

Prescribing Opioids, Providing Naloxone, and Preventing Drug Diversion: The West Virginia Requirement

HOW TO RECEIVE CREDIT

- Read the enclosed course.
- Complete the questions at the end of the course.
- Return your completed Evaluation to NetCE by mail or fax, or complete online at www.NetCE.com. (If you are a physician or Florida nurse, please return the included Answer Sheet/Evaluation.) Your postmark or facsimile date will be used as your completion date.
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Faculty

Mark Rose, BS, MA, LP, is a licensed psychologist in the State of Minnesota with a private consulting practice and a medical research analyst with a biomedical communications firm. Earlier healthcare technology assessment work led to medical device and pharmaceutical sector experience in new product development involving cancer ablative devices and pain therapeutics. Along with substantial experience in addiction research, Mr. Rose has contributed to the authorship of numerous papers on CNS, oncology, and other medical disorders. He is the lead author of papers published in peer-reviewed addiction, psychiatry, and pain medicine journals and has written books on prescription opioids and alcoholism published by the Hazelden Foundation. He also serves as an Expert Advisor and Expert Witness to law firms that represent disability claimants or criminal defendants on cases related to chronic pain, psychiatric/substance use disorders, and acute pharmacologic/toxicologic effects. Mr. Rose is on the Board of Directors of the Minneapolis-based International Institute of Anti-Aging Medicine and is a member of several professional organizations.

Faculty Disclosure

Contributing faculty, Mark Rose, BS, MA, LP, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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The division planners and director have disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

Audience

This course is designed for all physicians, physician assistants, and nurses in West Virginia who may alter prescribing practices or intervene to prevent drug diversion and inappropriate opioid use.

Accreditations & Approvals



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This activity has been approved for the American Board of Anesthesiology's[®] (ABA) requirements for Part II: Lifelong Learning and Self-Assessment of the American Board of Anesthesiology's (ABA) redesigned Maintenance of Certification in Anesthesiology.

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NetCE designates this continuing education activity for 3 ANCC contact hours.



This activity was planned by and for the healthcare team, and learners will receive 3 Interprofessional Continuing Education (IPCE) credits for learning and change.

NetCE designates this continuing education activity for 3.6 hours for Alabama nurses.

NetCE designates this continuing education activity for 3 pharmacotherapeutic/pharmacology contact hours.

AACN Synergy CERP Category A.

NetCE designates this activity for 3 hours ACPE credit(s). ACPE Universal Activity Numbers: JA4008164-0000-20-075-H01-P and JA4008164-0000-20-075-H01-T.

Individual State Nursing Approvals

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Special Approvals

This activity is designed to comply with the requirements of California Assembly Bill 1195, Cultural and Linguistic Competency.

This course fulfills the West Virginia State Board of Examiners for Licensed Professional Nurses requirement for 3 hours of education related to Chemical Dependency/Substance Abuse.

This course fulfills the West Virginia Board of Examiners for Registered Professional Nurses requirement for 3 hours of education related to Drug Diversion and Best Practice Prescribing of Controlled Substances. This program has been approved by the WV Board of Medicine and the WV Board of Osteopathic Medicine and will satisfy the required 3 hours of CME for Drug Diversion

Training and Best Practice Prescribing of Controlled Substances Training for MDs, DOs, and their licensed Physician Assistants.

About the Sponsor

The purpose of NetCE is to provide challenging curricula to assist healthcare professionals to raise their levels of expertise while fulfilling their continuing education requirements, thereby improving the quality of healthcare.

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Disclosure Statement

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Course Objective

The purpose of this course is to provide clinicians who prescribe or distribute opioids with an appreciation for the complexities of opioid prescribing and the dual risks of litigation due to inadequate pain control and drug diversion or misuse in order to provide the best possible patient care and to prevent a growing social problem.

Learning Objectives

Upon completion of this course, you should be able to:

1. Define opioid prescribing and opioid misuse.
2. Apply epidemiologic trends in opioid use and misuse to current practice so at-risk patient populations can be more easily identified, assessed, and treated.
3. Create comprehensive treatment plans for patients with chronic pain that address patient needs as well as drug diversion prevention.
4. Identify state and federal laws governing the proper prescription and monitoring of controlled substances.
5. Evaluate behaviors that may indicate drug seeking or diverting as well as approaches for patients suspected of misusing opioids.

Pharmacy Technician Learning Objectives

Upon completion of this course, you should be able to:

1. Outline the problem of opioid misuse.
2. Discuss the creation and management of an opioid treatment plan.



Sections marked with this symbol include evidence-based practice recommendations. The level of evidence and/or strength of recommendation, as provided by the evidence-based source, are also included so you may determine the validity or relevance of the information. These sections may be used in conjunction with the course material for better application to your daily practice.

INTRODUCTION

In the United States, the current status of pain care is complex, characterized by the widespread, simultaneous, and inappropriate prescribing patterns of analgesic underprescribing and opioid overprescribing. These practice patterns are especially prevalent in patients with chronic pain and have resulted in or contributed to unnecessary patient suffering from inadequately treated pain and increasing rates of opioid abuse, addiction, diversion, and overdose.

There is considerable evidence that major stakeholders have negatively influenced the delivery of safe, effective, and appropriate medical care to patients with chronic pain. This has occurred, in large part, by controlling the information used by clinicians to guide their practice and prescribing behavior. In addition to substantial differences in patient tolerability and analgesia with opioid analgesics, patients can also exhibit a range of psychologic, emotional, and behavioral responses to prescribed opioids, the result of inadequate pain control, an emerging opioid use problem, or both. An appreciation for the complexities of opioid prescribing and the dual risks of litigation due to inadequate pain control and drug diversion or misuse is necessary for all clinicians in order to provide the best possible patient care and to prevent a growing social problem.

DEFINITIONS

Definitions and use of terms describing opioid analgesic misuse, abuse, and addiction have changed over time, and their current correct use is inconsistent not only among healthcare providers, but also by federal agencies reporting epidemiologic data such as prevalence of opioid analgesic misuse, abuse, or addiction. Misuse and misunderstanding of these concepts and their correct definitions have resulted in misinformation and represent an impediment to proper patient care.

Inappropriate opioid analgesic prescribing for pain is defined as the non-prescribing, inadequate prescribing, excessive prescribing, or continued prescribing despite evidence of ineffectiveness of opioids [1]. Appropriate opioid prescribing is essential to achieve pain control; to minimize patient risk of abuse, addiction, and fatal toxicity; and to minimize societal harms from diversion. The foundation of appropriate opioid prescribing is thorough patient assessment, treatment planning, and follow-up and monitoring. Essential for proper patient assessment and treatment planning is comprehension of the clinical concepts of opioid abuse and addiction, their behavioral manifestations in pain patients, and how these potentially problematic behavioral responses to opioids both resemble and differ from physical dependence and pseudo-dependence. Prescriber knowledge deficit has been identified as a key obstacle to appropriate opioid prescribing and, along with gaps in policy, treatment, attitudes, and research, contributes to widespread inadequate treatment of pain [2]. For example, a 2016 survey of 1,000 internists, family physicians, and general practitioners found that while 100% believed that prescription drug abuse was a problem in their communities, their knowledge of the specifics of the epidemic were lacking [77]. Only 66% correctly identified swallowing pills whole as the most common route of abuse, and 46% supported the false claim that abuse-deterrent formulations were less addictive than other formulations. Perhaps most troubling, only 25% of participants reported being “not at all” or “only slightly” concerned about the diversion of opioids to the illicit market, a common practice at all levels of the pharmaceutical supply chain [77].

Another 2018 survey measuring more than 200 primary care physicians’ and medical students’ understanding of opioids and addiction found that [3]:

- Only 25% of students and 14% of physicians correctly identified the highest risk patient for opioid-related overdose.

- About half of students and physicians selected the best treatment practice for opioid use disorder.
- 31% of medical students and 22% of physicians did not believe sustained recovery from opioid use disorder is possible.

This last point is very important because confusion and conflation of the clinical concepts of dependence and addiction has led to accusations of many non-addicted chronic pain patients of misusing or abusing their prescribed opioid and in the failure to detect treatment-emergent opioid problems [3]. Knowledge gaps concerning opioid analgesics, addiction, and pain are related to attitude gaps, and negative attitudes may interfere with appropriate prescribing of opioid analgesics. Possibly contributing to healthcare professionals' knowledge deficit in pain treatment is the extent of educational exposure in school. A 2011 study found that U.S. medical school students received a median 7 hours of pain education and Canadian medical students a median 14 hours, in contrast to the median 75 hours received by veterinarian school students in the United States [6]. In 2016, the Association of American Medical Colleges issued a statement highlighting schools' and teaching hospitals' ongoing commitment to opioid-related education and training and the importance of incorporating the Centers for Disease Control and Prevention's (CDC's) guidelines for the prescription of opioids for chronic pain [5].

The terms related to addiction are often inconsistent, inaccurate, and confusing, partially reflecting the diverse perspectives of those working in the related fields of health care, law enforcement, regulatory agencies, and reimbursement/payer organizations. Changes over time in the fundamental understanding of addiction have also contributed to the persistent misuse of obsolete terminology [7]. The *Diagnostic and Statistical Manual of Mental Disorders* (DSM), published by the American Psychiatric Association, is perhaps the most influential reference for the diagnosis of addiction and all other psychiatric disorders.

Prior to the 2013 release of the DSM-5, versions of the DSM eschewed the term "addiction" in favor of "substance dependence," with a separate diagnostic entity of "substance abuse" representing a less severe version of dependence [8]. Also in earlier DSM versions, physiologic dependence, manifesting as substance tolerance and withdrawal, was considered a diagnostic criterion of substance dependence. The result was the perpetuation of patient and healthcare professional confusion between physical and substance dependence and the belief that tolerance and withdrawal meant addiction. This confusion also enhanced provider and patient fears over addiction developing from opioid analgesics and contributed to the undertreatment of pain. The DSM-5 has eliminated substance dependence and substance abuse by combining them into the single diagnostic entity of substance use disorder. The disorder is measured on a continuum from mild to severe [8].

In 2019, the American Society of Addiction Medicine (ASAM) published their latest revision in defining the disease of addiction. In the abbreviated version, the ASAM states [10]:

Addiction is a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences. Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases.

According to the ASAM, the five characteristics of addiction are [10]:

- Inability to consistently abstain
- Impairment in behavioral control
- Craving or increased "hunger" for drug or reward experiences

- Diminished recognition of significant problems with one's behaviors and interpersonal relationships
- A dysfunctional emotional response

The ASAM emphatically states this summary of addiction should not be used as diagnostic criteria for addiction because the core symptoms vary substantially among addicted persons, with some features more prominent than others [10].

EPIDEMIOLOGY OF CHRONIC PAIN AND OPIOID MISUSE

Chronic pain affects about 1 in 5 (approximately 50 million) American adults, with 19.6 million individuals indicating that the pain interferes with their daily lives [64]. It also costs the nation up to \$635 billion each year in medical treatment and lost productivity [3]. The lifetime prevalence of chronic pain ranges from 54% to 80%, and among adults 21 years of age and older, 14% report pain lasting 3 to 12 months and 42% report pain that persists longer than 1 year [2]. An estimated 41% of chronic pain patients report their pain is uncontrolled, and nearly 10% of all adults with pain suffer from severe, disabling chronic pain.

The increasing prevalence of chronic pain is the result of multiple factors, including the aging population; rising rates of obesity and obesity-related pain conditions, such as joint deterioration; advances in life-saving trauma interventions; poorly managed post-surgical pain; and greater public awareness of pain as a condition warranting medical attention [2]. In addition, many armed forces veterans returned from military action in Afghanistan and Iraq with traumatic injuries and chronic pain, and veterans' care clinicians have been reporting the perception that long-term pain management is lacking support in the veteran healthcare infrastructure [11].

The current extent of opioid analgesic use in the United States is unprecedented in the country's history and unparalleled anywhere in the world. Before 1990, physicians in the United States were skeptical of prescribing opioids for chronic non-cancer pain. But, according to the CDC, 20% of adults are prescribed an opioid such as oxycodone and hydrocodone for chronic pain, and sales of opioid analgesics totals approximately \$7 billion annually [65; 71].

Worldwide consumption of opioid analgesics has increased dramatically in the past few decades, with the United States driving a substantial proportion of this increase. For example, the 1990 global consumption of hydrocodone was 4 tons (3,628 kg), compared with the 2009 consumption of 39 tons (35,380 kg); 99% of this was consumed in the United States. Similarly, 3 tons (2,722 kg) of oxycodone were consumed globally in 1990, versus 77 tons (69,853 kg) in 2009, of which 62 tons (56,245 kg or 81%) were consumed in the United States [12]. With only 4.5% of the world's population, the United States annually consumes more than 80% of all opioid supplies, including [13]:

- 99% of all hydrocodone
- 80% of all oxycodone
- 58% of all methadone
- 54% of all hydromorphone
- 49% of all fentanyl
- 43% of all meperidine

This disproportionate rate of opioid consumption reflects sociocultural and economic factors and standards of clinical medicine.

However, it appears that opioid prescribing peaked in 2012 and has since decreased. Between 2012 and 2020, the number of opioid prescriptions (including buprenorphine, codeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, propoxyphene, tapentadol, and tramadol) decreased from a peak of 225.2 million to 142.8 million [78].

Between 1992 and 2003, the U.S. population increased 14%, while persons abusing opioid analgesics increased 94% and first-time non-medical opioid analgesic users 12 to 17 years of age increased 542% [13]. It is interesting to note that while opioid prescribing has increased precipitously among adults in the United States, the rate remained steady for children and young adults between 1996 and 2020 [56]. A 2021 study found that the opioid dispensing rate for patients younger than 25 years of age decreased from 14.28 in 2006 to 6.45 in 2018 [72]. However, the authors conclude that possible high-risk prescribing practices appear to be common, especially in younger children. To assist in monitoring the public health problem associated with prescribed opioids, numerous governmental, non-profit, and private sector agencies and organizations are involved in collecting, reporting, and analyzing data on the abuse, addiction, fatal overdose, and treatment admissions related to opioid analgesics.

Before it was halted in 2011, the Drug Abuse Warning Network (DAWN) provided estimates of the health consequences of nonmedical use of individual drugs, including opioid medications [14]. DAWN indicates that opioid abuse is a growing problem in the United States. In 2005 and 2011, hydrocodone and its combinations accounted for 51,225 and 97,183 emergency department visits, respectively. Oxycodone and its combinations resulted in 42,810 visits to the emergency department in 2005; this number increased to 175,229 visits in 2011 [15; 16]. Visits for nonmedical use of all opioids increased from 217,594 to 420,040 during the six-year period. In 2016–2017, the number of nonmedical opioid emergency department visits was 127,101; while this number is an improvement from previous years, nonmedical use still accounts for nearly half (47.6%) of all emergency department visits related to opioids [73].

West Virginia has been particularly affected by the nonmedical use of prescription drugs and was among the initial states to report oxycodone abuse and diversion. Oxycodone and hydrocodone are the most commonly abused prescription drugs in the state, accounting for more than 50% of all prescription opioid overdose deaths [51]. As prescription opioids have become more difficult to obtain, users tend to migrate to heroin and synthetic opioids (mainly fentanyl and fentanyl analogs). While there was a nearly 40% decrease in West Virginia related to prescription opioid-related overdose deaths between 2014 (383 deaths) and 2018 (234 deaths), synthetic opioid (other than methadone, mainly fentanyl) deaths increased more than 400%, from 122 deaths in 2014 to 551 deaths in 2018. Heroin overdose deaths increased nearly 20% during the same time period, from 163 to 195 [74]. However, preliminary data for 2021 indicate a significant increase in any opioid-related overdose deaths compared with 2018 [80].

In addition, West Virginia experienced the nation's largest increase in unintentional drug poisoning mortality rates (550%) between 1999 and 2004, and this trend unfortunately continues today [50; 52; 74]. In fact, West Virginia experienced the highest drug overdose death rate in the country in 2018, with 42.4 deaths per 100,000 population (a 14.5% decrease compared with 2017) [52; 74]. This rate is nearly 3.5 times the national average (14.6) and twice the state's rate in 2010 [74]. The number of deaths resulting from any drug overdose was 1,017 in 2017, the highest ever recorded and a 22.5% increase over the previous year (which was also a record). Preliminary data on 2020 overdoses in West Virginia is projected to be a 45% increase from 2019 data [75]. An opioid was involved in 89% of these deaths. Drug overdose is the leading cause of unintentional injury death in the state, surpassing motor vehicle accidents, falls, and drowning. Moreover, there are even more non-fatal overdoses and cases of opioid misuse and abuse, resulting in significant morbidity [75].

As prescription opioid abuse and unintentional overdose has become a growing concern, the amount of prescription opioids being provided to pharmacies in West Virginia has also grown. Between 2007 and 2012, more than 555 million prescriptions for hydrocodone and 224 million prescriptions for oxycodone were shipped to West Virginia pharmacies [49]. In 2018, West Virginia providers wrote 69.3 opioid prescriptions for every 100 persons, compared with the average U.S. rate of 51.4 prescriptions. This was among the top ten rates for 2018; however, it was also the lowest rate in the state since data became available in 2006 [74].

INITIATION AND MANAGEMENT OF THE PATIENT WITH CHRONIC PAIN

Healthcare professionals should know the best clinical practices in opioid prescribing, including the associated risks of opioids, approaches to the assessment of pain and function, and pain management modalities. Pharmacologic and nonpharmacologic approaches should be used on the basis of current knowledge in the evidence base or best clinical practices. Patients with moderate-to-severe chronic pain who have been assessed and treated, over a period of time, with non-opioid therapy or nonpharmacologic pain therapy without adequate pain relief, are considered to be candidates for a trial of opioid therapy [17; 65]. Initial treatment should always be considered individually determined and as a trial of therapy, not a definitive course of treatment [18].

In 2016, the CDC issued updated guidance on the prescription of opioids for chronic pain [65]. The guideline addresses when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. A revision of the guidelines is expected in 2022 [81].

PATIENT EVALUATION AND ASSESSMENT OF ADDICTION RISK

Information obtained by patient history, physical examination, and interview, from family members, a spouse, or state prescription drug monitoring program (PDMP), and from the use of screening and assessment tools can help the clinician to stratify the patient according to level of risk for developing problematic opioid behavioral responses (**Table 1**). Low-risk patients receive the standard level of monitoring, vigilance, and care. Moderate-risk patients should be considered for an additional level of monitoring and provider contact, and high-risk patients are likely to require intensive and structured monitoring and follow-up contact, additional consultation with psychiatric and addiction medicine specialists, and limited supplies of short-acting opioid formulations [19; 65].

Before deciding to prescribe an opioid analgesic, clinicians should perform and document a detailed patient assessment that includes [1]:

- Pain indications for opioid therapy
- Nature and intensity of pain
- Past and current pain treatments and patient response
- Comorbid conditions
- Pain impact on physical and psychologic function
- Social support, housing, and employment
- Home environment (i.e., stressful or supportive)
- Pain impact on sleep, mood, work, relationships, leisure, and substance use
- Patient history of physical, emotional, or sexual abuse

RISK STRATIFICATION FOR PATIENTS PRESCRIBED OPIOIDS	
Low Risk	
Definable physical pathology with objective signs and reliable symptoms Clinical correlation with diagnostic testing, including MRI, physical examination, and interventional diagnostic techniques With or without mild psychologic comorbidity With or without minor medical comorbidity No or well-defined and controlled personal or family history of alcoholism or substance abuse Age 45 years or older High levels of pain acceptance and active coping strategies High motivation and willingness to participate in multimodal therapy and attempting to function at normal levels	
Medium Risk	
Significant pain problems with objective signs and symptoms confirmed by radiologic evaluation, physical examination, or diagnostic interventions Moderate psychologic problems, well controlled by therapy Moderate coexisting medical disorders that are well controlled by medical therapy and are not affected by chronic opioid therapy (e.g., central sleep apnea) Develops mild tolerance but not hyperalgesia without physical dependence or addiction Past history of personal or family history of alcoholism or substance abuse Pain involving more than three regions of the body Defined pathology with moderate levels of pain acceptance and coping strategies Willing to participate in multimodal therapy, attempting to function in normal daily life	
High Risk	
Widespread pain without objective signs and symptoms Pain involving more than three regions of the body Aberrant drug-related behavior History of alcoholism or drug misuse, abuse, addiction, diversion, dependency, tolerance, or hyperalgesia Major psychologic disorders Age younger than 45 years HIV-related pain High levels of pain exacerbation and low levels of coping strategies Unwilling to participate in multimodal therapy, not functioning close to a near normal lifestyle	
HIV = human immunodeficiency syndrome, MRI = magnetic resonance imaging.	
Source: [20]	Table 1

If substance abuse is active, in remission, or in the patient's history, consult an addiction specialist before starting opioids [1]. In active substance abuse, do not prescribe opioids until the patient is engaged in treatment/recovery program or other arrangement made, such as addiction professional

co-management and additional monitoring. When considering an opioid analgesic (particularly those that are extended-release or long-acting), one must always weigh the benefits against the risks of overdose, abuse, addiction, physical dependence and tolerance, adverse drug interactions, and accidental exposure by children [21; 65].

Screening and assessment tools can help guide patient stratification according to risk level and inform the appropriate degree of structure and monitoring in the treatment plan. It should be noted that despite widespread endorsement of screening tool use to help determine patient risk level, most tools have not been extensively evaluated, validated, or compared to each other, and evidence of their reliability is poor [20].

Opioid Risk Tool (ORT)

The Opioid Risk Tool (ORT) is a five-item assessment to help predict aberrant drug-related behavior. The ORT is also used to establish patient risk level through categorization into low, medium, or high levels of risk for aberrant drug-related behaviors based on responses to questions of previous alcohol/drug abuse, psychologic disorders, and other risk factors [22].

Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)

The Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) is a patient-administered, 24-item screen with questions addressing history of alcohol/substance use, psychologic status, mood, cravings, and stress. Like the ORT, the SOAPP-R helps assess risk level of aberrant drug-related behaviors and the appropriate extent of monitoring [23].

CAGE and CAGE-AID

The original CAGE (Cut down, Annoyed, Guilty, and Eye-opener) Questionnaire consisted of four questions designed to help clinicians determine the likelihood that a patient was misusing or abusing alcohol. These same four questions were modified to create the CAGE-AID (adapted to include drugs), revised to assess the likelihood of current substance abuse [24].

Diagnosis, Intractability, Risk, and Efficacy (DIRE) Tool

The Diagnosis, Intractability, Risk, and Efficacy (DIRE) risk assessment tool is a clinician-rated questionnaire that is used to predict patient compliance with long-term opioid therapy [25]. Patients scoring lower on the DIRE tool are poor candidates for long-term opioid analgesia.

Mental Health Screening Tool

The Mental Health Screening Tool is a five-item screen that asks about a patient's feelings of happiness, calmness, peacefulness, nervousness, and depression in the past month [26]. A lower score on this tool is an indicator that the patient should be referred to a specialist for pain management.

CREATING A TREATMENT PLAN

Opioid therapy should be presented as a trial for a pre-defined period (e.g., ≤ 30 days). The goals of treatment should be established with all patients prior to the initiation of opioid therapy, including reasonable improvements in pain, function, depression, anxiety, and avoidance of unnecessary or excessive medication use [1; 65]. The treatment plan should describe therapy selection, measures of progress, and other diagnostic evaluations, consultations, referrals, and therapies.

In opioid-naïve patients, start at the lowest possible dose and titrate to effect. Dosages for opioid-tolerant patients should always be individualized and titrated by efficacy and tolerability [1; 65]. When starting opioid therapy for chronic pain, clinicians should prescribe short-acting instead of extended-release/long-acting opioid formulations [65].

The need for frequent progress and benefit/risk assessments during the trial should be included in patient education. Patients should also have full knowledge of the warning signs and symptoms of respiratory depression. Prescribers should carefully reassess evidence of benefits and risks when increasing the dosage to ≥ 50 mg morphine equivalent dose (MED) per day. Decisions to titrate dose to ≥ 90 mg MED/day should be avoided or carefully justified [65].

Prescribers should be knowledgeable of federal and state opioid prescribing regulations. Issues of equianalgesic dosing, close patient monitoring during all dose changes, and cross-tolerance with opioid conversion should be considered. If necessary, treatment may be augmented, with preference for nonopioid and immediate-release opioids over long-acting/extended-release opioids. Taper opioid dose when no longer needed [21].

Informed Consent and Treatment Agreements

The initial opioid prescription is preceded by a written informed consent or “treatment agreement” [1]. This agreement should address potential side effects, tolerance and/or physical dependence, drug interactions, motor skill impairment, limited evidence of long-term benefit, misuse, dependence, addiction, and overdose. Informed consent documents should include information regarding the risk/benefit profile for the drug(s) being prescribed. The prescribing policies should be clearly delineated, including the number/frequency of refills, early refills, and procedures for lost or stolen medications.

The treatment agreement also outlines joint physician and patient responsibilities. The patient agrees to using medications safely, refraining from “doctor shopping,” and consenting to routine urine drug testing (UDT). The prescriber’s responsibility is to address unforeseen problems and prescribe scheduled refills. Reasons for opioid therapy change or discontinuation should be listed. Agreements can also include sections related to follow-up visits, monitoring, and safe storage and disposal of unused drugs.

PERIODIC REVIEW AND MONITORING

When implementing a chronic pain treatment plan that involves the use of opioids, the patient should be frequently reassessed for changes in pain origin, health, and function [1]. This can include input from family members and/or the state PDMP. During the initiation phase and during any changes to the dosage or agent used, patient contact should be increased. At every visit, chronic opioid response may be monitored according to the “5 A’s” [1; 28]:

- Analgesia
- Activities of daily living
- Adverse or side effects
- Aberrant drug-related behaviors
- Affect (i.e., patient mood)



The American Society of Interventional Pain Physicians recommends monitoring patients prescribed opioids for adherence, abuse, and noncompliance by urine drug test and prescription drug monitoring programs.

(<https://painphysicianjournal.com/current/pdf?article=NDIwMg%3D%3D&journal=103>. Last accessed April 17, 2020.)

Strength of Recommendation/Level of Evidence:

Moderate-to-strong recommendation based on high-quality randomized controlled trials

Signs and symptoms that, if present, may suggest a problematic response to the opioid and interference with the goal of functional improvement include [27]:

- Excessive sleeping or days and nights turned around
- Diminished appetite
- Short attention span or inability to concentrate
- Mood volatility, especially irritability
- Lack of involvement with others
- Impaired functioning due to drug effects
- Use of the opioid to regress instead of re-engaging in life
- Lack of attention to hygiene and appearance

The decision to continue, change, or terminate opioid therapy is based on progress toward treatment objectives and absence of adverse effects and risks of overdose or diversion [1]. Satisfactory therapy is indicated by improvements in pain, function, and quality of life. Brief assessment tools to assess pain and function may be useful, as may UDTs. Treatment plans may include periodic pill counts to confirm adherence and minimize diversion.

Involvement of Family

Family members of the patient can provide the clinician with valuable information that better informs decision making regarding continuing opioid therapy. Family members can observe whether a patient is losing control of his or her life or becoming less functional or more depressed during the course of opioid therapy. They can also provide input regarding positive or negative changes in patient function, attitude, and level of comfort. The following questions can be asked of family members or a spouse to help clarify whether the patient's response to opioid therapy is favorable or unfavorable [27]:

- Is the person's day centered around taking the opioid medication? Response can help clarify long-term risks and benefits of the medication and identify other treatment options.
- Does the person take pain medication only on occasion, perhaps three or four times per week? If yes, the likelihood of addiction is low.
- Have there been any other substance (alcohol or drug) abuse problems in the person's life? An affirmative response should be taken into consideration when prescribing.
- Does the person in pain spend most of the day resting, avoiding activity, or feeling depressed? If so, this suggests the pain medication is failing to promote rehabilitation. Daily activity is essential, and the patient may be considered for enrollment in a graduated exercise program.
- Is the person in pain able to function (e.g., work, do household chores, play) with pain medication in a way that is clearly better than without? If yes, this suggests the pain medication is contributing to wellness.

Assessment Tools

VIGIL

VIGIL is the acronym for a five-step risk management strategy designed to empower clinicians to appropriately prescribe opioids for pain by reducing regulatory concerns and to give pharmacists a framework for resolving ambiguous opioid analgesic prescriptions in a manner that preserves legitimate patient need while potentially deterring diverters. The components of VIGIL are:

- Verification: Is this a responsible opioid user?
- Identification: Is the identity of this patient verifiable?
- Generalization: Do we agree on mutual responsibilities and expectations?
- Interpretation: Do I feel comfortable allowing this person to have controlled substances?
- Legalization: Am I acting legally and responsibly?

The foundation of VIGIL is a collaborative physician/pharmacist relationship [29].

Current Opioid Misuse Measure (COMM)

The Current Opioid Misuse Measure (COMM) is a 17-item patient self-report assessment designed to help clinicians identify misuse or abuse in chronic pain patients. Unlike the ORT and the SOAPP-R, the COMM identifies aberrant behaviors associated with opioid misuse in patients already receiving long-term opioid therapy [19]. Sample questions include: In the past 30 days, how often have you had to take more of your medication than prescribed? In the past 30 days, how much of your time was spent thinking about opioid medications (e.g., having enough, taking them, dosing schedule)?

PATIENT RISK LEVEL AND FREQUENCY OF MONITORING			
Monitoring Tool	Patient Risk Level		
	Low	Medium	High
Urine drug test	Every 1 to 2 years	Every 6 to 12 months	Every 3 to 6 months
State prescription drug monitoring program	Twice per year	Three times per year	Four times per year
Source: [31]			Table 2

Pain Assessment and Documentation Tool (PADT)

Guidelines by the CDC, the Federation of State Medical Boards (FSMB), and the Joint Commission stress the importance of documentation from both a healthcare quality and medicolegal perspective. Research has found widespread deficits in chart notes and progress documentation with chronic pain patients receiving opioid therapy, and the Pain Assessment and Documentation Tool (PADT) was designed to address these shortcomings [30]. The PADT is a clinician-directed interview, with most sections (e.g., analgesia, activities of daily living, adverse events) consisting of questions asked of the patient. However, the potential aberrant drug-related behavior section must be completed by the physician based on his or her observations of the patient.

The Brief Intervention Tool

The Brief Intervention Tool is a 26-item, “yes-no,” patient-administered questionnaire used to identify early signs of opioid abuse or addiction. The items assess the extent of problems related to drug use in several areas, including drug use-related functional impairment [26].

Urine Drug Tests

UDTs may be used to monitor adherence to the prescribed treatment plan and to detect unsanctioned drug use. They should be used more often in patients receiving addiction therapy, but clinical judgment is the ultimate guide to testing frequency (*Table 2*) [31]. The CDC recommends clinicians should use UDT before starting opioid therapy

and consider UDT at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs [65]. However, this recommendation was based on low-quality evidence that indicates little confidence in the effect estimate.

Initially, testing involves the use of class-specific immunoassay drug panels [1]. If necessary, this may be followed with gas chromatography/mass spectrometry for specific drug or metabolite detection. It is important that testing identifies the specific drug rather than the drug class, and the prescribed opioid should be included in the screen. Any abnormalities should be confirmed with a laboratory toxicologist or clinical pathologist. Immunoassay may be used point-of-care for “on-the-spot” therapy changes, but the high error rate prevents its use in major clinical decisions except with liquid chromatography coupled to tandem mass spectrometry confirmation.

Urine test results suggesting opioid misuse should be discussed with the patient using a positive, supportive approach. The test results and the patient discussion should be documented.

CONSULTATION AND REFERRAL

It is important to seek consultation or patient referral when input or care from a pain, psychiatry, addiction, or mental health specialist is necessary. Clinicians who prescribe opioids should become familiar with opioid addiction treatment options (including licensed opioid treatment programs for methadone and office-based opioid treatment for buprenorphine) if referral is needed [1].

Ideally, providers should be able to refer patients with active substance abuse who require pain treatment to an addiction professional or specialized program. In reality, these specialized resources are scarce or non-existent in many areas [1]. Therefore, each provider will need to decide whether the risks of continuing opioid treatment while a patient is using illicit drugs outweigh the benefits to the patient in terms of pain control and improved function [33].

MEDICAL RECORDS

As noted, documentation is a necessary aspect of all patient care, but it is of particular importance when opioid prescribing is involved. All clinicians should maintain accurate, complete, and up-to-date medical records, including all written or telephoned prescription orders for opioid analgesics and other controlled substances, all written instructions to the patient for medication use, and the name, telephone number, and address of the patient's pharmacy [1]. Good medical records demonstrate that a service was provided to the patient and that the service was medically necessary. Regardless of the treatment outcome, thorough medical records protect the prescriber.

PATIENT EDUCATION ON THE USE AND DISPOSAL OF OPIOIDS

Patients and caregivers should be counseled regarding the safe use and disposal of opioids. As part of its mandatory Risk Evaluation and Mitigation Strategy (REMS) for extended-release/long-acting opioids, the U.S. Food and Drug Administration (FDA) has developed a patient counseling document with information on the patient's specific medications, instructions for emergency situations and incomplete pain control, and warnings not to share medications or take them unprescribed [21]. A copy of this form may be accessed online at <https://www.fda.gov/media/114694/download>.

When prescribing opioids, clinicians should provide patients with the following information [21]:

- Product-specific information
- Taking the opioid as prescribed
- Importance of dosing regimen adherence, managing missed doses, and prescriber contact if pain is not controlled
- Warning and rationale to never break or chew/crush tablets or cut or tear patches prior to use
- Warning and rationale to avoid other central nervous system depressants, such as sedative-hypnotics, anxiolytics, alcohol, or illicit drugs
- Warning not to abruptly halt or reduce the opioid without physician oversight of safe tapering when discontinuing
- The potential of serious side effects or death
- Risk factors, signs, and symptoms of overdose and opioid-induced respiratory depression, gastrointestinal obstruction, and allergic reactions
- The risks of falls, using heavy machinery, and driving
- Warning and rationale to never share an opioid analgesic
- Rationale for secure opioid storage
- Warning to protect opioids from theft
- Instructions for disposal of unneeded opioids, based on product-specific disposal information

There are no universal recommendations for the proper disposal of unused opioids, and patients are rarely advised of what to do with unused or expired medications [34]. According to the FDA, most medications that are no longer necessary or have expired should be removed from their containers, mixed with undesirable substances (e.g., cat litter, used coffee grounds), and put into an impermeable, nondescript container (e.g., disposable container with a lid or a sealed bag) before throwing in the trash [35]. Any personal information should be obscured or destroyed. The FDA recommends that certain medications, including oxycodone/acetaminophen (Percocet), oxycodone (OxyContin tablets), and transdermal fentanyl (Duragesic

Transdermal System), be flushed down the toilet instead of thrown in the trash [35]. Patients should be advised to flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so.

The American College of Preventive Medicine has established best practices to avoid diversion of unused drugs and educate patients regarding drug disposal [34]:

- Consider writing prescriptions in smaller amounts.
- Educate patients about safe storing and disposal practices.
- Give drug-specific information to patients about the temperature at which they should store their medications. Generally, the bathroom is not the best storage place. It is damp and moist, potentially resulting in potency decrements, and accessible to many people, including children and teens, resulting in potential theft or safety issues.
- Ask patients not to advertise that they are taking these types of medications and to keep their medications secure.
- Refer patients to community “take back” services overseen by law enforcement that collect controlled substances, seal them in plastic bags, and store them in a secure location until they can be incinerated. Contact your state law enforcement agency or visit <https://www.dea.gov> to determine if a program is available in your area.

DISCONTINUING OPIOID THERAPY

The decision to continue or end opioid prescribing should be based on a physician-patient discussion of the anticipated benefits and risks. An opioid should be discontinued with resolution of the pain condition, intolerable side effects, inadequate analgesia, lack of improvement in quality of life despite dose titration, deteriorating function, or significant aberrant medication use [1; 65].

Clinicians should provide physically dependent patients with a safely structured tapering protocol. Withdrawal is managed by the prescribing physician or referral to an addiction specialist. Patients should be reassured that opioid discontinuation is not the end of treatment; continuation of pain management will be undertaken with other modalities through direct care or referral.

As a side note, cannabis use by patients with chronic pain receiving opioid therapy has traditionally been viewed as a treatment agreement violation that is grounds for termination of opioid therapy. However, some now argue against cannabis use as a rationale for termination or substantial treatment and monitoring changes, especially considering the increasing legalization of medical use at the state level [33].

CONSIDERATIONS FOR NON-ENGLISH-PROFICIENT PATIENTS

For patients who are not proficient in English, it is important that information regarding the risks associated with the use of opioids and available resources be provided in their native language, if possible. When there is an obvious disconnect in the communication process between the practitioner and patient due to the patient’s lack of proficiency in the English language, an interpreter is required. Interpreters can be a valuable resource to help bridge the communication and cultural gap between patients and practitioners. Interpreters are more than passive agents who translate and transmit information back and forth from party to party. When they are enlisted and treated as part of the interdisciplinary clinical team, they serve as cultural brokers who ultimately enhance the clinical encounter. In any case in which information regarding treatment options and medication/treatment measures are being provided, the use of an interpreter should be considered. Print materials are also available in many languages, and these should be offered whenever necessary.

CRISIS INTERVENTION: MANAGEMENT OF OVERDOSE

Individuals who have first contact with persons suspected of experiencing an opioid-related overdose are in the position to intervene to prevent the potentially devastating consequences. In these cases, care begins with crisis intervention directed at immediate survival by reversing the potentially lethal effects of overdose with an opioid antagonist.

Opioid antagonists have obvious therapeutic value in the treatment of opioid overdose. A 2015 study found that wider distribution of naloxone and training in its administration might have prevented numerous deaths from opioid overdoses in the United States [59]. Since the first community-based opioid overdose prevention program began distributing naloxone in 1996, more than 26,000 overdoses have been reversed [59].

In West Virginia, licensed healthcare providers may prescribe opioid antagonists (even as a standing order) for at-risk individuals, these individuals' relatives or other caregivers, and initial responders to be used in their course of duties [61]. Initial responders are legally defined as trained emergency medical service personnel, including (but not limited to) peace officers, firefighters, and persons acting under the color of the law [61].

OPIOID ANTAGONISTS

Relatively minor changes in the structure of an opioid can convert an agonist drug into one with antagonistic actions at one or more opioid receptor types. Opioid antagonists include naloxone, naltrexone, and nalmefene. Interestingly, naloxone also appears to block the analgesic effects of placebo medications and acupuncture. These agents have little or no potential for abuse [58].

In response to acute overdose, the short-acting opioid antagonist naloxone is considered the “gold standard,” and it remains the most widely used opioid antagonist for the reversal of overdose and opioid-related respiratory depression. It acts by competing with opioids at receptor sites in the brain stem, reversing desensitization to carbon dioxide, and reversing or preventing respiratory failure and coma. There is no evidence that subcutaneous or intramuscular use is inferior to intravenous naloxone. This has prompted some states, including West Virginia, to pass laws allowing opioid antagonists to be available to the general public for administration outside the healthcare setting to treat acute opioid overdose [60].

When used for opioid overdose, a dose of 0.4–2 mg of naloxone is administered intravenously, intramuscularly, or subcutaneously [62]. An intranasal formulation is also available in doses of 2 mg, 4 mg, or 8 mg [79]. If necessary, the dose may be repeated every 2 to 3 minutes for full reversal. For ease of use, naloxone is also available in a pre-filled auto-injection device. It is important that standard Advanced Cardiac Life Support (ACLS) protocols be continued while naloxone is being administered and that medical treatment (at a healthcare facility) be given immediately.

As of 2016, pharmacists and pharmacy interns in West Virginia are permitted to dispense naloxone without a prescription under specific conditions according to protocol [66]. The protocol mandates that before providing a naloxone product, the pharmacist or intern shall screen the potential recipient by asking whether the person to whom the naloxone would be administered has a known hypersensitivity to naloxone. The pharmacist or intern is also required to provide the recipient with appropriate counseling and information on the product, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety, and contact information (1-844-HELP-4-WV) for substance abuse treatment and recovery services near them if the recipient indicates interest in such services [9].

COMPLIANCE WITH STATE AND FEDERAL LAWS

In response to the rising incidence in prescription opioid abuse, addiction, diversion, and overdose since the late 1990s, the FDA has mandated opioid-specific REMS to reduce the potential negative patient and societal effects of prescribed opioids. Other elements of opioid risk mitigation include FDA partnering with other governmental agencies, state professional licensing boards, and societies of healthcare professionals to help improve prescriber knowledge of appropriate and safe opioid prescribing and safe home storage and disposal of unused medication [27].

Several regulations and programs at the state level have been enacted in an effort to reduce prescription opioid abuse, diversion, and overdose, including [36]:

- Physical examination required prior to prescribing
- Tamper-resistant prescription forms
- Pain clinic regulatory oversight
- Prescription limits
- Prohibition from obtaining controlled substance prescriptions from multiple providers
- Patient identification required before dispensing
- Immunity from prosecution or mitigation at sentencing for individuals seeking assistance during an overdose

CONTROLLED SUBSTANCES LAWS/RULES

The U.S. Drug Enforcement Administration (DEA) is responsible for formulating federal standards for the handling of controlled substances. In 2011, the DEA began requiring every state to implement electronic databases that track prescrib-

ing habits, referred to as PDMPs. Specific policies regarding controlled substances are administered at the state level [37].

According to the DEA, drugs, substances, and certain chemicals used to make drugs are classified into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential [38]. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs are considered the most dangerous class of drugs with a high potential for abuse and potentially severe psychologic and/or physical dependence.

In West Virginia, the prescribing, dispensing, and consumption of certain controlled substances are governed by West Virginia Code Chapter 60A (**Appendix**) [39]. This law establishes the standards for controlled substance prescribing, including reporting system requirements, for prescribers and pharmacists in West Virginia.

Senate Bills 362, 365, and 514 were all enacted in 2010 to modify or clarify points in Chapter 60A related to controlled substances prescribing, monitoring, or dispensing [53]. Senate Bill 362 clarifies that it is unlawful to provide misleading or false information to a medical practitioner in order to obtain more than one prescription for a controlled substance and increases penalties for this “doctor shopping” [53]. Senate Bill 365 requires all prescribers and dispensers of controlled substances to have electronic access to the Controlled Substances Monitoring Program database. Finally, Senate Bill 514 expanded the requirement to report the dispensing of Schedule III and IV drugs in addition to Schedule II [53].

Also in 2010, the state legislature enacted Senate Bill 81 to establish the West Virginia Official Prescription Program Act. This Bill requires the Board of Pharmacy to establish a rule implementing a statewide tamper-resistant prescription paper program [53].

WEST VIRGINIA SENATE BILL 437

In 2012, Senate Bill 437 was approved by the Governor Tomblin and enacted by the state legislature. This bill addresses the regulation of opioid treatment programs in the state, establishes limitations on the dispensing of controlled substances in pain management clinics, and requires that certain licensed or certified healthcare professionals complete training on drug diversion prevention and best practices in prescribing controlled substances, among many other actions [40]. This continuing education requirement applies to physicians, dentists, and nurses who prescribe, dispense, or administer controlled substances.

In addition, Senate Bill 437 created the Chronic Pain Clinic Licensing Act, which established licensing requirements for facilities that treat patients for chronic pain management [40]. A pain management clinic is defined in the Bill as any facility that advertises pain management services, employs a physician who is primarily engaged in the pharmacologic treatment of pain, includes the treatment of pain or chronic pain as the primary component of its practice, or for which the majority (more than 50%) of patients are provided treatment for pain or chronic pain [40].

In addition, licensed chronic pain management clinics must have at least one owner who is a physician actively licensed to practice medicine, surgery, or osteopathic medicine/surgery in West Virginia and is board-certified in pain management or has completed a pain medicine fellowship. This physician owner practices at and is responsible for the operation of the clinic [40]. Employees of the licensed pain clinic must not have been convicted of a felony; had their DEA number revoked for any reason; had their application to prescribe denied in any jurisdiction; or been convicted of or plead guilty or nolo contendere to an offense that constitutes a felony for receipt of illicit and diverted drugs, including controlled substances

[40]. Only physicians and pharmacists licensed in West Virginia may dispense any medication on the premises of a licensed pain management clinic. Certain facilities (e.g., licensed nursing homes, licensed hospice programs) are exempt from the requirements of this Act.

WEST VIRGINIA SENATE BILL 335

In 2015, the state legislature enacted Senate Bill 335, which included amendments related to accessing and administering opioid antagonists in overdose situations [61]. As one of several steps the state has taken to address the issue of opioid overdose deaths, the bill outlines the appropriate and legal prescription of opioid antagonists by licensed healthcare professionals to persons who may intervene to prevent fatality as a result of opioid overdose, including at-risk individuals, persons in a position to assist a person at risk for opioid overdose (e.g., relative, friend, caregiver), and initial responders [61]. All healthcare professionals who prescribe opioid antagonists are required to provide educational materials to the person/entity receiving the prescription, even if it is given by standing orders. The bill also limits the liability of healthcare professionals and administrators of the medication if it is given in good faith and with adequate education.

WEST VIRGINIA SENATE BILL 627

In 2016, Senate Bill 627 was enacted by the West Virginia Legislature [32]. This Bill amends the professional code of West Virginia to permit physicians to decline prescribing controlled substance in certain circumstances and to limit punishments to those who decline to prescribe, or decline to continue to prescribe, any controlled substance in certain circumstances. Specifically, prescribers are protected from disciplinary action and liability when they reasonably believe the patient is misusing or unlawfully diverting the controlled substance [32].

WEST VIRGINIA HOUSE BILL 2620

House Bill 2620, passed in 2017, establishes and sets the requirements for a central repository of drug overdose information in West Virginia, referred to as the Office of Drug Control Policy [4]. The Bill proposes that the following information will be collected and reported [4]:

- An emergency medical or law-enforcement response to a suspected or reported overdose or a response in which an overdose is identified by the responders
- Medical treatment for an overdose
- The dispensation or provision of an opioid antagonist
- Death attributed to overdose or “drug poisoning”

WEST VIRGINIA SENATE BILL 273

West Virginia Senate Bill 273 was enacted in September 2018 to address the ongoing opioid crisis in the state [68]. This bill, also referred to as the Opioid Reduction Act, establishes a voluntary nonopioid advance directive form and patient education requirements before prescribing a Schedule II opioid. It also sets opioid prescription limitations for all prescribers in West Virginia. According to this new law, opioid prescriptions should be limited to a three-day supply in all of the following cases [68]:

- Adult patients seeking treatment in an emergency room setting for outpatient use
- Any prescription to a minor (younger than 18 years of age)
- A prescription issued by a dentist or an optometrist

Physician prescribers are required to limit all other Schedule II opioid prescriptions to a maximum seven-day supply at the lowest effective dose. After issuing the initial prescription, the practitioner, after consultation with the patient, may issue a subsequent prescription for an opioid if the practitioner determines the prescription is necessary and appropriate to the patient’s treatment needs

and documents the rationale for the issuance of the subsequent prescription, and the practitioner determines that issuance of the subsequent prescription does not present an undue risk of abuse, addiction, or diversion and documents that determination [68; 76].

At the time of the issuance of the third prescription for a Schedule II opioid, the patient should be referred to a chronic pain clinic. If the patient remains a patient of the practitioner and the practitioner continues to prescribe an opioid for pain, the following steps must be taken [68]:

- Review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain, and the patient’s progress toward treatment objectives and document the results of that review.
- Assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychologic dependence and document the results of that assessment.
- Periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, and/or try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychologic dependence and document with specificity the efforts undertaken
- Review the Controlled Substance Monitoring Database as required.

The requirements of this bill do not apply to [69; 76]:

- Prescriptions for patients currently in active treatment for cancer, receiving hospice care from a licensed hospice provider or palliative care provider, or residents of a long-term care facility, or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

- An existing provider-patient relationship established before January 1, 2018, where there is an established and current opioid treatment plan reflected in the patient's medical record.
- Patients being prescribed, or ordered, any medication in an inpatient setting at a hospital.
- The prescribing of non-opioid Schedule II controlled substances and opioid medications not classified as Schedule II controlled substances.

Analysis of data collected from the Controlled Substances Monitoring Program analyzed the effects of SB 273 on prescribing practices in West Virginia [70]. After 2018 (and enactment of SB273), there was an average 22.1% decrease in overall opioid prescriptions. However, this trend started prior to 2018. Further, no change was noted in first-time opioid prescriptions or days' supply of opioid medication [70].

THE WV CONTROLLED SUBSTANCES MONITORING PROGRAM

Emerging trends and patterns of prescription opioid abuse, addiction, and overdose are monitored by several industry and government agencies through data collection from a variety of sources. These include health insurance claims; the Automation of Reports and Consolidated Orders System, a DEA-run program that monitors the flow of controlled substances from manufacturing through distribution to retail sale or dispensing; the Treatment Episode Data Set, which monitors treatment admissions; the National Center for Health Statistics state mortality data; and the Researched Abuse, Diversion, and Addiction-Related Surveillance System, which monitors prescription drug abuse, misuse, and diversion [41].

Almost all states, including West Virginia, have enacted PDMPs to facilitate the collection, analysis, and reporting of information on controlled substances prescribing and dispensing [1]. All clinicians who prescribe or dispense pain-relieving substances are required to register with the West

Virginia Controlled Substances Monitoring Program database within 30 days of licensure and to access the system for information regarding specific patients for whom they are providing controlled substances as part of a course of treatment for chronic, nonmalignant pain not due to terminal illness [54; 67]. This should be repeated at least annually for every patient who continues to be prescribed medications for pain. As of 2016, only physicians who maintain access to the Controlled Substances Monitoring Program may renew their licenses [67].

In addition to established patients, the Controlled Substances Monitoring Program may be queried prior to accepting a new patient in order to determine whether or not to accept the patient and provide treatment [63]. If relevant for the purposes of providing treatment, practitioners may also obtain information regarding a breastfeeding mother of a child patient. Clinicians may register and monitor prescriptions online at <https://www.csappwv.com>.

In West Virginia, all licensees who dispense Schedule II, III, and IV controlled substances to residents of West Virginia must provide the dispensing information to the West Virginia Board of Pharmacy each 24-hour period through the Controlled Substances Automated Prescription Program (CSAPP) [42]. This includes:

- Physicians
- Dentists
- Veterinarians
- Physician assistants
- Advanced practice nurses
- Other prescribers and dispensers

In addition, pharmacists and approved officers of law enforcement agencies whose primary mission involves enforcing prescription drug laws can register for a CSAPP account to access patient prescription reports. All patient information is kept confidential in compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules, and only those who have been credentialed and who agree to confidentiality requirements are provided access [42].

According to the Board of Pharmacy, prescribers and pharmacists authorized to access the patient information must certify before each search that they are seeking data solely for the purpose of providing health care to current patients [42]. Authorized users agree that they will not provide access to any other individuals, including members of their staff, unless and until they are authorized as designates. Any individual who violates this agreement is subject to civil penalties for each offense and disciplinary action by his or her professional licensing board [42].

The Board of Pharmacy is required to review records in the Controlled Substances Monitoring Program to identify abnormal or unusual practices of patients who exceed defined parameters and are therefore outliers in the collected data [63]. Prescribers and dispensers of the patients who exceed the parameters are contacted to inform them of the Board's findings. The Board of Pharmacy may also query the Controlled Substances Monitoring Program to identify abnormal prescribing and/or dispensing patterns of practitioners or for any relevant prescribing or dispensing records of involved patients or practitioners as it carries out its duty to review notices provided by the chief medical examiner and determine whether a practitioner who prescribed or dispensed a controlled substance may have resulted in or contributed to the drug overdose, and, if so, if the practitioner may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent [63].

IDENTIFICATION OF DRUG DIVERSION/SEEKING BEHAVIORS

Research has more closely defined the location of prescribed opioid diversion into illicit use in the supply chain from the manufacturer to the distributor, retailer, and the end user (the pain patient). This information carries with it substantial public policy and regulatory implications. The 2020

National Survey on Drug Use and Health asked non-medical users of prescription opioids how they obtained their most recently used drugs [43]. Among persons 12 years of age or older, 42.0% got them through a prescription from one doctor (vs. 17.3% in 2009–2010), 34.4% obtained their prescription opioids from a friend or relative for free, 9.2% bought them from a friend or relative, and 3.7% took them from a friend or relative without asking [43]. Less frequent sources included a drug dealer or other stranger (6.2%); multiple doctors (1.0%); and theft from a doctor's office, clinic, hospital, or pharmacy (0.6%) (vs. 0.2% in 2009–2010) [43].

As discussed, UDTs can give insight into patients who are misusing opioids. A random sample of UDT results from 800 pain patients treated at a Veterans Affairs facility found that 25.2% were negative for the prescribed opioid while 19.5% were positive for an illicit drug/unreported opioid [44]. Negative UDT results for the prescribed opioid do not necessarily indicate diversion, but may indicate the patient halted his/her use due to side effects, lack of efficacy, or pain remission. The concern arises over the increasingly stringent climate surrounding clinical decision-making regarding aberrant UDT results and that a negative result for the prescribed opioid or a positive UDT may serve as the pretense to terminate a patient rather than guide him/her into addiction treatment or an alternative pain management program [45].

In addition to aberrant urine screens, there are certain behaviors that are suggestive of an emerging opioid use disorder. The most suggestive behaviors are [33; 46; 47]:

- Selling medications
- Prescription forgery or alteration
- Injecting medications meant for oral use
- Obtaining medications from nonmedical sources
- Resisting medication change despite worsening function or significant negative effects

- Loss of control over alcohol use
- Using illegal drugs or non-prescribed controlled substances
- Recurrent episodes of:
 - Prescription loss or theft
 - Obtaining opioids from other providers in violation of a treatment agreement
 - Unsanctioned dose escalation
 - Running out of medication and requesting early refills

Behaviors with a lower level of evidence for their association with opioid misuse include [33; 46; 47]:

- Aggressive demands for more drug
- Asking for specific medications
- Stockpiling medications during times when pain is less severe
- Using pain medications to treat other symptoms
- Reluctance to decrease opioid dosing once stable
- In the earlier stages of treatment:
 - Increasing medication dosing without provider permission
 - Obtaining prescriptions from sources other than the pain provider
 - Sharing or borrowing similar medications from friends/family

INTERVENTIONS FOR SUSPECTED OR KNOWN DRUG DIVERSION

There are a number of actions that prescribers and dispensers can take to prevent or intervene in cases of drug diversion. These actions can be generally categorized based on the various mechanisms of drug diversion.

Prevention is the best approach to addressing drug diversion. As noted, the most common source of nonmedical use of prescribed opioids is from a family member or friend, through sharing, buying, or stealing. To avoid drug sharing among patients, healthcare professionals should educate patients on the dangers of sharing opioids and stress that “doing prescription drugs” is the same as “using street drugs” [34]. In addition, patients should be aware of the many options available to treat chronic pain aside from opioids. To prevent theft, patients should be advised to keep medications in a private place and to refrain from telling others about the medications being used.

Communication among providers and pharmacies can help to avoid inappropriate attainment of prescription drugs through “doctor shopping.” Prescribers should keep complete and up-to-date records for all controlled substance prescribing. When possible, electronic medical records should be integrated between pharmacies, hospitals, and managed care organizations [34]. It is also best practice to periodically request a report from the CSAPP to evaluate the prescribing of opioids to your patients by other providers [34].

When dealing with patients suspected of drug seeking/diversion, first inquire about prescription, over-the-counter, and illicit drug use and perform a thorough examination [34; 48]. Pill counting and/or UDT may be necessary to investigate possible drug misuse. Photo identification or other form of identification and social security number may be required prior to dispensing the drug, with proof of identity documented fully. If a patient is displaying suspicious behaviors, consider prescribing for limited quantities [48].

If a patient is found to be abusing prescribed opioids, this is considered a violation of the treatment agreement and the clinician must make the decision whether or not to continue the therapeutic relationship. If the relationship is terminated, it must be done ethically and legally. The most significant issue is the risk of patient abandonment, which is defined as ending a relationship with a

patient without consideration of continuity of care and without providing notice to the patient. The American Medical Association Code of Ethics states that physicians have an obligation to support continuity of care for their patients. While physicians have the option of withdrawing from a case, they should notify the patient (or authorized decision maker) long enough in advance to permit the patient to secure another physician and facilitate transfer of care when appropriate [55]. Patients may also be given resources and/or recommendations to help them locate a new clinician.

Patients with chronic pain found to have an ongoing substance abuse problem or addiction should be referred to a pain specialist for continued treatment. Theft or loss of controlled substances is reported to the DEA. If drug diversion has occurred, the activity should be documented and a report to law enforcement should be made [57].

CASE STUDY

An unemployed man, 64 years of age, is brought to an emergency department by ambulance, after his wife returned from work to find him lying on the couch, difficult to arouse and incoherent. He has a past history of hypertension, type 2 diabetes (non-insulin dependent), mild chronic obstructive pulmonary disease, and chronic back and shoulder pain, for which he has been prescribed hydrocodone/acetaminophen for many years. His wife reports that while he seemed his usual self when she left for work that morning, he had, in recent weeks, been more withdrawn socially, less active, and complained of greater discomfort from the back and shoulder pain. She knows little about his actual medication usage and expresses concern that he may have been taking more than the prescribed amount of “pain medicine.”

On evaluation, the patient is somnolent and arouses to stimulation but is non-communicative and unable to follow commands. His blood pressure is normal, he is afebrile, and there are no focal

neurologic deficits. Oxygen saturation, serum glucose, and routine laboratory studies (blood counts and metabolic profile) are normal except for mild elevation in blood urea nitrogen (BUN) and creatinine; the urine drug screen is negative except for opioids. Additional history from the family indicates that the patient has been admitted to other hospitals twice in the past three years with a similar presentation and recovered rapidly each time “without anything being found.”

Following admission, the patient remains stable-to-improved over the next 12 to 18 hours. By the following day, he is awake and conversant and looks comfortable. On direct questioning, he reports recent symptoms of depression but no suicidal ideation. The patient describes an increased preoccupation with his pain syndrome, difficulty sleeping at night, and little physical activity during the day, in part because of physical discomfort. He is vague about his medication regimen and admits to taking “occasional” extra doses of hydrocodone for pain relief.

The family is instructed to bring in all his pill bottles from home, which they do. In addition to the hydrocodone prescribed by his primary care physician, there is a recent refill of a prescription for the medication given to the patient at the time of his last hospital discharge six months earlier.

ASSESSMENT

A full evaluation, including radiographic studies and consultation with psychiatry and physical therapy, is completed. The working diagnosis for the patient’s acute illness is toxic encephalopathy caused by the sedative side effects of opioid medication on the central nervous system (CNS). It is explained that the combination of his advancing age and diabetes likely reduced the efficiency of his kidneys in clearing the medication and its metabolites, making him more susceptible to CNS sedation. It is noted that the patient and his wife have little understanding of the rationale, proper use and safeguards, potential side effects, and limited effectiveness of opioid use for chronic pain.

In addition, the patient is diagnosed with poorly controlled chronic pain syndrome secondary to osteoarthritis and degenerative disc disease; exacerbating factors include deconditioning and reactive depression. The use of an opioid analgesic, at least for the near term, is considered appropriate, if dosed properly, monitored closely, and integrated into a comprehensive, multidisciplinary plan that includes treatment of depression and the use of adjunctive, nonpharmacologic modalities of care. In the setting of possible early diabetic nephropathy, the option of utilizing an NSAID, except for very brief periods of break-through pain, is not considered to be a safe option.

At discharge, and in consultation with his primary care physician, a written treatment and management plan addressing all aspects of the patient's care is presented to the patient and his wife for discussion and consent. Among the key issues addressed are:

- Goals: Improvement in subjective pain experience; improved function of daily living manifested by regular walking exercise and improved social interaction with family and friends; relief of depression; and in the long-term, anticipated withdrawal of opioid medication and resumption of part-time work and/or volunteer community activity
- Outpatient physical therapy and back exercise program to increase core muscular strength, improve flexibility, reduce pain, and increase exercise tolerance
- Patient and family counseling regarding the safe use, dosage regulation, side effects, and proper disposal of opioid medication
- Joint patient-physician responsibilities as regards to regular follow-up, monitoring of goals and treatment effectiveness, avoidance of "doctor-shopping," and assent to single provider for prescription medication

FOLLOW-UP

On follow-up six weeks after discharge, the patient is noticeably improved. He reports that he feels stronger and is sleeping better. His affect is brighter, and he is getting out more. He has maintained his physical therapy and exercise routine and is compliant with his medication. Though he still has pain, it is noticeably less and he is coping better. He and his wife are encouraged by his progress, particularly in regard to his improved functional status.

CONCLUSION

Opioid analgesic medications can bring substantial relief to patients suffering from pain. However, the inappropriate use, abuse, and diversion of prescription drugs in America, particularly prescription opioids, has increased dramatically in recent years and has been identified as a national public health epidemic. A set of clinical tools, guidelines, and recommendations are now available for prescribers who treat patients with opioids. By implementing these tools, the clinician can effectively address issues related to the clinical management of opioid prescribing, opioid risk management, regulations surrounding the prescribing of opioids, and problematic opioid use by patients. In doing so, healthcare professionals are more likely to achieve a balance between the benefits and risks of opioid prescribing, optimize patient attainment of therapeutic goals, and avoid the risk to patient outcome, public health, and viability of their own practice imposed by deficits in knowledge.

APPENDIX

WEST VIRGINIA CODE CHAPTER 60A: UNIFORM CONTROLLED SUBSTANCES ACT

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

§60A-9-1. Short title.

This article shall be referred to as the West Virginia Controlled Substances Monitoring Act.

§60A-9-2. Establishment of program; purpose.

There is hereby established a West Virginia controlled substances monitoring act the purpose of which is to require the recordation and retention in a single repository of information regarding the prescribing, dispensing, and consumption of certain controlled substances.

§60A-9-3. Reporting system requirements; implementation; central repository requirement.

- (a) The Board of Pharmacy shall implement a program wherein a central repository is established and maintained which shall contain such information as is required by the provisions of this article regarding Schedule II, III, and IV controlled substance prescriptions written or filled in this state. In implementing this program, the Board of Pharmacy shall consult with the West Virginia State Police, the licensing boards of practitioners affected by this article, and affected practitioners.
- (b) The program authorized by subsection (a) of this section shall be designed to minimize inconvenience to patients, prescribing practitioners, and pharmacists while effectuating the collection and storage of the required information. The State Board of Pharmacy shall allow reporting of the required information by electronic data transfer where feasible, and where not feasible, on reporting forms promulgated by the Board. The information required to be submitted by the provisions of this article shall be required to be filed no more frequently than within twenty-four hours.

- (c) (1) The State Board of Pharmacy shall provide for the electronic transmission of the information required to be provided by this article by and through the use of a toll-free telephone line.
- (2) A dispenser who does not have an automated record-keeping system capable of producing an electronic report in the established format may request a waiver from electronic reporting. The request for a waiver shall be made to the State Board of Pharmacy in writing and shall be granted if the dispenser agrees in writing to report the data by submitting a completed "Pharmacy Universal Claim Form" as defined by legislative rule.

§60A-9-4. Required information.

- (a) Whenever a medical services provider dispenses a controlled substance listed in Schedule II, III, or IV, as established under the provisions of article 2 of this chapter or an opioid antagonist, or whenever a prescription for the controlled substance or opioid antagonist is filled by: (i) a pharmacist or pharmacy in this state; (ii) a hospital, or other healthcare facility, for outpatient use; or (iii) a pharmacy or pharmacist licensed by the Board of Pharmacy, but situated outside this state for delivery to a person residing in this state, the medical services provider, healthcare facility, pharmacist, or pharmacy shall, in a manner prescribed by rules promulgated by the Board of Pharmacy under this article, report the following information, as applicable:
 - (1) The name, address, pharmacy prescription number, and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing physician or dentist;
 - (2) The full legal name, address, and birth date of the person for whom the prescription is written;
 - (3) The name, address, and Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription;

- (4) The name and national drug code number of the Schedule II, III, and IV controlled substance or opioid antagonist dispensed;
 - (5) The quantity and dosage of the Schedule II, III, and IV controlled substance or opioid antagonist dispensed;
 - (6) The date the prescription was written and the date filled;
 - (7) The number of refills, if any, authorized by the prescription;
 - (8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, the first name, last name and middle initial, address, and birth date of the person picking up the prescription as set forth on the person's government-issued photo identification card shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the Board of Pharmacy; and
 - (9) The source of payment for the controlled substance dispensed.
- (b) The Board of Pharmacy may prescribe by rule promulgated under this article the form to be used in prescribing a Schedule II, III, and IV substance or opioid antagonist if, in the determination of the board, the administration of the requirements of this section would be facilitated.
- (c) Products regulated by the provisions of article ten of this chapter shall be subject to reporting pursuant to the provisions of this article to the extent set forth in said article.
- (d) Reporting required by this section is not required for a drug administered directly to a patient by a practitioner. Reporting is, however, required by this section for a drug dispensed to a patient by a practitioner: provided that the quantity dispensed by a prescribing practitioner to his or her own patient may not exceed an amount adequate to treat the patient for a maximum of 72 hours with no greater than two 72-hour cycles dispensed in any 15-day period of time.
- (e) The Board of Pharmacy shall notify a physician prescribing buprenorphine, or buprenorphine/naloxone within sixty days of the availability of an abuse-deterrent form of buprenorphine or buprenorphine/naloxone is approved by the Food and Drug Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch their patients using buprenorphine or buprenorphine/naloxone to the abuse-deterrent form of the drug.

§60A-9-4a. Verification of identity.

Prior to releasing a Schedule II, III, or IV controlled substance sold at retail, a pharmacist or pharmacy shall verify the full legal name, address, and birth date of the person receiving or otherwise acquiring the controlled substance by requiring the presentation of a valid government-issued photo identification card. This information shall be reported in accordance with the provisions of this article.

§60A-9-5. Confidentiality; limited access to records; period of retention; no civil liability for required reporting.

- (a) (1) The information required by this article to be kept by the State Board of Pharmacy is confidential and not subject to the provisions of chapter 29b of this code or obtainable as discovery in civil matters absent a court order and is open to inspection only by inspectors and agents of the State Board of Pharmacy, members of the West Virginia State Police expressly authorized by the Superintendent of the West Virginia State Police to have access to the information, authorized agents of local law-enforcement agencies as members of a federally affiliated drug task force, authorized agents of the federal Drug Enforcement Administration, duly authorized agents of the Bureau for Medical Services, duly authorized agents of the Office of the Chief Medical Examiner for use in post-mortem examinations, duly authorized agents of licensing boards of practitioners in this state and other states

authorized to prescribe Schedules II, III, and IV controlled substances, prescribing practitioners and pharmacists, and persons with an enforceable court order or regulatory agency administrative subpoena: provided that all law-enforcement personnel who have access to the Controlled Substances Monitoring Program database shall be granted access in accordance with applicable state laws and Board of Pharmacy legislative rules shall be certified as a West Virginia law-enforcement officer and shall have successfully completed United States Drug Enforcement Administration Diversion Training and National Association of Drug Diversion Investigation Training. All information released by the State Board of Pharmacy must be related to a specific patient or a specific individual or entity under investigation by any of the above parties except that practitioners who prescribe or dispense controlled substances may request specific data related to their Drug Enforcement Administration controlled substance registration number or for the purpose of providing treatment to a patient: provided, however, that the West Virginia Controlled Substances Monitoring Program Database Review Committee established in subsection (b) of this section is authorized to query the database to comply with said subsection.

- (2) Subject to the provisions of subdivision (1) of this subsection, the board shall also review the West Virginia Controlled Substance Monitoring Program database and issue reports that identify abnormal or unusual practices of patients who exceed parameters as determined by the advisory committee established in this section. The board shall communicate with practitioners and dispensers to more effectively manage the medications of their patients in the manner recommended by the advisory committee. All other reports produced by the board shall be kept con-

fidential. The board shall maintain the information required by this article for a period of not less than five years. Notwithstanding any other provisions of this code to the contrary, data obtained under the provisions of this article may be used for compilation of educational, scholarly, or statistical purposes, and may be shared with the West Virginia Department of Health and Human Resources for those purposes, as long as the identities of persons or entities and any personally identifiable information, including protected health information, contained therein shall be redacted, scrubbed, or otherwise irreversibly destroyed in a manner that will preserve the confidential nature of the information. No individual or entity required to report under section four of this article may be subject to a claim for civil damages or other civil relief for the reporting of information to the Board of Pharmacy as required under and in accordance with the provisions of this article.

- (3) The board shall establish an advisory committee to develop, implement, and recommend parameters to be used in identifying abnormal or unusual usage patterns of patients in this state. This advisory committee shall:
 - (A) Consist of the following members:
 - A physician licensed by the West Virginia Board of Medicine, a dentist licensed by the West Virginia Board of Dental Examiners, a physician licensed by the West Virginia Board of Osteopathic Medicine, a licensed physician certified by the American Board of Pain Medicine, a licensed physician board certified in medical oncology recommended by the West Virginia State Medical Association, a licensed physician board certified in palliative care recommended by the West Virginia Center on End of Life Care, a pharmacist licensed by the

West Virginia Board of Pharmacy, a licensed physician member of the West Virginia Academy of Family Physicians, an expert in drug diversion, and such other members as determined by the board.

- (B) Recommend parameters to identify abnormal or unusual usage patterns of controlled substances for patients in order to prepare reports as requested in accordance with subsection (a), subdivision (2) of this section.
 - (C) Make recommendations for training, research, and other areas that are determined by the committee to have the potential to reduce inappropriate use of prescription drugs in this state, including, but not limited to, studying issues related to diversion of controlled substances used for the management of opioid addiction.
 - (D) Monitor the ability of medical services providers, health care facilities, pharmacists, and pharmacies to meet the twenty-four hour reporting requirement for the Controlled Substances Monitoring Program set forth in section three of this article, and report on the feasibility of requiring real-time reporting.
 - (E) Establish outreach programs with local law enforcement to provide education to local law enforcement on the requirements and use of the Controlled Substances Monitoring Program database established in this article.
- (b) The Board of Pharmacy shall create a West Virginia Controlled Substances Monitoring Program Database Review Committee of individuals consisting of two prosecuting attorneys from West Virginia counties, two physicians with specialties which require extensive use of controlled substances, and a pharmacist who is trained in the use and abuse of controlled sub-

stances. The review committee may determine that an additional physician who is an expert in the field under investigation be added to the team when the facts of a case indicate that the additional expertise is required. The review committee, working independently, may query the database based on parameters established by the advisory committee. The review committee may make determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns indicated by outliers in the system or abnormal or unusual usage patterns of controlled substances by patients which the review committee has reasonable cause to believe necessitates further action by law enforcement or the licensing board having jurisdiction over the practitioners or dispensers under consideration. The review committee shall also review notices provided by the chief medical examiner pursuant to subsection (h), section 10, article 12, chapter 61 of this code and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance resulting in or contributing to the drug overdose may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent. Only in those cases in which there is reasonable cause to believe a breach of professional or occupational standards or a criminal act may have occurred, the review committee shall notify the appropriate professional licensing agency having jurisdiction over the applicable practitioner or dispenser and appropriate law-enforcement agencies and provide pertinent information from the database for their consideration. The number of cases identified shall be determined by the review committee based on a number that can be adequately reviewed by the review committee. The information obtained and developed may not be shared except as provided in this article and is not subject to the provisions of chapter 29b of this code or obtainable as discovering in civil matters absent a court order.

- (c) The Board of Pharmacy is responsible for establishing and providing administrative support for the advisory committee and the West Virginia Controlled Substances Monitoring Program Database Review Committee. The advisory committee and the review committee shall elect a chair by majority vote. Members of the advisory committee and the review committee may not be compensated in their capacity as members but shall be reimbursed for reasonable expenses incurred in the performance of their duties.
 - (d) The board shall promulgate rules with advice and consent of the advisory committee, in accordance with the provisions of article 3, chapter 29a of this code on or before June 1, 2013. The legislative rules must include, but shall not be limited to, the following matters: (1) identifying parameters used in identifying abnormal or unusual prescribing or dispensing patterns; (2) processing parameters and developing reports of abnormal or unusual prescribing or dispensing patterns for patients, practitioners and dispensers; (3) establishing the information to be contained in reports and the process by which the reports will be generated and disseminated; and (4) setting up processes and procedures to ensure that the privacy, confidentiality, and security of information collected, recorded, transmitted, and maintained by the review committee is not disclosed except as provided in this section.
 - (e) Persons or entities with access to the West Virginia Controlled Substances Monitoring Program database pursuant to this section may, pursuant to rules promulgated by the Board of Pharmacy, delegate appropriate personnel to have access to said database;
 - (f) Good faith reliance by a practitioner on information contained in the West Virginia Controlled Substances Monitoring Program database in prescribing or dispensing or refusing or declining to prescribe or dispense a schedule II, III, or IV controlled substance shall constitute an absolute defense in any civil or criminal action brought due to prescribing or dispensing or refusing or declining to prescribe or dispense.
 - (g) A prescribing or dispensing practitioner may notify law enforcement of a patient who, in the prescribing or dispensing practitioner's judgment, may be in violation of section 410, article four of this chapter, based on information obtained and reviewed from the controlled substances monitoring database. A prescribing or dispensing practitioner who makes a notification pursuant to this subsection is immune from any civil, administrative or criminal liability that otherwise might be incurred or imposed because of the notification if the notification is made in good faith.
 - (h) Nothing in the article may be construed to require a practitioner to access the West Virginia Controlled Substances Monitoring Program database except as provided in section 5a of this article.
 - (i) The Board of Pharmacy shall provide an annual report on the West Virginia Controlled Substance Monitoring Program to the Legislative Oversight Commission on Health and Human Resources Accountability with recommendations for needed legislation no later than January 1 of each year.
- §60A-9-5a. Practitioner requirements to conduct annual search of the database; required rulemaking.
- (a) All practitioners, as that term is defined in section 101, article 2 of this chapter who prescribe or dispense Schedule II, III, or IV controlled substances shall register for and have online or other form of electronic access to the West Virginia Controlled Substances Monitoring Program database, provided that upon issuance of a new license to a practitioner, the practitioner shall, within 30 days of issuance of the license, register for and have online or other form of electronic access to the West Virginia Controlled Substances Monitoring Program database.

- (b) Upon initially prescribing or dispensing any pain-relieving controlled substance for a patient and at least annually thereafter should the practitioner or dispenser continue to treat the patient with controlled substances, all persons with prescriptive or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and who are licensed by the Board of Medicine as set forth in article 3, chapter 30 of this code, the Board of Registered Professional Nurses as set forth in article 7, chapter 30 of this code, the Board of Dental Examiners as set forth in article 4, chapter 30 of this code and the Board of Osteopathic Medicine as set forth in article 14, chapter 30 of this code shall access the West Virginia Controlled Substances Monitoring Program database for information regarding specific patients for whom they are providing pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain but who are not suffering from a terminal illness. The information obtained from accessing the West Virginia Controlled Substances Monitoring Program database for the patient shall be documented in the patient's medical record. A pain-relieving controlled substance shall be defined as set forth in section 1, article 3a, chapter 30 of this code.
- (c) The various boards mentioned in subsection (b) above shall promulgate both emergency and legislative rules pursuant to the provisions of article 3, chapter 29a of this code to effectuate the provisions of this section.

§60A-9-6. Promulgation of rules.

The state board of pharmacy shall promulgate legislative rules to effectuate the purposes of this article in accordance with the provisions of chapter 29a of this code.

§60A-9-7. Criminal penalties.

- (a) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who fails to do so as directed by the board is guilty of a misdemeanor and, upon conviction thereof, shall be fined not less than \$100 nor more than \$500.
- (b) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who knowingly and willfully refuses to submit the information required by this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than six months or fined not more than \$1,000, or both confined and fined.
- (c) Any person who is required by the provisions of this article to submit information to the state Board of Pharmacy who knowingly submits thereto information known to that person to be false or fraudulent is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than one year or fined not more than \$5,000, or both confined and fined.
- (d) No practitioner required to register and access the West Virginia Controlled Substances Monitoring Program database under subsection (a), section 5-a, article 9 of this chapter, shall be granted a renewal of an existing license by the applicable state licensing board without first certifying that the practitioner has registered for and has access to the West Virginia Controlled Substances Monitoring Program database.
- (e) Any practitioner who fails to register for and have access to the West Virginia Controlled Substances Monitoring Program database as required in subsection (a), section 5a, article 9 of this chapter, shall, beginning July 1, 2016, be fined \$1,000 by the applicable licensing board.

All such fines collected pursuant to this subsection shall be transferred by the applicable licensing board to the Fight Substance Abuse Fund created under section 8 of this article.

- (f) Any practitioner or dispenser who is required to access the information contained in the West Virginia Controlled Substances Monitoring Program database as set forth in subsection (a) of section 5a of this article and fails to do so as directed by the rules of their licensing board shall be subject to such discipline as the licensing board deems appropriate and beginning July 1, 2016, subject to a \$100 fine per violation by the applicable licensing board. All such fines collected pursuant to this subsection shall be transferred by the applicable licensing board to the Fight Substance Abuse Fund created under section 8 of this article.
- (g) Any person granted access to the information required by the provisions of this article to be maintained by the state Board of Pharmacy, who shall willfully disclose the information required to be maintained by this article in a manner inconsistent with a legitimate law-enforcement purpose, a legitimate professional regulatory purpose, the terms of a court order or as otherwise expressly authorized by the provisions of this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail for not more than six months or fined not more than \$1,000, or both confined and fined.

(h) Unauthorized access or use or unauthorized disclosure for reasons unrelated to the purposes of this article of the information in the database is a felony punishable by imprisonment in a state correctional facility for not less than one year nor more than five years or fined not less than \$3,000 nor more than \$10,000, or both imprisoned and fined.

- (i) No practitioner who is required to register or submit information to the database pursuant to this article and who maintains a practice in an area of this state without available Internet connectivity is not subject to the penalties set forth in this section.

§60A-9-8. Creation of Fight Substance Abuse Fund.

There is hereby created a special revenue account in the state treasury, designated the Fight Substance Abuse Fund, which shall be an interest-bearing account. The fund shall consist of all moneys received from whatever source to further the purpose of this article. The fund shall be administered by the West Virginia Bureau for Public Health to provide funding for substance abuse prevention, treatment, treatment coordination, recovery and education. Any moneys remaining in the fund at the close of a fiscal year shall be carried forward for use in the next fiscal year. Fund balances shall be invested with the state's consolidated investment fund and any and all interest earnings on these investments shall be used solely for the purposes that moneys deposited in the fund may be used pursuant to this article.

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