JOINT STATE GOVERNMENT COMMISSION

General Assembly of the Commonwealth of Pennsylvania

HOUSE RESOLUTION 659

INTERIM REPORT
GUIDELINES FOR PRESCRIBING OPIOID ANALGESICS

DECEMBER 2014

JOINT STATE GOVERNMENT COMMISSION
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December 3, 2014

To the Members of the General Assembly of Pennsylvania:

House Resolution 659 of 2014 directed the Joint State Government Commission to establish a legislative task force and appoint an advisory committee to study opioid addiction in Pennsylvania.

HR659 further directed that the Commission, Task Force, and Advisory Committee produce an interim report of guidelines for prescribers. This report contains information about illicit use of opioids, research about guidelines, other states' experiences with establishing guidelines, and guidelines released in July 2014 by the Pennsylvania Department of Drug & Alcohol Programs' Safe and Effective Prescribing Practices and Pain Management Task Force.

This report, "Guidelines for Prescribing Opioid Analgesics," contains the Advisory Committee's recommendations on establishing opioid prescribing guidelines for Pennsylvania. It is available on our website, http://jsg.legis.state.pa.us/.

Respectfully submitted,

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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 study opioid addiction in Pennsylvania. The Commission, Task Force, and Advisory Committee are expected to make recommendations for state laws and regulations that will provide for safer and more effective pain 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. This report contains information about illicit use of opioids, research about guidelines, other states' experiences with establishing guidelines, and guidelines released in July 2014 by the Pennsylvania Department of Drug & Alcohol Programs' Safe and Effective Prescribing Practices and Pain Management Task Force.

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 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.[1] This Task Force, after lengthy and comprehensive deliberations that began December 16, 2013, formed a set of guidelines. The final draft was released to the public on July 10, 2014.[2] 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 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 document should reflect the DDAP guidelines. There was round agreement that the DDAP guidelines should first be thoroughly reviewed. A number of members raised the concern that to release a new set of guidelines may sow confusion among healthcare regulators, providers, insurers, and patients in instances where the HR659 Advisory Committee's guidelines may differ

[1] At this time, the DDAP Task Force continues its work with regard to opioid prescribing guidelines.
[2] DDAP Task Force Guidelines are found in Appendix 1.

from the DDAP guidelines. Further, the DDAP guidelines had been developed and thoroughly vetted by the DDAP Task Force's many participants, several of whom also serve 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.

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. They 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 number of visits to hospital emergency rooms related to the misuse or abuse of pharmaceuticals rose dramatically during the latter part of the last decade.[3] 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. The startling increases raised alarms across the country and led public health authorities to dedicate themselves to understanding the problem.

The U.S. Centers for Disease Control and Prevention (CDC) responded with research into the nationwide problem of the illicit use of prescription pain medications.[4] Misuse and abuse of pain management medications, which consumers often combined with other potentially dangerous

[3] 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. http://www.samhsa.gov/data/2k13/DAWN127/sr127-DAWN-highlights.htm.

[4] "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.

medications, such as benzodiazepines, have led to devastating consequences for individuals and their families, and have resulted in enormous costs to local economies and social networks. The CDC's 2011 data show that:

- 22,801 deaths were attributed to pharmaceutical overdoses;
- 16,917 of the deaths were associated with opioid analgesics, and benzodiazepines were associated with 6,872;
- Hospital emergency departments reported 420,040 visits for overdoses related to opioid analgesics;
- One in 20 people over the age of 12 reported using prescription painkillers for nonmedical reasons;
- 259 million prescriptions were written for opioid analgesics; and
- Nonmedical use of prescription painkillers cost the nation $55.7 billion.

Of great concern is the 153 percent growth in the number of visits for the misuse or abuse of opioid analgesics, as recorded by the federal Substance Abuse and Mental Health Services Administration (SAMHSA) from 2004 to 2011. See Table 1.

Table 1
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.
http://www.samhsa.gov/data/2k13/DAWN127/sr127-DAWN-highlights.htm.

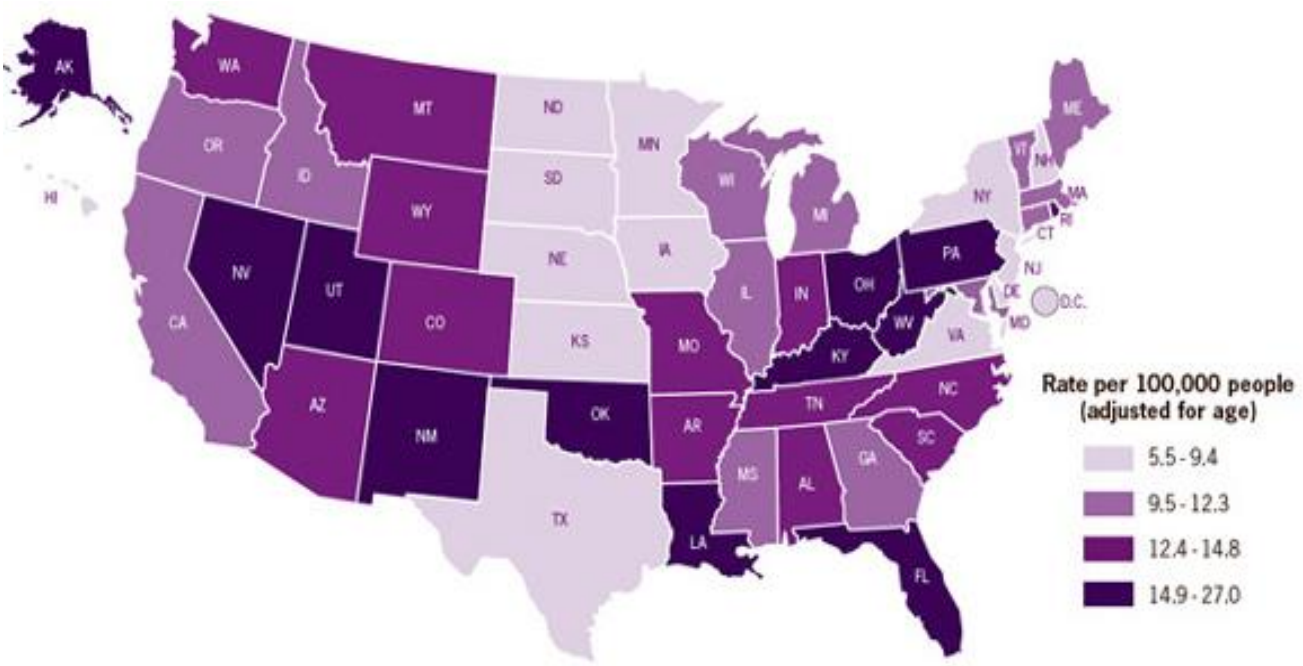
Data further revealed that those who suffered from an overdose of prescription painkillers tended to be middle aged men more often than women. Fifty-six percent of overdoses are among men, and men are 60 percent more likely to die of an overdose.[5] The gender gap, however, is closing at an astonishing rate. Between 1999 and 2010 overdose deaths from prescription pain

[5] "Prescription Drug Overdose in the United States: Fact Sheet" Centers for Disease Control and Prevention. Last updated July 3, 2014. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html.

medications among women increased more than 400 percent.[6] The incidence of overdose death for men grew as well, by an alarming 265 percent.[7] 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. Whites and Native Americans (including Alaska Natives) have higher rates of overdose than people identifying as other races or ethnicities. At the time of the CDC's 2011 report, an estimated 10 percent of Native Americans, 5 percent of whites, and 3 percent of blacks were using prescription pain medication for nonmedical uses.[8]

As illustrated by Figure 1, a 2011 report showed that Pennsylvania ranks among the 12 states with the highest death rates for prescription opioid overdoses. The other states are Alaska, Nevada, Utah, New Mexico, Oklahoma, Louisiana, Florida, Kentucky, West Virginia, Ohio, and Rhode Island, which have rates between 14.9 and 27 deaths per 100,000 people. [9]

Figure 1
Drug overdose death rates by state per 100,000 people
2008



Source: "Prescription Pain Killer Overdoses in the US" CDC. Last updated November 1, 2011. Accessed June 24, 2014.
http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html.

[6] "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.
[7] Ibid.
[8] Ibid.
[9] Ibid.

Estimates vary in terms of the dollar costs of opioid analgesic illicit use and abuse, but the costs borne by the public and private sectors create an enormous drain on the economy. The Coalition Against Insurance Fraud estimated public and private insurers' costs related to opioid theft and abuse at $72.5 billion in 2007.[10] *Pain Medicine* published a study of 2007 costs that showed the societal costs as being $55.7 billion.[11] Included among these costs were workplace costs, including premature death, reduced compensation, and lost employment that were estimated at $25.6 billion.[12] 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.[13]

Several factors have been identified as contributing to the epidemic growth in the illicit use of prescription pain medications. First, the quantity of prescription pain medications sold to pharmacies, hospitals, and doctor's offices was four times larger in 2010 than it was in 1998. Figure 2 shows the amounts of prescription pain medications sold in each state.[14] Interestingly, only five of the 12 with the highest death rates are included among the states with the highest amounts of medications sold. Legal loopholes in various states have allowed unscrupulous prescribers to provide large quantities prescription medications to people who do not need them for legitimate purposes. Further, gaps in laws and regulations provide opportunities for "doctor shopping," by which individuals illicitly obtain multiple prescriptions for pain management medications. It is widely believed that many of these medications end up in illegal drug trafficking. However, there are also those individuals who keep the drugs for their own use as a consequence of various factors. Some patients suffer from iatrogenic addiction, which is an addiction that develops as a consequence of opioid therapies prescribed for legitimate medical purposes. Others may be engaged in doctor shopping to ameliorate pain that has not been properly addressed by their medical caregivers.

Pennsylvania

- Pennsylvania, like many states, is suffering from the epidemic use of illicit prescription pain medication. According to 2008 data, slightly fewer than 8 percent of Pennsylvania residents reported that they had taken illicit prescription pain medication in the previous month; the national average was 8.82 percent.[15]

- Despite the marginally lower rate of illicit use in 2008, in 2009 the rate of drug-induced deaths in Pennsylvania was higher than the national average. Pennsylvania drug-induced deaths (15.7 per 100,000 population) exceeded the national rate (12.8 per 100,000).

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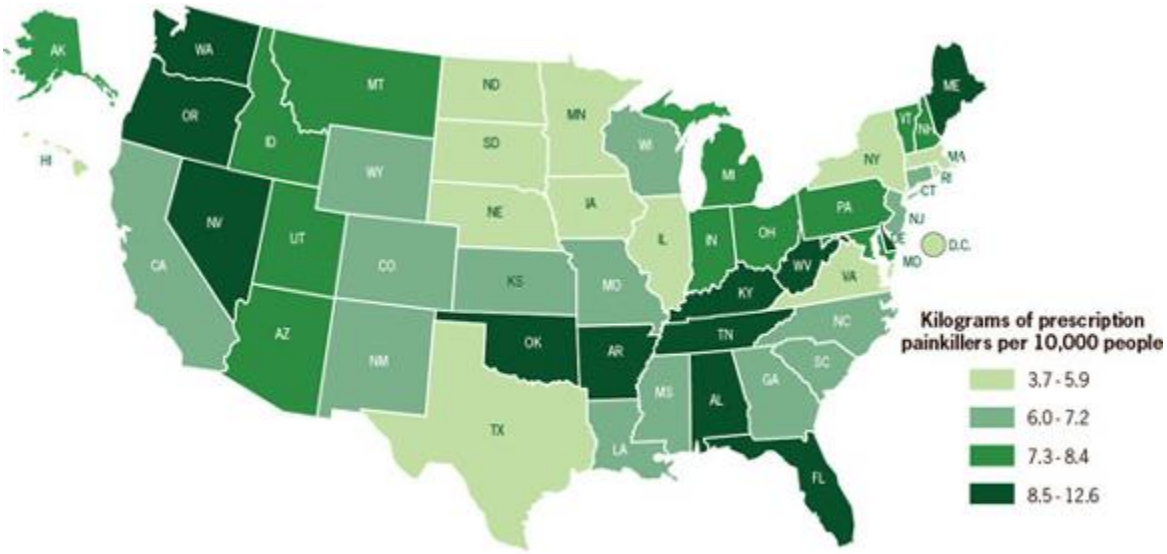
[10] Coalition Against Insurance Fraud, *Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs*, 2007. www.insurancefraud.org/downloads/drugDiversion.pdf.
[11] H.G. Birnbaum, et al. "Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States." *Pain Medicine.* http://www.ncbi.nlm.nih.gov/pubmed/21392250.
[12] Ibid.
[13] Ibid.
[14] "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.
[15] National Survey on Drug Use and Health (NSDUH) 2009-2010.

- Of the drugs involved, heroin is the most commonly cited among treatment admissions in Pennsylvania. In 2010, almost one-third of drug treatment admissions in Pennsylvania were for heroin.

- As a direct consequence of drug use, 1,983 persons died in Pennsylvania in 2009. More Pennsylvanians died from drug-related deaths than from motor vehicle accidents (1,378) and firearms (1,349).

- Pennsylvania's Prescription Monitoring Program (PMP) collects data from approximately 3,000 pharmacies on prescriptions of Schedule II controlled substances.[16] The PMP, which became operational circa 1973, is administered by the Pennsylvania Attorney General's Office. The database system is used by the office to identify suspected criminal or fraudulent activities related to Schedule II prescribing. Requests for patient information are limited to law enforcement.

Figure 2
Amount of prescription painkillers sold by state per 100,000 people
2010 Data



Source: "Prescription Painkiller Overdoses in the US." *CDC Vital Signs*. November 2011. http://www.cdc.gov/vitalsigns/painkilleroverdoses/. Accessed August 6, 2014.

[16] 28 Pa. Code § 25.72(c). Schedule II. In determining that a substance comes within this schedule, the Secretary will find: a high potential for abuse; currently accepted medical use in the United States; or currently accepted medical use with severe restrictions and abuse may lead to severe psychic or physical dependence.

STUDIES OF OPIOID ANALGESIC PRESCRIBING GUIDELINES

Studies of the widespread abuse of opioid analgesics have been the focus of numerous public health authorities and researchers. 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.[17] 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.[18]

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 but 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:

[17] 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. DOI: 10.1371/journal.pone.0069241. Accessed September 5, 2014.
[18] Ibid.

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 medical record (EMR) based protocol and educational intervention to standardize documentation and management of patients prescribed opioids by primary care physicians.[19] Their objective was to evaluate provider adherence to this protocol, attitudes toward the management of these patients, and knowledge of opioid prescribing.

[19] Robin E. Canada, M.D., Danae DiRocco, MPH, Susan Day, M.D., MPH, "A better approach to opioid prescribing in primary care," *The Journal of Family Practice*. June 2014. Accessed June 16, 2014.

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 medical record (EMR) problem list.

5. Complete a standardized EMR "smart set" documenting evaluation and management in the overview section of the EMR'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 EMR) 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.

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.

Ohio

Ohio, for example, experienced a 440 percent increase in drug overdoses, most of which were attributed to opioid analgesics. 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.[20]

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 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 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

[20] Opiate Action Team, "Ohio's Opioid Prescribing Guidelines." Ohio.gov. n.d. http://www.med.ohio.gov/webhost/OOAT_RX_Guidelines.html.

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.[21]

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.[22]It is 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.[23] 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

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[21] 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." January 2014. Accessed August 8, 2014.
http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=8&ved=0CG0QFjAH&url=http%3A%2F%2Fwww.mc.vanderbilt.edu%2Fdocuments%2Fcph%2Ffiles%2FTN%2520Prescribing_with%2520title%2520page%281%29.pdf&ei=-hrlU6KEOsrM8QG81YGgBg&usg=AFQjCNF7RPLnrDOREh7a-eWFME_kTrIkMA&sig2=ED-wb-FnfbUjA09-TrnypQ&bvm=bv.72676100,d.b2U. 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).

[22] "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.

[23] 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. Accessed June 20, 2014.

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 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.

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. 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 is 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.

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 not 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.[24] 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

[24] Joint State Government Commission. *Methadone Use and Abuse: Reducing the Incidence of Methadone Overdoses and Deaths*. 2011. http://jsg.legis.state.pa.us/publications.cfm?JSPU_PUBLN_ID=202. Accessed September 4, 2014.

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 ensure 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.

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.

APPENDIX I

DDAP Effective Prescribing Practices and Pain Management Task Force, "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. 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. 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).

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. 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. 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.

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 weigh 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 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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