had decided to home-school our children. We did this for several reasons: to teach our faith, to provide stability, to have the opportunity to spend time with our children, and to protect them from a family member who had been imprisoned for sexually abusing our oldest child but was now on work release not more than a couple miles from our house. After the shattering experience of the betrayal of sexual

abuse, we desperately needed to be with our children, to assure ourselves that they were safe, and that we were together. We had many years of close family times: field trips, bike trips, and camping trips. My husband taught the children to play roller hockey; they spent many hours playing together on the local tennis court together.

We did not realize that there would be long-reaching effects of the abuse that would not be evident for years. We took all three children to a therapist who told us that they were doing well. If we were just supportive of the children, everything should be fine. Looking back, however, I realize that the true damage of the abuse was the mindset of keeping secrets. The children were coached by their abuser to keep everything a secret: don't tell mom and dad. They continue to this day to keep things secret, from themselves and from us.

Our first efforts at research brought us information about rehab facilities we could not afford. The message was simple, if you had the money, you had options. Since my son was involved with the juvenile justice system, he had a probation officer, fines to pay, and community service to perform. In my ignorance of the disease of addiction, I thought that these consequences would be sufficient. In reality, it allowed him the time to get deeper into his addiction as he fulfilled his requirements.

It wasn't until we moved to another county, and police picked up him with my older son in a car getting high together at the end of our driveway that things started to change. His new probation officer started to drug test him on a regular basis. As he continued to fail his drug tests, while still fulfilling his new additional requirements of community service, his new probation officer referred him for a drug evaluation. It was determined that he needed outpatient rehab services, but our insurance did not cover it. He was adjudicated a delinquent, which apparently allowed coverage for rehab services.

Over the years, he has been detained in juvenile centers, sent to inpatient rehab, "302'd" twice, hospitalized, and sent home on house arrest. This last was the most laughable and useless consequence of all: my husband and I both worked, and his friends came to see him and got high on the porch. Over this chaotic time, we learned about support groups for parents and that families of addicts actually need to work on recovery as well. Recovery from emotional abuse, enabling, blaming, and the trauma of life with an addict. As we worked on becoming healthy ourselves, we learned to live this difficult life with two addicts in our family.

Over time, I have become convinced that no rehab program offers a "silver bullet." I believe that recovery is a long and complex process that usually includes relapses, but on the way, the addict can begin to learn things that help him to grow. Each period of addiction and recovery teaches the addict more life skills and abilities that allow him to live free from addiction. When will my two sons learn enough about addiction and recovery to be truly free? I don't know. We wait, and we pray. We believe that one day we will see our children healthy. Meanwhile, we work on getting healthy ourselves and helping others who walk this road.

OUR JOURNEY *by Joan and Bob W., Pittsburgh Area*

For the first 15 years of Rob's life we lived in a small town in rural PA. He was a good student, a dedicated athlete and consistently described by his teachers as quiet and polite. His father and I were both educators and for the most part, Rob attended classes in the school where

either his father or I worked. Rob has one sister, Robin, who is also an educator living in Dallas, Texas with her family.

In the winter of 1998 Rob's paternal grandparents, both near 80, began to suffer a series of serious health problems. Frequent trips to their home in the Pittsburgh area (4 hours away) were needed to assist with care-giving and doctors' appointments. I vividly remember the dinner conversation when Rob first began urging us to move back to Pittsburgh to be closer to his grandparents. We shared with him our reservations about uprooting him at this time in his life but he assured us that he would be "just fine." Over time we began to believe his assurances. I accepted a principal's position in the Pittsburgh area. Rob's father took a leave of absence, and eventually an early retirement from his teaching position. Late that summer we moved to Cranberry Township, Pa. While in treatment, Rob described this move as "the turning point" of his life.

At first things seemed to be going well. Rob was doing well in school. He had joined the wrestling team and had made some friends. After about a year things began to change. He began changing friends on a regular basis and his grades began to suffer. In hindsight I see that the warning signs were there but denial is its own drug. It numbs reality and suppresses the unthinkable, the unspeakable. In February of 2002 a warning came that could be neither minimized nor denied. Rob was caught with a substance at school that was eventually identified as heroin. We left the school and went directly to the closest treatment center. I remembered my friends who specialize in the field of drug and alcohol treatment telling me that a local rehabilitation program was the best around, so we went there. They tested Rob, took our insurance information and sent us home to wait for the results of their test and approval from our insurance carrier.

It took six weeks to get approval from our insurance company and set up an intake appointment. At the time, it felt like the longest six weeks of our life—but as it turned out—we were wrong—there were to be many, many longer days, weeks, and years. At our intake appointment we were told that the substance Rob was abusing was heroin. They were recommending intensive out-patient treatment. I was terrified by the thought of my child using heroin. As a former counselor, I knew how resistant to treatment heroin abuse could be. I specifically asked, "How can you effectively treat heroin addiction with out-patient treatment?" Their reply is still ringing in my ears, "We do it all of the time." Next, they reviewed our insurance coverage with us. Rob would have a LIFE TIME cap of 90 hours outpatient care and 30 days inpatient care. That evening, Rob began attending intensive out-patient therapy—and I began counting backwards from 90.

The drug charges were still pending at this time. Eventually, Rob was accepted into the Butler County ARD program which meant he had to meet with a probation officer once a month for 18 months. Initially, we saw this as a good thing. Perhaps the additional "supervision" as the court referred to it, would help Rob in his efforts to remain clean. Unfortunately, that did not prove to be the case. All that was required of Rob during his probation was to stop by his PO's office once a month, any Tuesday of the month, any time of the day, for a meeting and a drug test. Essentially, Rob was being drug tested (supervised) whenever he made an appointment to do so.

By mid-summer 2002 Rob had relapsed and was back in treatment, but this time he was really struggling to maintain sobriety. He asked to be voluntarily committed to the in-patient program. Facilitating this became a battle with the insurance company. Finally, we were able to

get an Administrative Override to the insurance company's initial denial and Rob was approved for a five-day voluntary inpatient commitment. This was eventually extended two more days. Rob spent a total of seven days at the inpatient facility.

After his brief hospitalization, Rob returned home with a new determination to remain clean. Rob continued with outpatient treatment until he was discharged for a second time. He joined the Army National Guard and planned to begin college after completing six months of basic and advanced military training. While he did struggle to maintain sobriety during this time, we naively hoped that if we could hold on until January when Rob was scheduled to leave for boot camp, he would once again be on the right track.

On the morning of Monday, December 23, two days before Christmas, Rob left for work as he always did. I vividly remember kissing him good bye. As it turned out, it would be the last time I would be able to touch him for ten months. A little later that morning, I received a call from his boss, Mark, who was checking to make sure Rob was coming to work that day for he had been ill the Friday before. I was surprised that he didn't know, because Rob should have already arrived at the job site in Franklinville by the time of Mark's call. Mark told me that he and the rest of the crew had stopped by another job site first and were just then on their way to Franklinville. A few hours later, the phone rang again. I listened as a police officer told me of Rob's arrest. Eighteen years of dreaming and planning for our child's future were about to turn into a nightmare.

We were to learn later that Rob had picked up a young man who he barely knew. The young man had been recently released from prison after serving time for robbery. He was apparently without a job and literally living off the kindness of others. Rob knew they were short-handed at the job site and had hopes of getting this young man a job. When the two boys arrived to find no one at the Franklinville site, they apparently left. They ended up at a strip mall in Cranberry. The young man Rob was with was charged with attempted to grab a woman's purse. There was a struggle. The woman fell and hit her head—in that second, an innocent woman was in critical condition, and a purse-snatching had turned into A-1 Robbery. Media frenzy followed, and this became one of the most widely covered cases that year.

Rob admitted from the very beginning that he knew of the purse-snatching plan. He maintains that in the end he couldn't do it and never touched the woman. His co-conspirator verified this. The victim, who thank God, has now recovered, has no memory of the event. The other witnesses present were unable to tell exactly what was happening when the woman fell. Rob was charged with three felonies—aggravated assault, robbery and conspiracy. Rob's attorney told him that under the law, if he was guilty of the conspiracy charge, he was guilty (culpable) of all of the crimes committed. Following his attorney's advice, Rob pleaded guilty, indicating at the time that he was pleading guilty of being culpable for the crimes, not guilty of actually committing the crimes. Our hope was that with Rob's zero prior record score and limited involvement in the crime we would find some mercy in the courts. We did not. In spite of witness testimony in support of Rob's good character, and a total of 25 letters sent to the judge from teachers, counselors, friends and family members the judge elected to run Rob's sentence for the three crimes consecutively instead of concurrently. This essentially doubled the time Rob would spend in prison. He is serving a term of 8 1/2 to 17 years. He has now been in prison for over five years. He has been moved 13 times and he has yet to receive a single hour of treatment. *They* may be able to successfully treat heroin addiction through outpatient treatment "all of the time" as I had been told by treatment personnel at Rob's intake interview—but not this time. The next seventeen years of our lives will be witness to that.

JEFF'S STORY *by Chuck K.*

I served as a Police Officer for 26 years and have been employed as an Erie County Sheriff for the past seven years. I have been married for 29 years, and my wife and I have one child, our son Jeff, age 24. Currently he is incarcerated and awaiting sentencing. Our story began long before we found out that Jeff was an addict. He has told us that he began using marijuana around age 12, and then at 15 he began experimenting with cocaine, oxycodone, ecstasy, and heroin.

In the fall of 2002, at age 18, Jeff, was living at home and attending Penn State Behrend in Erie. He was commuting and left each day for "classes" as scheduled. When my wife left work ill one morning and came home to find our son still in bed at the time he was supposed to be taking a final, we knew something was wrong, but he quickly explained everything away—Mom had the wrong day, he had already taken that test, he had enough points to be excused from the test, etc. We believed him because we wanted to believe him.

His report card came right before Christmas, and he had failed all of his classes due to not attending. We made him get a job at the local gas station, and he worked there from January through August 2003. There were many phone calls from his boss about Jeff being late for work or not showing up. He lost the job in August. Again, we knew something was wrong, but we still could not put our finger on the exact problem. So many of his behaviors mirrored typical teenage behaviors—distancing from his parents, wanting his own space in the basement, sleeping late, and staying up late.

When he lost his job August of 2003, my wife asked me to get a drug test kit and to take a urine sample. We told our son that we were going to do a test, but we didn't know when. He was addicted to oxycodone by then. He had tried to get off on his own and was unable to do so. He used every day until we did the test about four days later. He tested positive for opiates and other drugs. I shared the results with my wife after dinner that night, and we were stunned. We had no idea what to do next.

My wife was friends with the school district psychologist, who happens to live nearby, and we went to talk to him. He told us that Jeff needed to get into a rehab, and he explained how to do an intervention. He agreed to do the intervention so we scheduled it for the following evening. Jeff was given the option of rehab, or he would have to leave our home. He chose rehab.

He spent 10 days at a facility in Franklin, PA. At the time, Jeff had insurance through my wife's policy, at a cost of \$400 per month. We thought the stay was short, but what did we know. After his discharge, Jeff was assigned to an Intensive Out-Patient group in Erie, and we started going to the family group night every Wednesday. We were encouraged to go to Al-Anon as well, and we did. We started educating ourselves about this disease. Jeff agreed to go to AA or NA, get a job, and follow our rules. We bought him a car so he could get to work and meetings.

Jeff is in five years of recovery and he's working his program, is employed, in a relationship, has 2 children, and by the grace of God, he made it through it.

ERIN'S STORY *by Tom and Betty M.*

Erin was born on January 20, 1974, the first of our three children, and our only daughter.

She was the perfect little girl—blue eyes, lots of charm, very outgoing. She was the one that everybody loved. Elementary school was never a problem, but when Erin transitioned to the middle school; her behavior began to be more difficult. We started taking her to see a counselor who made a diagnosis of Oppositional Defiant Disorder. Looking back now, a more accurate diagnosis probably would have been that Erin was suffering from depression and anxiety.

We wish we could pinpoint when everything started to go downhill. In high school, Erin was a cheerleader, took dance classes, and made some new friends. It was obvious to us, however, that Erin did not want any kind of rules or boundaries, and she was exhibiting some risk-taking behavior that worried us all the time. By the end of junior year, Erin was dating an older boy, was drinking and smoking, and experimenting with marijuana. During her senior year, Erin was arrested for under-age drinking, and we placed her at a residential treatment facility.

Clear Brook Lodge was an excellent facility. We could see signs that Erin was beginning to understand why she was there and was making some progress...or so we thought. Erin was so good at manipulating and saying what she thought you wanted to hear. That's what she did at Clear Brook. She knew she would be turning 18 in January, and she also knew that Clear Brook couldn't make her stay there after that. On January 20, her birthday and a few days short of her thirty-day stay; Erin had her boyfriend pick her up. Since she was now 18, she signed herself out of the facility. This would become a pattern for Erin—entering a facility for help but never staying long enough to really be helped.

Erin stayed away from home for a few weeks but finally decided to come home and return to school. The remainder of senior year was manageable. Erin applied to several colleges and graduated in June, 1992, with plans to attend a nearby college. The rest of Erin's Story consists of recollections, and some information we read in her journals. We have to fill in the blanks sometimes because she didn't share much with us once she went away for college.

After her freshman year, which was spent being stoned on marijuana much of the time; she transferred to Temple University in Philadelphia to be close to her boyfriend. Erin was in and out of school, in and out of Marworth Treatment Facility, and in and out of our lives. We would not always know where she was. She liked it like that. When she was clean and sober, she did well in school. Just like that, she would be dropping out, and we always knew that her demons were at it again.

Erin came home for a while 1995 and worked at a temp agency. She was her old self and appeared to be happy. Then she was off to Pittsburgh to visit her brother who was going to college there. She met a new boyfriend in Pittsburgh, got an apartment, and stayed there for some time. We think she got very involved with cocaine and heroin while she was there, but again we're not sure. In 1997 she traveled from there, to New Orleans to work as a waitress during the Super Bowl and then on to Florida. Sometimes we would not hear from her for weeks at a time, and then there would be that call in the middle of the night: "Hi, Mom," as if nothing had happened.

In 2000, Erin began to receive methadone at a clinic in Philadelphia. For about a year she was back at Temple and doing well. We surmise that she used heroin while she was being treated at the methadone clinic, failed a urine test, and, consequently, had to leave the clinic. There are terrible gaps in the next two years of her life. We were told to use "Tough Love" and to let her hit "bottom." We received lots of advice but nothing worked. We don't think much of that advice now. Waiting until someone hit's "bottom" is probably the most reckless advice that anyone can give.

In February 2002, we went to see Erin to beg her to enter treatment. She was about 90 pounds, had been evicted from the apartment she shared with her boyfriend who had moved to Philadelphia with her from Pittsburgh, and obviously was in need of immediate help. She promised she would seek help. It was June, however, before we got another one of those, "Hi, Mom" calls asking for our help.

Erin entered the Caron Foundation outside Reading on June 5, 2002. We had researched and read great things about this facility, and felt it would be the one that would finally help Erin to get clean for good. We said goodbye on a Wednesday. We knew that we could not speak to her right away, but we felt that she was as safe as she had been for a very long time. On Sunday, June 9th, the phone rang. On the other end was Erin. We knew this could not be good because she was not allowed to call for at least a week. Erin again had signed herself out of a facility and taken a bus to Philadelphia. We spoke to her for a very long time. She knew she had to go back, and she promised she would take a bus back to the Caron Foundation on Monday.

How we wished that the next phone call would have been one of those "Hi Mom" calls, but instead it was the hysterical voice of Erin's boyfriend. He had left for work the morning of June 10 with Erin promising that she was taking the bus back to the Caron Foundation. When he returned home, he found Erin. We are surmising that she had to have that last "fix" before she got on the bus, and, in her weakened condition, she died from an overdose. We honestly feel that this was accidental and that Erin really did want to get help. There is no way to explain what it is like to have a child with the disease of addiction.

There is no pity from people who still feel it is a bad choice that was made and that it is the addict's fault. There is no comprehension that relapses is a real symptom of the disease, and that you must expect that many relapses may occur. People continue to picture the addict as the creepy looking guy on the corner instead of the blue-eyed cheerleader.

Erin was only 28 years-old when she died. She had abused drugs and alcohol for at least ten years. Because of this, she had not achieved anything that she had planned for her life. Trying to find help for Erin was the most frustrating and difficult task we, as parents, had ever faced. When Erin needed help and made up her mind to seek help, there was never a bed available, or she didn't have the financial resources necessary. We maxed out credit cards and worked extra jobs, but we would do it all again in a heartbeat. Erin was arrested several times, but rehab was never mandated for her, and there was no Drug Court available as there is now.

This was not the life Erin wanted to lead. We along with Erin's younger brothers and extended family still grieve for her life cut short because of the disease of addiction.

In her memory, we established the *Erin Jessica Moreken Drug & Alcohol Treatment Fund, Inc.*

Each year we have an event called the *Tour de Scranton*, which is a noncompetitive bike ride through our city and surrounding counties. The money raised is donated to help young people who have completed Drug Treatment Court, and who are trying to lead clean and sober lives. We have raised over \$50,000 thus far. We know Erin would be pleased that we are trying to help others conquer the disease of addiction, something that eluded her throughout her short lifetime. Erin loved to write and wanted to be a journalist. We just wish she could have written this story herself—but with a happier ending.

Anthony Fiore

Anthony was a true and loyal friend. After Anthony passed away, a few young men told me stories about how they were shy or kept to themselves, and Anthony reached out to them and became their friends. Anthony tried to fit in with the good kids, but was shunned on many occasions. So he began to change to a group that accepted him. They started smoking pot in 8th grade, and started taking Oxycontin in 12th grade. Anthony always wanted to have friends and he was very loyal to them. In 12th grade he started selling pot, and everyone loved Anthony. This is what he always wanted, to fit in, to be liked, to belong. He told me later that the kids who bought pot from him told him he was the nicest dealer they ever met.

I do believe Anthony had some issues, although throughout his life I took him to four psychologists and the only diagnosis he got was ODD, Oppositional Defiant Disorder.

Anthony was very intelligent, never had to study, and always had above a 3.5 GPA. He liked to make people laugh, and he joked around a lot. He got into Penn State Main Campus in State College, PA, based on his SAT scores and his GPA. In his sophomore year, he joined the fraternity Alpha Sigma Phi.

During the Christmas break of 2009, he told us he was addicted to Oxycontin. He said he could detox at home, and would just take more time before returning to Penn State. This was the first time we had heard any of this. He promised he wouldn't use anymore. Looking back at this, we were very naïve and did not understand the disease of addiction.

He returned to school in January, 2010, and began using again. When he came home at the end of the semester, we sent him to a relative's house for the summer, away from his addicted "friends." The whole time we kept in touch, he was passing urine tests, and everything seemed to be going well. Anthony wanted to go back and finish college at the main campus. Once again, we did not understand the disease of addiction, and let him go back in the fall of 2010. We found out in the beginning of 2011 he was using again and pulled him out on a medical leave. This time we sent him to a rehab in Florida named "Stepping Stones." It was a 28 day inpatient treatment.

When he returned, everything seemed fine. He had a friend pick him to go to NA meetings. He would show us a chip for being clean for a certain amount of time. We thought he was clean, therefore we let him return to Penn State in 2012.

At some point he switched to heroin because it was cheaper. The switch started at Alpha Sigma Phi at Penn State main campus. Anthony had periods of time where he actually was clean. During those times, he would tell us things he had lied about in the past. One thing he told us was that he had never been going to the NA meetings, he was just taking the chips and still using. In the beginning of 2012, two of his best friends, came to our house and told us he had

switched to heroin and was injecting it. Because of their courage, we had more time with Anthony. We went up and picked him up and left everything there. We just had to get him home.

We were then referred to an inpatient rehab facility named “Bowling Green” in PA. We didn’t have insurance, so they only kept him about 5 days, just long enough to detox. He was diagnosed with depression, but we were never informed of that. Once again, when he came home he said he wouldn’t use anymore. He stayed home that summer, worked, and seemed to be doing fine. In the fall he enrolled in the Abington campus, about 30 minutes from home, since we refused to let him go back to the main campus. He had totaled his car, so my husband drove him to school in the morning and he hitched a ride home with one of his classmates or, sometimes, took the bus.

What we didn’t know was that he had made a copy of his Dad’s car key and was sneaking out in the middle of the night to go to Kensington, also known as the “Badlands” to get heroin. At some point he and his “friends” added cocaine to the mix. He had been on Suboxone in the past, and while on it, he did not use. But he did not take it all the time. He overdosed May 23, 2013, in our basement, but one of the boys came and got me and I called 911. He was given Naloxone, which saved his life. In the ER the nurses tried to give him another naloxone shot, but he fought them and wouldn’t allow it because he wanted to enjoy what was left of his high. That’s how powerful of a hold heroin has on its victims. Less than an hour earlier Anthony had almost died but he still wanted the drug. Because his heroin usage had depressed his breathing so much and allowed fluid to collect in his lungs, Anthony developed pneumonia.

We then tried Vivitrol. This is a shot a doctor gives every 28 days. When he got his shot, it worked. He found a way around it, and didn’t take it every 28 days as prescribed. He would wait till about 32 days, get high, wait a couple more days, then get the shot. Then one day, he said he wasn’t going to get it anymore. We did the hardest thing we had ever done, and said he could no longer live with us if he wasn’t getting the Vivitrol. We were all crying. At some point he had gotten another car, which he packed up with clothes and left. He was out of the house for 9 days, living in his car and shooting heroin. Every day we worried. He finally agreed to get the shot. I said I would meet him at the doctor’s and only after getting the shot could he come home.

In the summer of 2013, Anthony and the other boys robbed a drug dealer, thinking that a drug dealer wouldn’t go to the police. Well, the boy’s mom did and a warrant was issued. Months later, Anthony was stopped in Kensington for possession of heroin, and when they found out about the warrant in Bucks County for the robbery, they sent him to Bucks County Prison. We refused to bail him out, despite his constant pleas, because we felt, at the time, prison was where he needed to be and at least he was clean.

After he had been in prison for a month, we hired a private criminal defense attorney who was able to arrange for Anthony to be released on his own recognizance on the condition that he immediately go to an inpatient rehab facility. Livengrin was recommended. By this time we had insurance, but once again, the program was only 21 days. I begged Livengrin to keep him, but they said that’s all insurance pays for. After the 21 days, they sent him to a sober living house. The person in charge was the recovering addict who had been there the longest. Anthony was told to go out for 8 hours a day and look for work. The first day he called me and told me he was passing corners where dealers were, and where he used to buy drugs. We went and picked him up and brought him home that night.

This time he said HE wanted to stay clean. All the other times we had made him go to rehab, but this time was different. HE wanted to be sober. He started cooking dinner for the family and hanging out with his younger brother Nick, which he never did before. They would

go to the movies, go to the gym, and various other things brothers would do. I said, "I finally have my Anthony back." We felt like he had won. He looked good, acted fine, and was not argumentative and agitated as he was when using. He got a job at Passanante's Food Service in Bensalem, PA, which he really enjoyed. He was doing well. He bought a pure bred boxer he named Caesar. He was saving to move out on his own. We told him none of the boys he had hung around with in the past could come over again and he should find new friends. This lasted about 4-5 months, and one day he said Phil is coming over. Anthony said he was the only person he knew who was clean. In fact, Phil was not clean and still using. Phil was with Anthony the entire night and morning when he died. Phil said he didn't have any idea what happened, but he did find time to steal Anthony's debit/credit card from his deceased body and proceed to spend \$2,500.

I found my son's body. What an awful thing for a mother to go through. We are broken. Anthony received four years' probation for the robbery. We think he wanted to get high "one more time" since he had received a letter from his probation officer who was coming to our house the following Thursday. He knew he would be urine tested.

There is no greater pain than for a parent to bury a child.

When my child died, I lost someone I would die for.

We love you always and forever Anthony,

Love, Mom, Dad, and Nick

MY ROUGH ROAD BACK TO NORMAL *by Karen V.*

The addict in my life is my 26 year-old son, a recovering intravenous heroin user. He has been in recovery for a little more than 5 years. The details are his history to tell, not mine.

It has taken many years, many hours in fellowship meetings, many therapy sessions, and much introspection to realize that I have my own story.

I have a graduate degree, am well-traveled, make a comfortable income, speak my mind, have good insurance, and am a single parent. I knew the details of Act 106; learned to overcome the shame and stigma and insist on decent treatment and help for my addict and for me. I say this only because I still was unable to get help for my son from the medical community, law enforcement agencies, legal system, or private and public addiction services.

By the age of 16, my son was out of control, had left school, been arrested, had broken windows and doors and punched holes in my walls. My son was court-mandated to see a psychologist more than 20 miles from our home. After a few months of these visits, I was told I needed to get my son away somewhere. Not where, how or why; just away. The therapist would no longer see him and reported that to the court. I could get no information from anyone.

I lived in terror from the time my son was 16. I lived in the insane and frightening roller coaster of life with an out of control, angry, destructive, and strong son. I lost my moral compass; eventually I lost myself. I was terrified and in denial. I was naïve. I had no idea my son's problems stemmed from drugs and neither did any of the professionals involved.

I had my son kidnapped and taken to a wilderness program in Utah. At that point, it was the worst day of my life. He got better therapy and education out in the middle of that isolated desert than he ever did here at home. Six weeks and he graduated and was ready to come home.

I thought having put both of us through this, he would be cured. Many worse days were to come, and many attempts at help were to fail, before I came to realize that each attempt was a small step forward and that the inevitable steps backwards for us both were part of the process.

Professionals diagnosed him as oppositional defiant, but a name and a diagnosis are of little help. He saw a series of therapists; none said he had a drug problem; although he had by that time had one for years. Some said I did not support him or praise him enough; I had given him low self-esteem. They believed everything he told them. I felt like the villain.

I was desperate and barely able to continue myself. After several visits to a therapist of my own, I found the courage to attend my first Nar-Anon meeting. It was awkward and depressing. I heard stories from people who must have been looking in my windows so similar were their accounts to my life. At last, it hit me that my son was an addict. Horrible as that revelation was, finally I knew what his problem was and I was not alone with my terror.

I put my son in many rehabs, sometimes forcing him, sometimes he begged me to take him. The need for a rehab was always an absolute emergency: get me in today or I will keep using, get me in today or I might die, get me in now this minute or I will take this kitchen knife and go stab and rob the first person I see. My child had become an abusive terrorist in my home; when I looked at him, all I saw was the enveloping specter of heroin, his drug of choice, commanding his every action.

It is difficult and frustrating to get someone into a rehab. Even now when a desperate parent calls me for help, and I am calm and rational and have had years of experience with many rehabs, I still do not know how to help. Take the addict, dump him on the rehab steps, and drive away. Call around to rehabs and see if they have room and go with the addict and wait (you don't understand waiting until you sit in the lobby of a rehab with your addict freaking out, itching, pulling at eyes, jerking their legs, chain smoking and always threatening to go on another run). I would have done anything just to get the rehab to take him. Not because I any longer thought he would be cured; but I thought he would be safe for a while and I could be safe for a while from my son. What a dreadful thing for a mother to have to feel: safe from her son; safe from the incoherent phone calls at 3:00 AM, the crazy drives to emergency rooms or war zones of drug dealers, the pain of looking at my son as he crumbled physically, the anguish at his irrationality.

Once he was out of the house in rehab or on the street meant scouring his room for drugs. Addicts are clever. I would find those dreaded little blue paper holders from the heroin. Hundreds of them, under the bed, under the rug, in the slots of his video games, under the insoles of his shoes; needles chucked behind bureaus; rolled dollar bills, burned spoons, empty water bottles, rubber hoses, rolled up belts, empty plastic Bic pens—the tools of his addiction. Filth all over. I had to remove all the remains of his drug use because inevitably I knew he would be back. I thought of starting a sideline to help pay for rehabs, offering to clean and de-drug rooms of kids in rehab.

We were lucky if, with or without insurance, he got a week in rehab, maybe. That is, if the addict didn't take off before then. Visiting days in rehabs were hard—taking the cigarettes, the blue raspberry milkshakes, losing so many bed pillows to rehabs. The depression of seeing the young children visiting their parents; the older people visiting there middle-aged children, was significant. I saw my future. I kept a rehab kit in my trunk with underwear and socks, comfortable clothes, the pillow, cigarettes, and the assorted toiletries.

Most police treated my son like the lowest scum on earth, and I was the scum's mother; they were nasty, brutal, and uncaring. The rare officers I met who were more gentle and supportive, who offered to drive my son to a detox, asked if I felt safe to have my son in the house or wanted him removed, who treated us both with dignity, seemed like saints.

The justice system was little help; it depended on the judge's experience with addicts. My son was never court-ordered to rehab or outpatient help. Once he was mandated to attend 90 NA meetings in 90 days; he did and had his longest recovery time up to that point, 97 days. I guess he needed to be mandated to a lifetime of meetings. He was sent to jail several times. Those visits were demeaning and pathetic. There were no meetings; no drug therapy; in jail. He learned to play a mean game of spades and make cheddar cheese soup from orange cheese twists, cinnamon lifesavers, and water. I am glad he did not learn worse. Each time he came out, he used within a week. Probation officers were useless.

I got my son into halfway houses when he got out of rehabs. He never lasted more than 2 weeks. I took him in, but eventually I learned to put him out. I put him out in the middle of blizzards with nowhere to go. I had alarms put on my house. Not to keep burglars out but to keep my son out (and sometimes if he were home, to know when he got out again). I slept for years with a metal baseball bat under my bed in fear of my son and the people he brought into my house at night when I was asleep. I slept with my wallet under my pillow. Still I visited pawn shops to retrieve belongings my son had stolen. My son was an addict; my son knew the secrets of survival.

I always loved my son. I always knew that my son was a decent human being somewhere deep inside. I knew that I was not fighting my son; I was fighting for my son; I was fighting the monster Heroin who controlled my son.

He called on his 21st birthday from what, unbeknownst to us, was to be his final rehab. His buddies in his unit bought him a Krimpet and put 21 match stubs on for candles and sang to him. That was not the 21st birthday I imagined for my son, like so many other rites of passage. I cried and cried for my 21 year-old son and for myself that night, I was grateful to those newly recovering addicts who had cared enough to make him a celebration.

After that rehab, my son relapsed again when his best friend died of an overdose. Sometime after, he learned of a medication that might help him sustain recovery. He began on a program of Suboxone. In the beginning, he took 5 pills a day. No insurance covers this medicine. You could get 30 pills at a time. A six-day supply was \$285. Nor were the weekly doctor visits of \$90 covered by insurance. I was lucky that I could make some sacrifices, take on extra freelance work, but I had the wherewithal to find the money. So many parents cannot. My son no longer needs the medication. In May of 2008, he graduated from college with honors. He is just beginning as a professional MMA fighter. My son is a wonderful and caring human being. My son has been through hell and fought so hard to make it back. My son has friends, my son just got married, and my son is happy and fulfilled. My son will always be an addict, and I will always love him.

APPENDIX C

Kentucky Opioid Case Law

In 2007, Purdue settled litigation with federal prosecutors, resulting in \$634 million in fines.¹⁸⁰ A portion of the fines was set aside to reimburse federal and state governments for damages suffered by Medicaid programs as a result of the improper promotion of OxyContin.¹⁸¹ Kentucky was offered \$500,000, but refused the money; Kentucky was the only state to refuse the money.¹⁸²

In October 2007, Kentucky filed its own lawsuit against Purdue in Pike County Circuit Court.¹⁸³ Kentucky asserted claims for:

- (1) violation of the Kentucky Medicaid Fraud Statute, KRS § 205.8463 and § 446.070;
- (2) violation of KRS § 15.060, which authorizes Kentucky's Attorney General to institute an action to recover fraudulent monies that have been paid out of the state's treasury;
- (3) violation of the Kentucky False Advertising Statute, KRS § 517.030 and § 446.070;
- (4) public nuisance;
- (5) unjust enrichment and restitution;
- (6) indemnity;
- (7) negligence;
- (8) violation of state antitrust law;
- (9) strict liability;
- (10) common-law fraud;
- (11) conspiracy and concert of action; and
- (12) punitive damages.¹⁸⁴

Purdue successfully removed the case to the U.S. District Court for the Eastern District of Kentucky, claiming federal subject matter jurisdiction.¹⁸⁵ The United States Judicial Panel on Multidistrict Litigation (“MDL”) transferred the case to the U.S. District Court for Southern District of New York in April 2008 based on Purdue’s claim that Kentucky had asserted antitrust claims against Purdue.¹⁸⁶

In October 2009, Kentucky moved to remand the case to Kentucky state court.¹⁸⁷ Purdue opposed the motion on the ground that the court had stayed all activity in the MDL proceeding pending final determination of the validity of certain patents.¹⁸⁸ In March 2011, the court granted the parties’ joint request to lift the stay for the limited purpose of deciding Kentucky’s motion to remand.¹⁸⁹ The U.S. District Court

¹⁸⁰ David Armstrong, “Purdue Says Kentucky Suit Over OxyContin Could Be Painful,” Bloomberg.com, (October 20, 2014), <http://www.bloomberg.com/news/articles/2014-10-20/purdue-says-kentucky-suit-over-oxycontin-could-be-painful>.

¹⁸¹ Ibid.

¹⁸² Ibid.

¹⁸³ *In re OxyContin Antitrust Litigation*, 821 F.Supp.2d 591, 594 (S.D.N.Y. 2011).

¹⁸⁴ Ibid.

¹⁸⁵ Ibid.

¹⁸⁶ *In re OxyContin Antitrust Litigation*, 821 F.Supp.2d 591, 595 (S.D.N.Y. 2011).

¹⁸⁷ Ibid.

¹⁸⁸ Ibid.

¹⁸⁹ Ibid.

for Southern District of New York granted Kentucky's motion to remand the case to Kentucky state court was granted in September 2011.¹⁹⁰

Purdue moved to stay the remand order pending appeal to the U.S. Court of Appeals for the Second Circuit, but because the remand order was already transmitted, federal jurisdiction had ended, and the case was not a class action subject to the Class Action Fairness Act of 2005, which would have permitted limited appellate jurisdiction.¹⁹¹ As a result, Purdue's motion was dismissed in October 2011.¹⁹²

Nevertheless, Purdue petitioned for leave to appeal.¹⁹³ In January 2013, the U.S. Court of Appeals for the Second Circuit determined that the District Court correctly remanded the case to Kentucky state court and denied Purdue's petition.¹⁹⁴

When Kentucky filed its case against Purdue in 2007, it served Purdue with discovery, including requests for admissions.¹⁹⁵ Purdue removed the case to federal court before the answer or discovery requests were due, but Purdue subsequently filed its answer to Kentucky's complaint in federal court, which included denials to allegations substantively identical to those set forth in the requests for admissions.¹⁹⁶

Upon remand to state court in February 2013, Kentucky moved to have the requests for admissions deemed admitted in March 2013, and the trial court granted the motion.¹⁹⁷ Because the admissions would likely resolve the issue of liability, Purdue moved in April 2013 to rescind the order granting Kentucky's motion, and then also moved to withdraw or amend the deemed admissions.¹⁹⁸ Following a hearing and briefing, the trial court denied Purdue's motion. Purdue then filed a petition for a writ of prohibition seeking to prohibit the Pike County Circuit Court from enforcing an order deeming certain requests for admissions served upon Purdue as admitted.¹⁹⁹

In February 2014, the Kentucky Court of Appeals denied Purdue's petition.²⁰⁰ Purdue appealed this decision to the Kentucky Supreme Court.²⁰¹ Oral arguments were scheduled for March 26, 2015.²⁰²

¹⁹⁰ *In re OxyContin Antitrust Litigation*, 821 F.Supp.2d 591, 603 (S.D.N.Y. 2011).

¹⁹¹ *In re OxyContin Antitrust Litigation*, 2011 WL 4801360 (S.D.N.Y. 2011).

¹⁹² Ibid.

¹⁹³ *Purdue Pharma L.P. v. Kentucky*, 704 F.3d 208 (2d Cir. 2013).

¹⁹⁴ Ibid.

¹⁹⁵ Ibid.

¹⁹⁶ Ibid.

¹⁹⁷ Ibid.

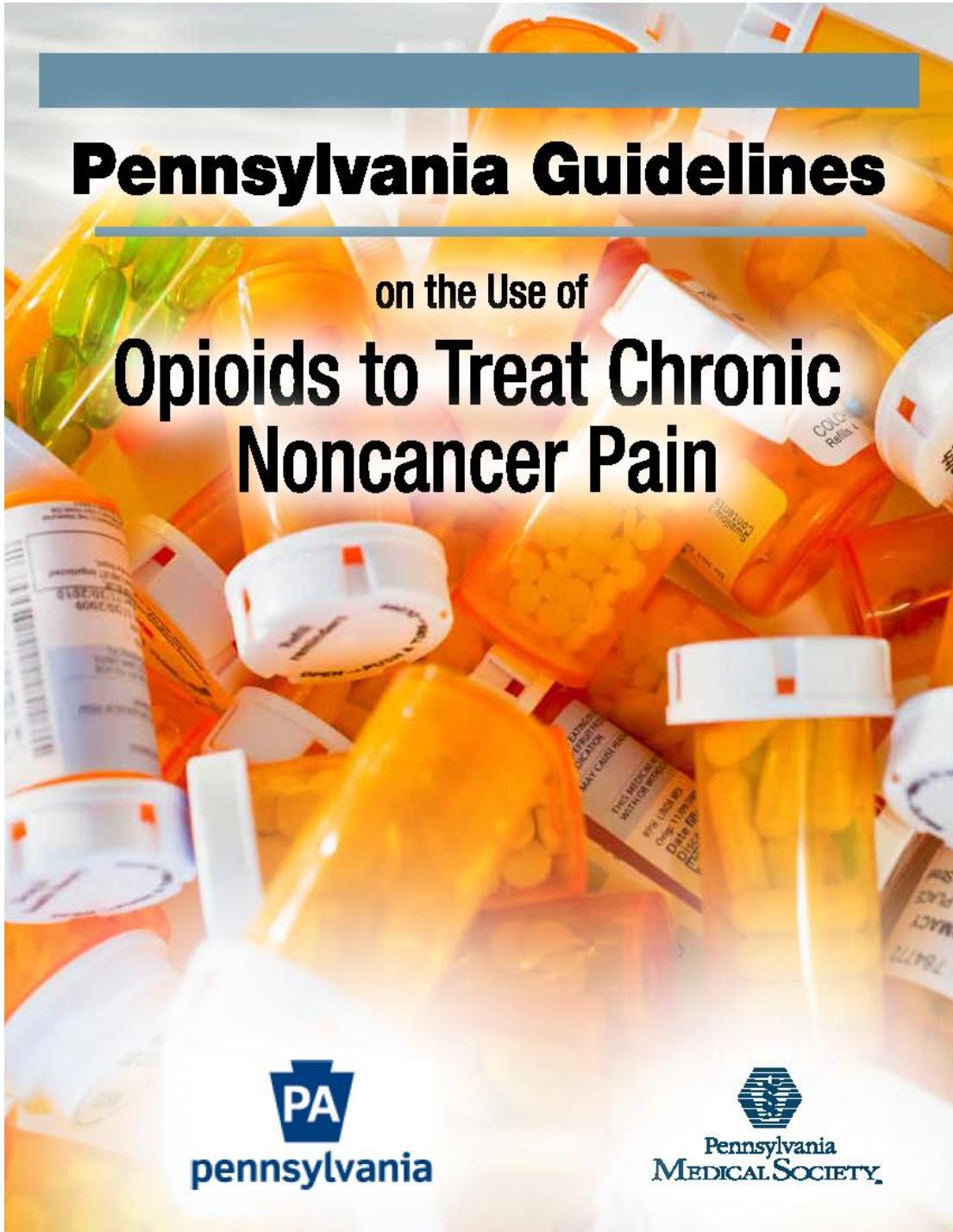
¹⁹⁸ Ibid.

¹⁹⁹ Ibid.

²⁰⁰ Ibid.

²⁰¹ Supra note 180.

²⁰² Supreme Court of Kentucky, "Oral Argument Calendar," available at <http://apps.courts.ky.gov/Supreme/CALENDAR/SCOMAR15.pdf>, p. 2.





Pennsylvania Guidelines on the Use of Opioids to Treat Chronic Noncancer Pain

Chronic pain is a major health problem in the United States, occurring with a point-prevalence of about one-third of the US population.¹ More women than men experience chronic pain, and the prevalence of chronic pain increases with age. The impact of pain on individuals and society is substantial. In a recent survey, individuals reporting frequent or persistent pain within the last 3 months reported that their pain often caused problems with sleep and mood, and 32% reported not being able to work.² The economic impact of chronic pain in the United States is staggering. A recent Institute of Medicine report estimated the annual cost in the United States was \$560 to over \$600 billion, including healthcare costs (\$261-300 billion) and lost productivity (\$297-336 billion).³

Chronic pain is best treated using an interdisciplinary, multi-modal approach. The treatment team often includes the patient and his or her family, the primary care provider, a physical therapist, a behavioral health provider and one or more specialists. Patient outcomes are optimized when several treatments are used in a coordinated manner. These treatments may include activating physical therapy, cognitive-behavioral therapy, proper use of medications, and interventions when indicated. Reliance on only one medication or treatment modality can lead to inadequate pain control and increased risk of harm.

Chronic opioid therapy is a common treatment option for chronic pain, and its use has increased substantially over the last 15 years, in spite of limited evidence of safety and long-term efficacy in the general patient population. Prescription drug abuse has increased significantly over the last 15 years, and this increase has been attributed in part to the increased use of opioids to treat chronic noncancer pain.⁴ About 6.1 million Americans abused or misused prescription drugs in 2011. Drug poisoning deaths, the vast majority of which involve prescription drugs, surpassed traffic-related accidents as the leading cause of injury-related deaths in the United States in 2009.⁵

Prescription opioids are now responsible for over 16,000 deaths and 475,000 Emergency Department visits a year in the United States.

These guidelines address the use of opioids for the treatment of chronic noncancer pain. These guidelines do not address the use of opioids for acute pain, nor do they address the use of opioids for the treatment of pain at the end-of-life. These guidelines are intended to help health care providers improve patient outcomes when providing this treatment, including avoiding potential adverse outcomes associated with the use of opioids to treat pain. These guidelines are intended to supplement and not replace the individual prescriber's clinical judgment. Additional detailed information may be obtained from recently published evidence based guidelines.⁶⁻⁸

Opioid analgesics may be necessary for the relief of pain, but improper use of opioids poses a threat to the individual and to society. Providers have a responsibility to diagnose and treat pain using sound clinical judgment, and such treatment may include the prescribing of opioids. Providers also have a responsibility to minimize the potential for the abuse and diversion of opioids. Therefore, providers should use proper safeguards to minimize the potential for abuse and diversion of opioids.

These guidelines suggest that health care providers incorporate the following key practices into their care of the patient receiving opioids for the treatment of chronic noncancer pain:

- Before initiating chronic opioid therapy, clinicians should conduct and document a history, including documentation and verification of current medications, and a physical examination. Appropriate testing should be completed before starting chronic opioid therapy. The initial evaluation should include documentation of the patient's psychiatric status and substance use history. Clinicians should consider using a valid



screening tool to determine the patient's risk for aberrant drug-related behavior.

- Opioids should rarely be used as a sole treatment modality. Rather, opioids should be considered as a treatment option within the context of multimodality therapy. Providers should recognize that high risk patients, including those with significant psychiatric co-morbidities, may require specialty care, and that chronic opioid therapy may not be possible absent needed specialty care.
- Patients at risk for obstructive sleep apnea (OSA) are at increased risk for harm with the use of chronic opioid therapy. Providers should consider the use of a screening tool for OSA, refer patients for proper evaluation and treatment when indicated, and seek to ensure patients with OSA are compliant with treatment.
- When starting chronic opioid therapy, the provider should discuss the risks and potential benefits associated with treatment, so that the patient can make an informed decision regarding treatment. Reasonable goals and expectations for treatment should be agreed upon, and the patient should understand the process for how the care will be provided, including proper storage and disposal of controlled substances. Providers should proactively review the necessity of periodic compliance checks that may include urine or saliva drug testing and pill counts. Providers may wish to document this discussion through the use of an opioid treatment agreement.
- Initial treatment with opioids should be considered by clinicians and patients as a therapeutic trial to determine whether chronic opioid therapy is appropriate. Both clinicians and patients should understand that chronic opioid therapy will not be effective for all patients, either due to lack of efficacy or the development of unacceptable adverse events, including aberrant drug-related behavior.
- Patient's opioid selection, initial dosing, and dose adjustments should be individualized according to the patient's health status, previous exposure to opioids, response to treatment (including attainment of established treatment goals), and predicted or observed adverse events.
- Caution should be used in patients also taking benzodiazepines, as the use of benzodiazepines in addition to chronic opioid therapy increases the risk of serious adverse events.
- Caution should be used with the administration of methadone, as the administration of methadone for the treatment of chronic pain is associated with increased risk of harm. Providers should be aware of the special pharmacokinetics of methadone and the need for careful dosing and monitoring.
- Caution should be used with the administration of chronic opioids in women of childbearing age, as chronic opioid therapy during pregnancy increases risk of harm to the newborn. Opioids should be administered with caution in breastfeeding women, as some opioids may be transferred to the baby in breast milk.
- When chronic opioid therapy is used for an elderly patient, clinicians should consider starting at a lower dose, titrating slowly, using a longer dosing interval, and monitoring more frequently.
- Patients with co-existing psychiatric disorder(s) may be at increased risk of harm related to chronic opioid therapy. Therefore, clinicians should carefully weight the risk of harm against the potential for benefit when considering chronic opioid therapy, and if chronic opioids are used, consider careful dose selection, frequent monitoring and consultation where feasible.
- It is not appropriate to refer patients receiving chronic opioid therapy to the emergency department to obtain prescriptions for opioids.
- When a dose of chronic opioid therapy is increased, the clinician is advised to provide counseling the patient on the risk of cognitive impairment that can adversely affect the patient's ability to drive or safely do other activities. The risk of cognitive impairment is increased when opioids are taken with other centrally acting sedatives, including alcohol and benzodiazepines.
- Total daily opioid doses above 100 mg / day of oral morphine or its equivalent is not associated with improved pain control, but is associated with



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Pennsylvania Guidelines on the Use of Opioids to Treat Chronic Noncancer Pain

a significant increase in risk of harm. Therefore, clinicians should carefully consider if doses above 100 mg / day of oral morphine or its equivalent are indicated. Consultation for specialty care may be appropriate for patients receiving high daily doses of opioids.

- Clinicians should reassess patients on chronic opioid therapy periodically and as warranted by changing circumstances. Monitoring should include documentation of response to therapy (pain intensity, physical and mental functioning, including activities of daily living, and assessment of progress toward achieving therapeutic goals), presence of adverse events, and adherence to prescribed therapies.
- Clinicians should carefully monitor patients for aberrant drug-related behaviors. Monitoring may include periodic review of available information regarding the prescribing of opioids and other controlled substances to the patient through available databases, urine or saliva drug screening or pill counts. Consideration should be given to routine periodic urine drug screening as a monitoring tool.
- Clinicians should consider increasing the frequency of ongoing monitoring, as well as referral for specialty care, including psychological, psychiatric and addiction experts for patients identified to be at high risk for aberrant drug-related behavior.
- In patients who have engaged in aberrant drug-related behaviors, clinicians should carefully determine if the risks associated with chronic opioid therapy outweigh documented benefit. Clinicians should consider restructuring therapy (frequency or intensity of monitoring), referral for assistance in management, or discontinuation of chronic opioid therapy. Appropriate referral for addiction evaluation and treatment should be provided.

- Clinicians should discontinue chronic opioid therapy in patients who engage in repeated aberrant drug-related behaviors or drug abuse/diversion, experience no progress toward meeting therapeutic goals, or experience intolerable adverse effects.
- Clinicians should be aware of and understand current federal and state laws, regulatory guidelines, and policy statements that govern the use of chronic opioid therapy for chronic non-cancer pain.

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Emergency Department (ED) Pain Treatment Guidelines

Background

Prescription drug abuse has become an issue of national importance as the number of deaths from prescription opioids now exceeds those caused by heroin and cocaine combined. In order to help stem this epidemic, there has been a call for more judicious prescribing on the part of physicians and other health-care providers.

Objective

To appropriately relieve pain for patients and attempt to identify those who may be abusing or addicted to opioid analgesics and refer them for special assistance.

Guidelines

All patients with a complaint of acute or chronic pain will receive an appropriate history and physical examination, including review when appropriate and, when available, of prior visits. Providers may order additional diagnostic testing as needed. Emergency Department (ED) Providers ("providers" for this document) include physicians and other healthcare providers that care for patients in an ED or other emergency setting.

Treatment of Non-Cancer Pain

1. Opioid analgesics may be appropriate for acute illness or injury.
 - a. Discharge prescriptions should be limited to the amount needed until follow-up and typically should not exceed seven days.
 - b. When selecting a medication for pain control, the provider should consider non-opioid medications as alternative or concurrent therapy.
 - c. When opioids are indicated, the provider should choose the lowest potency opioid necessary to relieve the patient's pain.
 - d. An emergency department provider should only dispense the amount of opioid medication needed to control the patient's pain until they are able to access a pharmacy.

2. Emergency providers should not prescribe long acting opioid agents such as OxyContin®, extended-release morphine, or methadone, unless coordinated with the outpatient provider.
3. The patient should not receive opioid prescriptions for chronic or recurrent pain from multiple providers.
4. Upon development of a controlled substances database by the Commonwealth of Pennsylvania, emergency providers should access this as indicated.
5. Emergency providers should not replace lost or stolen prescriptions for controlled substances.
6. Emergency providers should not fill prescriptions for patients who run out of pain medications; refills are to be arranged with the primary or specialty prescribing provider.
7. Patients whose behavior raises the provider's concern for addiction should be encouraged to seek detoxification assistance, and emergency department staff should provide information to assist in this process.

N.B., Care must be given to recognize the complicated and unique aspects of caring for patients in the emergency department setting. The above document represents guidelines which may not necessarily apply to each individual patient. Each patient is different and emergency providers should use their judgment and other resources to best care for each individual patient with acute or chronic pain.

APPENDIX F

PRIOR PRINTER'S NOS. 3034, 3181

PRINTER'S NO. **3289**

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 659 Session of
 2014

INTRODUCED BY HEFFLEY, COHEN, CALTAGIRONE, MACKENZIE,
DiGIROLAMO, BOBACK, V. BROWN, SCHLOSSBERG, MASSER, MILLARD,
CORBIN, GROVE, MILNE, TOEPEL, MENTZER, PICKETT, MURT, THOMAS,
BENNINGHOFF, GRELL, GIBBONS, MARSICO, LAWRENCE, HACKETT,
GINGRICH AND FRANKEL, FEBRUARY 24, 2014

AS AMENDED, HOUSE OF REPRESENTATIVES, APRIL 1, 2014

A RESOLUTION

1 Establishing the task force on opioid prescription drug
2 proliferation and its impact on heroin use in this
3 Commonwealth; and creating an advisory committee.

4 WHEREAS, The United States makes up 4.5% of the world's
5 population; and

6 WHEREAS, The United States consumes 80% of the opioid
7 prescription drugs; and

8 WHEREAS, The human suffering associated with addiction for
9 affected families has now reached epidemic proportions; and

10 WHEREAS, Criminal court dockets are crowded with people who
11 are living with an addiction to prescription drugs; and

12 WHEREAS, The death toll is surging from opioid prescription
13 drug overdoses; and

14 WHEREAS, Those who become addicted to prescription drugs,
15 left untreated, tend to shift to abusing heroin, and this has
16 resulted in a huge increase in heroin use across this
17 Commonwealth; and

1 WHEREAS, The proliferation of opioid prescription drug abuse
2 has become a crisis; therefore be it

3 RESOLVED, That the House of Representatives direct the Joint
4 State Government Commission to establish a task force on opioid
5 prescription drug proliferation; and be it further

6 RESOLVED, That the task force consist of four members
7 appointed by the Speaker of the House of Representatives, two
8 appointed in consultation with the Majority Leader and two
9 appointed in consultation with the Minority Leader; and be it
10 further

11 RESOLVED, That the Joint State Government Commission create
12 an advisory committee, including, but not limited to, the
13 following individuals:

14 (1) A representative recommended by the Department of
15 Drug and Alcohol Programs.

16 (2) A representative recommended by the Department of
17 Public Welfare.

18 (3) A representative recommended by the Insurance
19 Department.

20 (4) A physician recommended by the Department of Health.

21 (5) A representative recommended by the State Board of
22 Pharmacy.

23 (6) A representative recommended by the Attorney
24 General.

25 (7) A representative recommended by the Pennsylvania
26 Fraternal Order of Police.

27 (8) A representative recommended by the Pennsylvania
28 Athletic Oversight Committee.

29 (9) Two physicians recommended by the Pennsylvania
30 Medical Society, one of whom holds membership in the American

1 Society of Addiction Medicine and the other who is a
2 physician with expertise in chronic pain management and
3 treatment.

4 (10) A physician who is a member of the Pennsylvania
5 Psychiatric Society specializing in addiction psychiatry.

6 (11) A representative recommended by the Drug and
7 Alcohol Service Providers Organization of Pennsylvania.

8 (12) A representative recommended by the Pennsylvania
9 Recovery Organizations Alliance.

10 (13) A representative recommended by the Pennsylvania
11 Association for the Treatment of Opioid Dependence.

12 (14) A representative recommended by a manufacturer of
13 opioid drugs.

14 (15) A wholesale distributor representative recommended
15 by the Healthcare Distribution Management Association.

16 (16) A representative recommended by the Pennsylvania
17 District Attorneys Association.

18 (17) The Commissioner of Pennsylvania State Police or
19 his designee.

20 (18) A representative recommended by the Pennsylvania
21 Coroners Association.

22 (19) A representative of chronic pain patients
23 recommended by a physician with expertise in chronic pain
24 management.

25 (20) A representative of pharmacies recommended by the
26 Pennsylvania Association of Chain Drug Stores.

27 (21) A representative of pharmacists recommended by the
28 Pennsylvania Pharmacists Association.

29 (22) A representative recommended by the Pennsylvania
30 State Nurses Association.

1 (23) A representative recommended by the Pennsylvania
2 Osteopathic Medical Association. <--

3 (24) A REPRESENTATIVE RECOMMENDED BY THE AMERICAN CANCER
4 SOCIETY.

5 (25) A REPRESENTATIVE OF A NATIONAL NONPROFIT WITH THE
6 MISSION OF DEVELOPING SOLUTIONS TO PRESCRIPTION DRUG
7 DIVERSION.

8 (26) A REPRESENTATIVE OF A NATIONAL NONPROFIT WITH THE
9 MISSION TO CONNECT, INFORM AND EDUCATE THOSE LIVING WITH
10 PAIN.

11 (27) A REPRESENTATIVE OF A HEALTH SYSTEM PHARMACY
12 RECOMMENDED BY THE HOSPITAL AND HEALTHSYSTEM ASSOCIATION OF
13 PENNSYLVANIA.

14 (28) A REPRESENTATIVE OF A RECOVERY SUPPORT INITIATIVE
15 RECOMMENDED BY THE PENNSYLVANIA RECOVERY ORGANIZATION-
16 ACHIEVING COMMUNITY TOGETHER;

17 and be it further

18 RESOLVED, THAT AS A FIRST ORDER OF BUSINESS, THE JOINT STATE <--
19 GOVERNMENT COMMISSION BE DIRECTED TO RECOMMEND GUIDELINES FOR
20 PRESCRIBERS WHICH SHALL BE SUBMITTED WITHIN 60 DAYS OF THE
21 FORMATION OF THE ADVISORY COMMITTEE; AND BE IT FURTHER

22 RESOLVED, That the advisory committee examine existing laws
23 relative to the prescribing and dispensing of prescription
24 opioid drugs; and be it further

25 RESOLVED, That the advisory committee gather facts from
26 existing public hearings that have been held by legislative
27 committees; and be it further

28 RESOLVED, That the advisory committee accept and review any
29 briefs or comments submitted by any stakeholders; and be it
30 further

1 RESOLVED, That parents, siblings or family members who have
2 lost loved ones are welcome to submit their testimony for the
3 record; and be it further

4 RESOLVED, That the task force and advisory committee make a
5 report to the General Assembly with suggested changes to current
6 State laws and regulations that will provide for safer and more
7 effective pain management practices, ensure that pain management
8 practitioners are sufficiently trained in identifying addiction
9 and referring addicted patients to appropriate care and help
10 combat the proliferation of misuse and abuse of opioid
11 prescription drugs within one year of the adoption of this
12 resolution.