Drug Diversion and Best Prescriptive Practices

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Purpose The purpose of this course is to train nurse about drug diversion and best practices in prescribing controlled substances for acute and chronic pain.

Goals Upon completion of this course, the healthcare provider should be able to:

- Discuss types of drugs being abused.
- · Explain 4 primary methods of obtaining diverted drugs.
- Discuss the 3 types of most commonly diverted drugs.
- · Discuss 2 main types of pain.
- Discuss the 5 classifications of controlled substances.
- Explain the Pain Care Bill of Rights.
- · Explain DEA registration.
- Explain the WV Controlled Substances Monitoring Program (CSMP).
- Discuss 4 different types of risk factors for substance abuse.
- Describe at least 5 patient indications that drugs have been diverted.
- Describe at least 8 characteristics of diverting/impaired healthcare workers.
- Describe at least 8 characteristics of drug diverters.
- Describe physical and other signs of substance abuse.
- Describe pain assessment.
- Discuss common adverse effects of opioid analgesia.
- Discuss treatment plan for treating acute pain.
- Discuss treatment plan for treating chronic non-malignant pain.

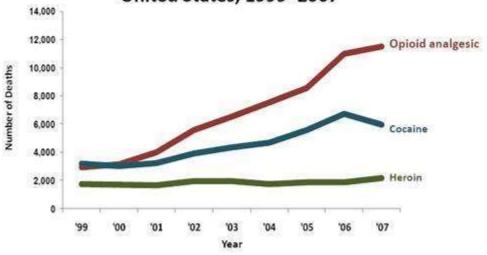
- Discuss alternative treatments, including medications and complementary therapies.
- Discuss the use of a functional capacity assessment.
- Describe West Virginal regulations regarding prescription of controlled substances for chronic non-malignant pain.
- · Describe a treatment contract.
- Discuss documentation, counts, and disposal of controlled substances.

Introduction

While healthcare providers are rightly concerned about the abuse of illegal drugs, following marijuana, prescription drugs are the secondmost abused category of drugs in the United States, and they are some of the most deadly if used for non-medical reasons. Diverted opioid drugs have been implicated in almost as many overdose deaths in recent years as illicit drugs.

Between 1998 and 2008, there was a 400% increase in treatment admissions related to abuse of prescription pain relievers. In 2007 alone, 28,000 people in the US died of unintentional overdoses with about 12,000 involving the use of prescription opioid analgesics.

Unintentional Overdose Deaths Involving Opioid Analgesics, Cocaine and Heroin United States, 1999–2007

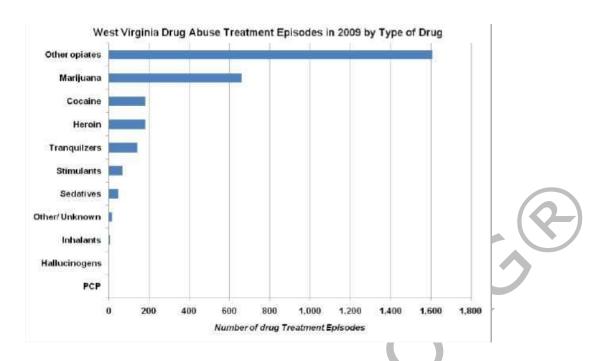


Source: Centers for Disease Control and Prevention. Unintentional Drug Poisoning in the United States (July 2010).

According to one-month statistics compiled in the 2009 National Survey on Drug Use and Health, the number of people abusing drugs is of great concern:

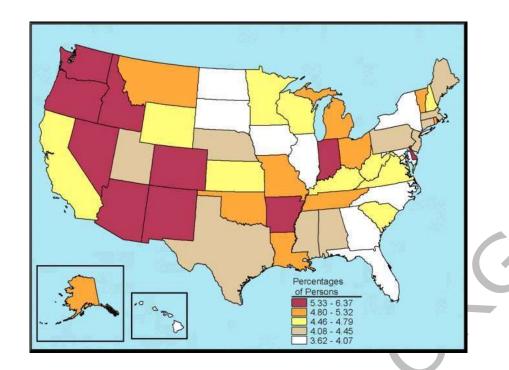
- 16.7 million: Marijuana.
- 7 million: Prescription drugs.
- 1.6 million: Cocaine.
- 0.5 million: Crack.
- 0.8 million: Ecstasy.
- 0.6 million: Inhalants.
- · 0.5 million: Methamphetamine.
- 0.2 million: Heroin.
- 0.2 million: LSD.

In West Virginia, statistics from 2009 regarding primary treatment admissions for substance abuse show that opiates, including prescription drugs, are the most commonly abused drugs.



West Virginia has made a concerted effort to reduce diversion of prescription drugs and use of illicit drugs. National drug surveys conducted in 2010-2011 show the percentages of the state populations 12 years and older using prescription pain medications for non-medical reasons ranging from a high of 6.37% (Oregon) to a low of 3.62% (Iowa) with West Virginia in the middle with a rate of 4.79%, with the highest rates of use for those between the ages of 18 and 25.

Non-medical use of prescription drugs (2010-2011), ages 12 & older:



Drugs can be diverted anywhere from the process of manufacturing to distribution and administration, but most drugs are diverted from family or friends. Methods of drug diversion include telephone fraud, prescription altering/forgery, drug-seeking from healthcare practitioners, theft (internal/external), and indiscriminate prescribing.

In some cases, prescriptions have been modified to increase the number of units ordered, such as increasing dosage from 10 to 40 pills. Prescription pads have been stolen or forged.

Methods of obtaining diverted drugs		
70%	From friend or relative (free, purchased, or stolen). (Eighty percent of these were from prescriptions obtained from one healthcare provider.)	
18%	From one healthcare provider (usually a physician).	
5%	From dealer or stranger.	
<0.5%	From the Internet.	

While only 18% of diverted drugs are directly obtained from one healthcare practitioner, in many cases controlled drugs diverted from medicine cabinets in homes can be traced to over-prescription. In the

United States, far more controlled substances are prescribed than needed for legitimate treatment.

Most-commonly diverted drugs		
Opioids		Oxycodone (Percocet, Tylox, OxyContin)
		Hydrocodone (Vicodin, Lortab)
		Methadone (Dolophine)
CNS		Butalbital (Fiorinal, Fiorocet)
depressants		Diazepam (Valium)
		Alprazolam (Xanax)
Stimulants		Methylphenidate (Ritalin)
		Amphetamine/ dextroamphetamine (Adderall)

Types of pain

Nociceptive (Acute pain)

Nociceptive (acute) pain occurs as a response to stimulation of the

peripheral nerves, such as from trauma. Acute pain relates directly to the type and extent of injury and is usually self-limiting in that, as the condition that caused the pain heals, the pain subsides.

Acute pain may be related to trauma (falls, injuries), procedures (manipulation of wounds or dressing changes), acute inflammation (appendicitis), and surgical incisions.

Acute pain may be continuous or intermittent and is often described and aching or throbbing. This type of pain usually responds well to analgesia, but if the pain is uncontrolled it may result in neural changes that lead to neuropathic pain. Trauma may also damage nerve endings and lead to neuropathic pain.

Acute pain may be described according to location with **visceral pain** resulting from stretching and inflammation from injury to internal organs. This pain is often diffuse, aching, or cramping and poorly localized. Pain may be referred to other areas.

Somatic pain results from stimulation of the peripheral nerves in the cutaneous and musculoskeletal tissues. Deep somatic pain may be dull, aching, and poorly localized. Superficial somatic pain results from stimulation of peripheral nerves in superficial tissue, such as the skin (cuts, burns). This pain may be localized, sharper, burning, and more intense.

While acute pain may be described as lasting up to 3 to 6 months, in reality most acute injuries heal within 6 weeks, so pain that persists beyond that time frame should be reassessed.

Neuropathic (Chronic pain)

Neuropathic or chronic pain occurs with damage to nerve fibers or

lesions within the nervous system. Neuropathic pain is often associated with chronic diseases (diabetes, cancer, post-herpetic syndrome), traumatic injury of the nervous system, or chronic wounds (such as ulcers). Common examples of chronic pain include headaches, low back pain, peripheral neuropathy, and arthritic pain.

Neuropathic pain may be described as shooting, burning, stabbing, or "electric" and responds poorly to analgesia although antidepressants or anticonvulsants may help to control symptoms.

Normal pain responses may be altered with neuropathic pain, making assessment more difficult.

Neuropathic pain usually persists longer than 3 months and has a significant impact on the quality of life, leading to depression, insomnia, and inability to carry out normal work and living activities.

Classifications of neuropathic pain		
Mononeuropathies (involve one nerve)	Radiculopathy, herpes zoster (shingles), trigeminal neuralgia, and post-mastectomy pain.	
Polyneuropathies (involve multiple nerves)	Alcoholic neuropathy, diabetic neuropathy, and AIDS neuropathy.	

Deafferentiation (Impaired sensory input into central nervous system)	Post-herpetic syndrome, phantom pain, brachial plexus evulsion.
Sympathetically-mediated pain (damage to sympathetic nervous system):	Complex regional pain syndrome, types I and II.

Classifications of Controlled Substances

In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control act, which included the Controlled Substances Act (CSA). The CSA established the current classification system used for narcotics (Schedule I through IV). Both the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) control the classification of drugs, determining which drugs to add or remove. The DEA regulates controlled substances.

Criteria for classification include an estimation of the potential for abuse, risk to public health, potential for psychic or physiological dependence, as well as the current medical use, and limitations resulting from international treaties. It's important to note that some drug classification systems are not consistent internationally and some drugs (such as heroin) classified as Schedule I in the United States are used medically in other countries.

Narcotic (opiate) analgesics may be natural, semisynthetic, or synthetic alkaloid derivatives of opium and are classified as opiate agonists and opiate agonist-antagonists.

- Opiate agonists: These include natural opiate agonists (morphine, codeine), semi-synthetic analogs (hydromorphone, oxycodone), and synthetic opioids (meperidine, fentanyl, methadone). They act by binding to opiate receptors in the central nervous system, both interfering with the pain pathway and with the perception of pain.
- Opiate agonist-antagonists: These include pentazocine (Talwin®), nalbuphine HCL (Nubain®), Dezocine (Dalgan®), butorphanol (Stadol®) and buprenorphine (Buprenex®). They act by stimulating some receptor sites and antagonizing (blocking) others, resulting in depression of the CNS and alterations in perception of pain.

Schedules (include some non-narcotic drugs)

I Criteria: High potential for abuses, no accepted medical use in treatment, and lack of accepted safety for use under medical supervision.

Drugs (Opiates, opiate derivatives, psychedelic substances, depressants, and stimulants): Include heroin, marijuana (currently approved for medical use in some states), peyote, GBH, MDMA AKA as "Ecstasy," LSD, mescaline, and MMDA.

Prescription: None allowed in the US.

Criteria: High potential for abuse, currently accepted medical use in treatment, and abuse may lead to severe psychological or physical dependence.

Drugs: Include cocaine, opium, morphine, methadone, Ritalin®, Concerta®, Focalin®, oxycodone, oxymorphone, fentanyl,

hydromorphone, hydrocodone (pure), codeine (=/> 90 mg per unit dose), secobarbital, meperidine, pentobarbital, and amphetamines. **Prescription:** May be directly dispensed by practitioner to user or with a written prescription. (Some limited emergency situations allow for oral prescription). No refills are allowed and prescriptions must be retained but practitioners may provide a patient with multiple prescriptions for the same controlled substance to allow the patient to receive a 90-day supply for legitimate medical purpose, but each prescription must indicate the earliest date by which it can be filled

III Criteria: Potential for abuse less than for schedule I or II drugs, currently accepted medical use in treatment, and abuse may lead to moderate or low physical dependence or high psychological dependence.

Drugs: Anabolic steroids, intermediate-acting barbiturates (talbutal), buprenorphine (Buprenex®), dihydrocodeine, ketamine, hydrocodone/codeine when compounded with an NSAID, marinol, and paregoric.

Prescription: May be directly dispensed by practitioner to user or with written or oral prescription, with a 6-month or 5-refill limitation without renewal by practitioner.

Criteria: Low potential for abuse compared to Schedule III drugs, currently accepted medical use in treatment, and abuse may lead to limited physical or psychological dependence compared to Schedule III drugs.

Drugs: Include benzodiazepines (Xanax®, Librium®, Klonopin®, Valium®), benzodiazepine-like drugs (Ambien®, zopiclone, zaleplon AKA Sonata®), long-acting barbiturates (phenobarbital), partial agonist opioid analgesics (Talwin®), butorphanol (Stadol®, stimulant-like drugs (modafinil), pentazocine, and antidiarrheal drugs (difenoxin).

Prescription: May be directly dispensed by practitioner to user or with written or oral prescription, with a 6-month or 5-refill limitation without renewal by practitioner.

V Criteria: Low potential for abuse compared to Schedule IV drugs, currently accepted medical use in treatment, and abuse may lead to limited physical or psychological dependence compared to Schedule IV drugs.

Drugs: Include cough suppressants with low-dose codeine, antidiarrheals with low does opium or diphenoxylate, pregabalin (Lyrica®), dezocine, pyrovalerone, and centrally-acting antidiarrheals when mixed with atropine (Lomotil®).

Prescription: For medical purposes only.

[See CE Course: **Narcotics**]

Schedule II through V drugs must be handled as controlled substances and securely locked (usually with double locks or special locks) in a substantially constructed cabinet. Options in medical facilities include locked cabinet and medicine carts.

In the home environment, however, medications are typically kept in a medicine cabinet, on a bedside stand, or on a kitchen counter, all easily accessible to others. Most patients do not have locked cabinets in their homes, but patients should be advised to keep medications in as secure a place as possible in the home, out of sight.

Additionally, patients should be advised not to discuss their use of opioid drugs with anyone who does not have a direct need to know or to tell others where drugs are kept.

In addition to laws regarding other controlled substances, the Combat Methamphetamine Epidemic Act (2005) regulates the marketing, distribution, and sale of products that contain ephedrine, pseudoephedrine, or phenylpropanolamine. These products must be kept in locked cabinets where customers do not have direct access and

a vendor may not sell more than 7.5 grams of product to a customer during a 30-day period.

Pain management, laws and regulations

Pain Care Bill of Rights

In 2003, the American Pain Foundation developed the Pain Care Bill of Rights (which is not mandated by law in most

states), and virtually all healthcare practitioners agree that pain control is an important component of care, but laws regarding pain control vary from state to state, and often there are no clear guidelines.

Pain Care Bill of Rights

Patients have the right to

- Have their reports of pain taken seriously and to be treated with dignity and respect by healthcare providers.
- Have their pain thoroughly assessed and promptly treated.
- Be informed about the causes of pain, possible treatments, and benefits, risk, and costs of treatments.
- Participate actively in decisions about managing their pain.
- Have their pain assessed regularly and treatment adjusted accordingly.
- Be referred to a pain specialist if pain persists.
- Get clear and prompt answers to questions.
- Allowed time to consider options and make decisions.
- Allowed to refuse a particular type of treatment.

States have different laws regarding end-of-life and palliative care pain management, but most laws allow higher than usual doses and more frequent administration of controlled substances to control pain for those facing death.

DEA registration number

The U.S. Drug Enforcement
Administration (DEA) issues a **DEA**registration number to healthcare

practitioners who prescribe controlled substances. The DEA registration number must be used on all prescriptions for federally

controlled substances (Schedules I-V) and when ordering stocks of these medications for immediate treatment. The DEA works closely with state licensing boards to ensure that drugs are prescribed, administered, and dispensed for medical purposes only in order to avoid drug diversion.

Application for a DEA registration number may be found at the U.S. Department of Justice, Drug Enforcement Administration, Drug Diversion Control website:

http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

Note that some states require a state controlled substance license (obtained either before or after DEA registration) as well as DEA registration, but West Virginia does not.

Any DEA registrant who is aware of theft or significant loss of controlled substances is required to report this theft or loss immediately to the nearest DEA office as well as to the police department.

If a state revokes a practitioner's license, the DEA then requests a voluntary surrender of the practitioner's DEA registration number but will take administrative action to revoke the registration if the practitioner does not comply with the request for voluntary surrender.

West Virginia Controlled Substances Monitoring Program

West Virginia Code Chapter 60A, Article 9 requires that practitioners with a DEA registration identification number to administer controlled

substances in West Virginia apply for and receive capability to access the **Controlled Substances Monitoring Program (CSMP)** database for information about patients to whom they are prescribing controlled substances in schedules II to IV.

Application forms for advance practice nurses to access the CSMP may be downloaded from the West Virginia Board of Pharmacy or through a link from the West Virginia board of Examiners for Registered Nursing.

[See Appendix A]

According to WV Code 60A-9-5:

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.

Risk factors for substance abuse

While there is no clearly identifiable addictive personality, people who abuse drugs often have a low tolerance for frustration and may tend to act impulsively, be manipulative, and have fear of failure. They may have poor control of feelings and react quickly with hostility, anger, and resentment. People with personality traits that predispose them to substance abuse may use drugs to relieve emotional distress or to escape reality.

Risk factors f	or substance abuse
Familial	Chaotic or unstable home environment. Ineffective parenting, neglect. Physical, emotional, or sexual abuse. Inadequate parental attachment. Family history of substance abuse. Adolescence.
Social	Poor coping skills. Poor sense of self-esteem. Poor school performance. Association with gang members or other deviant peer groups. Poverty.
Conditional	Chronic pain. Chronic disability. Mental health disorder (bipolar, schizophrenia, PTSD), including mood disorders (depression, anxiety).
Professional	Health care professionals with easy access to drugs, emotional problems, stress.

People with mental health disorders may turn to substance abuse in an attempt to self-medicate. Chronic disease is associated with increased rates of depression, so those with chronic conditions—mental or physical—should be considered at risk for substance abuse.

Socioeconomic factors are also an important consideration. People who live in poverty, for example, may see no possibility of escape and turn to drugs to escape reality or turn to selling drugs as a means of making money. The more risk factors a person has, the greater the risk of substance abuse. In some areas, a new problem has arisen in that drug dealers prey on those on Medicaid or Medicare, paying them to "fake" pain and gain prescriptions, which are then sold as street drugs.

Peer pressure is a factor in substance abuse, especially among adolescents. They may take drugs in an attempt to "belong," believing with the magical thinking that sometimes persists into adolescence that they can avoid addiction or harm.

One of the biggest concerns with drug diversion is simply availability. If drugs are readily available, the risk of those with access diverting drugs increases. This is especially true for healthcare providers, who work in high stress professions. Increasingly, availability in homes, schools, and neighborhoods is becoming a problem as prescription drugs are stolen, shared, and sold.

Drugs are often diverted from the most vulnerable patients—the elderly, the disabled, the confused, and the terminally ill—because these groups are the least likely to recognize or report that drugs have been diverted.

With controlled dispensing of single dose medications, diversion of drugs in a licensed facility has become more difficult from the point of storage, so diversion is more likely to occur at the point of administration. That is, a person who is diverting drugs may inject sterile water or sterile saline into the patient while diverting an injectable opioid for personal use. Pills and capsules are easily replaced with NSAID, acetaminophen, or even vitamins or other drugs.

Often drug diversion directly from patients can be identified by careful observation of the patient and the patient's response to pain medications.

Patient indications that their drugs have been diverted

- Patient who had been well controlled with pain medication has marked change and increasingly states pain is poorly controlled or exhibits signs (moaning, restlessness) of increased pain.
- Response to pain medication varies with different caregivers.
- Request for prescription refills are made with increasing frequency.
- Appearance of drugs (pills, capsules) has changed (indicating they may have been replaced with non-opioid drugs).
- Caregivers try to keep the patient isolated. In the home environment, this
 can include refusing home health care, turning away family or friends, and
 stating that the patient is "too tired" or "too weak" for visitors. Caregivers
 may work excessive hours to prevent others from caring for the patient, or
 family member caregivers may refuse to accept outside help.
- Patient may show signs of neglect (poor hygiene, pressure sores, weight loss).
- Patient may exhibit fear or anxiety, especially in the presence of a suspect caregiver.

Another concern with drug diversion is related to healthcare workers, who often have easy access to drugs and may go undetected for long periods of time.

Profile of diverting/impaired healthcare workers

- Chronic absenteeism, often without notification, and use of excessive sick days.
- Long unexplained breaks or absences from workplace, including taking frequent trips to the bathroom or medicine room where drugs are kept.
- Excessive amounts of time spent near a drug supply, such as a cart or medicine room.
- Worker may volunteer for overtime or appear at work when not scheduled.
- Unreliability in keeping appointments and meeting deadlines.
- Work performance varies widely and mistakes may increasingly occur resulting from inattention, impaired decision-making, and poor judgment.
- Worker appears confused at time and may exhibit memory loss and difficulty concentrating or recalling details or instructions. May work

quite slowly.

- ☐ Worker's interpersonal relations with colleagues, staff and patients suffer.
- ☐ Worker rarely admits errors or accepts blame for errors or oversights.

□ Worker experience heavy "wastage" of drugs. ☐ Recording keeping is sloppy, and some falsification of records may occur along with drug shortages. ☐ Those with prescriptive authority write inappropriate prescriptions for large narcotic doses; ☐ Worker insists on personally administering injections of narcotic drugs to patients. ☐ Worker may appear progressively disheveled and lacking in personal hygiene. Changes are evident in handwriting and charting. ☐ Worker wears long sleeves in appropriately, such as in very hot weather. Personality changes become evident with mood swings, anxiety, depression, lack of impulse control, suicidal thoughts or gestures. Others, including patients and staff begin to make complaints about the co-worker's attitude or behavior.

If a healthcare practitioner has cause to believe that a co-worker is a substance abuser, then this issues should be addressed immediately or reported to administrative personnel to address because the longer a person abuses drugs, the more likely the person is to divert drugs from others.

☐ Worker becomes increasing isolated from others.

One way to address the issue is to begin with "This is what I see...." and to describe the appearance or behavior that has caused concern. If policies are in place to allow drug testing, then drug testing should be completed. Suspect workers should be encouraged to self-report and to seek professional help in dealing with substance abuse problems.

West Virginia has a monitoring and recovery program for nurses, West Virginia Restore, to help restore nurses to a state of wellness. This is a non-disciplinary, confidential program that requires and assessment, treatment, and a contract that includes various work restrictions.

Healthcare practitioners who divert drugs must be reported immediately to the appropriate state board, such as the West Virginia Board of Pharmacy or the West Virginia board of Examiners for Registered Nursing, which will take action against the licensee.

Stealing medications, such as occurs if a nurse or other person diverts drugs from a patient, is also a criminal offense and must be reported to the police.

Best practices for prescription of controlled substances

Preventing drug diversion often begins with careful procedures by the prescribing practitioner. The practitioner should have clear procedures in place and should follow them consistently with all patients. Many of the steps recommended as best practices for prescription of drugs are simply good medical practice.

Identification

Patients should routinely be asked to show more than one piece of identification prior to prescription of drugs. This may include driver's license, social security card, and insurance cards, but at least one ID should contain a picture, and this information should be documented.

History/Physical exam

The practitioner should take a complete history and verify the physical complaint of the patient through the appropriate examination and confirming tests. In many cases, patients fill out history forms at the first visit, but the healthcare practitioner may not take the time to carefully review the form, but this should be done consistently, looking carefully for inconsistencies or items that may raise suspicion of substance abuse.

People may divert drugs for their own use or to sell to others. They often seek drugs from multiple health practitioners and may use false identification to avoid detection. Drug diverters are often between the ages of 20 and 40 and may appear in a health practitioner's office well-groomed to deflect attention.

Profile of drug diverters (Patients)

- Patient is reluctant to provide identification, such as driver's license.
- Patient states s/he is a visitor to the area and in need of emergency medication or has just moved to the area and has no physician.
- Patient requests pain medication over the telephone or per email.
- Patient requests pain medication when usual practitioner is not available, such as on the weekend when others are covering the practice.
- Patient asks for specific drugs by name and is often adamant that other drugs are ineffective or may claim allergies to other less potent drugs, such as NSAIDs.
- ☐ Patient may appear agitated or in a hurry.
- ☐ Patient maintains eye contact with practitioner and may try to take control of the interview.
- Patient appears knowledgeable about medical terminology and describes needs in medical terms despite lack of medical education.
- ☐ Patient may be evasive or inconsistent in answers or tell unlikely stories.
- ☐ Patient may avoid follow-up appointment.
- Patient has wounds that inexplicably do not heal.

Patients should be screened for current or past substance abuse and should be assessed for signs of drug abuse. Patients should be asked specifically if they have obtained controlled substances from any other health practitioner within the previous 30 days and if they have used any controlled substances during that time. The patient should be carefully observed for any signs of evasiveness. Additionally, in West Virginia, the healthcare practitioner must access the CSMP database prior to prescribing controlled substances for chronic non-malignant pain.

The healthcare practitioner should ask for the names and addresses of the patient's previous physicians and should contact them for verification. It is a warning sign if patients refuse to give this information, state that they "don't remember," or refuse to sign a release form to allow the healthcare practitioner to get records from other practitioners.

Signs of substance abuse

People seeking drugs may attempt to persuade healthcare practitioners to provide prescriptions and often

complain of chronic health conditions, such as migraines, dental pain, back pain, and temporomandibular joint pain, which are difficult to verify by examination, especially since these patients are often wellversed in expected symptoms. Patients may feign a persistent cough from bronchitis in order to obtain opioid-containing cough suppressants or may claim to suffer from narcolepsy to obtain amphetamines.

Practitioners should be aware that methylphenidate and amphetamines are frequently being diverted for "study aid" drugs by adolescents and college-age students. In some cases, students may ask directly for drugs for this purpose, but in other cases, they may feign ADHD in an attempt to gain a prescription.

Physical signs of substance Other signs abuse Odor of alcohol/marijuana on Needle tracks on arms or legs. □ clothing or breath. Itching, scratching excessively. Labile emotions, including mood Burns on fingers or lips. swings, agitation, and anger Pupils abnormally dilated or (especially if in withdrawal). constricted, eyes watery, eyelids droopy. (May wear dark glasses Inappropriate, impulsive, and/or inside.) risky behavior. Slurring of speech, slow speech. Lying. Lack of coordination, instability of Missing appointments. gait. Difficulty concentrating/short term memory loss, Tremors. disoriented/confused. Sniffing repeatedly, rubbing nose, nasal irritation. Experiences blackouts. Lethargic, sleepy during daytime. Persistent cough. Rigid movements, muscle cramps. Insomnia or excessive sleeping. Weight loss. Poor personal hygiene. Answers evasively. Dysrhythmias. Pallor or flushing, puffiness of face.

Pain assessment The healthcare practitioner should complete a pain assessment form for those patients presenting with complaints of pain. Various

forms are available, and when possible, all practitioners within a network or area or associated with a specific hospital should use the same form for consistency as patients may be seen by more than one physician.

Some forms are quite complex and provide a detailed outline of the effects of pain, but often a simple form is adequate for first assessment. It is not time-consuming but can yield valuable information for the healthcare practitioner.

Sample Pain Assessment Form	
Name:	Date:
Where is your pain located?	
When did the pain first start?	
How frequently does the pain	
occur?	
Has the pain changed in	
frequency or intensity?	
What does your pain feel like?	
(Sharp, dull, aching, stabbing,	
tingling, burning, electric)	
Right Left Right	Rate your pain at its worst: Rate your pain at its best:
Mark with an X or circle the areas where you have pain.	
How does the pain affect your	
physical functioning?	
How does the pain affect your	
social functioning?	

Adverse effects

Assessment of pain should also include informed consent, which outlines the benefits and drawbacks of different pain control medications and control methods. This includes discussion of the types of medications and their adverse effects as well as the expectations of the patient in relation to analgesia.

Patients should be provided printed information sheets about any controlled substances prescribed to them as well as information about dosage and adverse effects, with a focus on the dangers of overdose.

Common adverse effects related to opioid analgesia		
Adverse effects	Management	
Sedation	Decrease in dosage or addition of stimulant.	
Nausea & vomiting	Antiemetics, such as phenothiazines or	
	metoclopramide.	
Itching, rash	Change in medication or diphenhydramine.	
Respiratory depression	Opioid antagonist if severe. Careful titrating of dosage.	
Constipation	Increased fluid intake, stool softeners, or bulk laxatives.	
Urinary retention	Low dose opioid agonist-antagonist or antagonist.	

Contraindications include a drug allergy to substances in a drug and severe asthma. Those with respiratory insufficiency should be carefully evaluated and resuscitative equipment available before administration of opioids. Other conditions that may be relative contraindications include morbid obesity, severe sleep apnea, increase intracranial pressure, paralytic ileus, myasthenia gravis, and pregnancy.

Interactions may occur when opioids are given with other drugs or substances. For example, co-administration with alcohol, antihistamines, barbiturates, benzodiazepines, phenothiazine, or other CNS depressants may potentiate respiratory depression. Some opioids, such as meperidine, combined with MAOIs may cause respiratory depression, hypotension, and seizures.

Psychological dependence occurs with drug addiction. Typical signs and symptoms of addiction include drug craving, inability to control drug use, continued use despite illness or harm, and compulsive use of the substance. People who are addicted to drugs often lie and/or steal in order to procure the drugs they need and may engage in high-risk behavior, such as prostitution or drug peddling.

Physical dependence occurs when stopping administration of a drug, lowering the dosage, or administering an antagonist result in withdrawal symptoms. Symptoms may vary depending upon the type of drug involved but typically include:

- Rebound pain.
- Agitation.
- Tachycardia.
- · Hypertension.
- · Seizure.

Opioid tolerance is an adaptive state in which the effects of a drug diminish over time, leading the person to need increased dosage in order to obtain the same result. Opioid tolerance is common among addicts but can also occur with legitimate use of prescription opioids, resulting in "medical addiction." However, in the case of severe chronic pain, such as may occur with cancer, the need for pain control is more important than concerns about addiction.

Acute pain management Patients have very different responses to pain. In many cases, in the first few days after an acute injury, including

surgery, pain may be intense, and taking pain medications regularly may promote recovery by allowing the patients to be more active and to rest adequately. However, at some point in the recovery period, the adverse effects may actually slow the recovery process.

Patients may feel too sleepy or lethargic to carry out normal activities or exercises, and constipation often becomes a problem, even with preventive measures. Patients taking opioids should not drive motor vehicles, and this restriction may not be realistic. Therefore, the healthcare practitioner should discuss these matters with patients.

Some patients may indicate that they want to be completely pain free, but this is also not always realistic. However, many patients expect and tolerate mild discomfort as part of the healing process. Telling the patients what to expect and giving them some options helps them to have some feeling of control.

Treatment plans usually focus on pain reduction as a means to facilitate recovery and prevent development of chronic pain. Goals are usually time-limited and treatment for pain control ends when pain subsides. Because it's clear from statistics that twice as many opioids are prescribed as actually needed, a better approach than simply ordering, for example, a 30-day supply of opioid medication for acute pain is to order a 3 to 5 day supply of medication and then to reassess the need for further treatment.

As part of this approach, the healthcare practitioner together with the patient should outline a plan for pain management, including a stepdown approach to pain control.

Example:

- □ Days 1-3: Opioid pain pill routinely, every 6 to 8 hours as needed.
- \square Days 4-5: $\frac{1}{2}$ pain pill in the AM along with ibuprofen. Ibuprofen in afternoon. One or $\frac{1}{2}$ pain pill in the evening.
- \square Days 5 on: Ibuprofen or acetaminophen as needed. Supplement with $\frac{1}{2}$ pain pill at bedtime as needed.

It's important to remember that one plan will not suffice for all patients. For example, a patient recovering from an appendectomy may experience a marked reduction in pain earlier than a patient recovering from extensive second-degree burns.

Common non-opioid analgesics

Acetaminophen	 Most-commonly used non-opioid analgesic. Blocks peripheral nerve pain impulses and acts on hypothalamus to lower fever but has weak antiinflammatory effects. Used for mild to moderate pain and as adjunctive pain medication. Contraindicated with liver disease. Adverse effects are usually mild but can include rash, nausea, and vomiting. Toxic reactions can occur with overdose, leading to hepatic necrosis and liver failure. Alcohol intake should not exceed 3 drinks daily while taking acetaminophen because of increased risk of liver disease.
Aspirin/ Salicylate	 Has anti-inflammatory, antipyretic, analgesic, and antirheumatic properties. Contraindicated for children, teenagers, and young adults because it may cause Reye's syndrome for those with fever-causing or viral disorders, such as influenza and upper respiratory infections. Adverse effects include GI irritation (heartburn, GI bleedings, ulcerations, nausea, vomiting), altered platelet function, tinnitus and hearing loss, rash, non-cardiogenic pulmonary edema, reversible hepatotoxicity, and acute tubular necrosis).
Other NSAIDS (Ibuprofen, naproxen, etc,)	 Widely used for antipyretic, analgesic, antiinflammatory, and antirheumatic, and antigout effects. Used for mild to moderate pain and as adjunctive pain medication in acute as well as chronic pain.
	 Ceiling effect to pain control—beyond a certain level, an increased dose does not bring about an increase in pain relief but does increase adverse effects. Contraindicated for those with allergy or at risk for bleeding. Adverse effects are similar to those for aspirin and salicylates.

Note: Patients receiving opioid medications that contain acetaminophen should be advised to take only NSAIDs, such as ibuprofen, until no longer taking the opioid medication to avoid overdosage of acetaminophen.

Chronic non-malignant pain management

Chronic non-malignant pain is continuous or episodic pain that has persisted for 3 months or longer despite medical efforts

to treat the pain or identify the cause of the pain. Chronic nonmalignant pain is not associated with terminal disease; therefore, this category of pain does not cover pain related to cancer or progressive disease (such as scleroderma) that will eventually result in death.

Treating chronic pain with controlled substances, such as opioids, can lead to a number of different complications because all these medications carry a strong potential for abuse. Chronic pain is usually not well controlled with opioids, so alternatives must be explored. One problem with chronic pain is that people may suffer acute episodes of pain, such as with rheumatoid arthritis when joints become severely inflamed. Thus, pain control may require multiple strategies and ongoing supervision.

Pain journals are a valuable tool to help assess a patient's pain. As part of an initial assessment, patients may be asked to keep a detailed journal for at least a week to help establish the type of pain, precipitating and aggravating factors, and response to medications, but the pain journal is also useful for ongoing assessment. Various types of journals, from narrative to checklists, may be used, but a simple form may include: ☐ Date and time. ☐ Pain score (0-10) ☐ Location of pain.

- Characterization of pain (aching, sharp, stabbing, throbbing, shooting, etc.)
- Activity at onset of pain.
- Name and dosage of drug to control pain.
- Non-drug technique used to control pain (meditation, massage, acupressure, etc).
- · Duration of pain.
- · Other notes.

Alternative medications to control chronic pain		
Antidepressants	 Tricyclic antidepressants (TCAs) raise the level of some neurotransmitters, reducing the sensation of pain. Examples include amitriptyline HCL, and nortriptyline. Serotonin and norepinephrine reuptake inhibitors (SNRIs) may also reduce chronic pain. Examples include duloxetine and venlafaxine. Note: Selective serotonin reuptake inhibitors (SSRIs) tend to be less effective for chronic pain. 	
Anticonvulsants	Anticonvulsants suppress pain signals going to the brain and may be used to control chronic pain, such as that caused by diabetic neuropathy and fibromyalgia. Examples include gabapentin and pregabalin.	
Corticosteroids	Corticosteroids may be prescribed to control pain related to inflammation if NSAIDs are not adequate; however, there are many adverse effects associated with steroids so they must be monitored carefully. Steroids may be used to treat arthritis, back pain, and migraines. Examples include prednisone and decadron.	
Muscle relaxants	Muscles relaxants are more often used to treat acute pain related to muscle spasms, but may help reduce chronic low back pain and pain associated with fibromyalgia. Examples include carisoprodol and baclofen.	
Topical analgesics	Application of topical analgesics may interrupt the transmission of the pain signal for conditions such as diabetic neuropathy, postherpetic syndrome, and osteoarthritis. Examples include lidocaine patch and	

capsaicin cream. Note that capsaicin should be applied only on intact skin and may require frequent
administration for up to 6 weeks to achieve adequate results.

Termination strategies for discontinuing or decreasing the use of controlled substances should be discussed and outlined for patients using opioids for chronic pain. In the case of a flare-up of chronic pain, this may be a straightforward plan for decreasing pain medication over a few days (similar to that for acute pain), but for those who have been on long-term opioids or even addicted, a variety of individualized approaches must be considered:

- Gradual reduction in opioids while introducing other therapies.
- In-patient withdrawal of opioids and treatment for addiction.
- Referral to a pain clinic or consultation with a pain specialist:
 Patients whose chronic pain cannot be easily managed often benefit from referral to a pain clinic or pain specialist where those with expertise in pain management can fully assess the patient's needs and take the time to tailor a care plan for the individual.

A variety of complementary approaches to pain control may be explored.

Complementary therap	Complementary therapies for pain control	
Acupressure/ Acupuncture	Applying pressure or inserting needles into specific points in the body to reduce pain.	
Aromatherapy	Using essential oils to relax the patient.	
Art therapy	Using art to stimulate creativity and positive emotional response.	
Behavioral therapy	Helping patients to change their perception of pain and methods of dealing with it.	
Biofeedback	Using equipment to furnish patients with information about the state of physiologic functioning, such as heart rate, to allow the patient to gain control over this functioning.	

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Comfort measures	Providing basic comforts, such as reassuring patients, soft pillows, repositioning, clean clothes and sheets.
Counselling	Helping patients articulate feelings about pain and find methods of controlling pain responses.
Distraction	Using methods to keep the patient from
	thinking about pain, such as through watching movies, laughing, reading, or other activities.
Hot/Cold packs	Applying external heat or cold to increase circulation or decrease nerve response.
Hypnosis/Imagery	Using the power of the mind to help control the perception of pain.
Massage	Using various massage techniques to relax muscles and provide a whole-body relaxation and feeling of well being.
Meditation/Relaxation	Utilizing mind-focusing techniques to reduce tension and promote relaxation.
Music therapy	Listening to music to reduce anxiety and distract from pain. May also be used as part of mediation or visualization and exercise programs.
Pet therapy	Interacting with animals to provide distraction and external focus of attention.
Therapeutic baths	Using warm water, sometimes containing essential oils, to relax muscles and joints.
Transcutaneous electric nerve stimulation	Using external electric stimulation devices to interrupt pain signals.
Yoga/Tai chi	Using exercises to reduce tension, increase flexibility, focus the mind, and reduce discomfort.

Treatment plans, while still focusing on pain control, also must incorporate functional plans because long-term disease management and rehabilitation are ongoing concerns. Completing a functional

treatment plan begins with a discussion with patients about what they want in terms of function and whether these plans are realistic and achievable.

Aspects to functioning include:

- Physical: The ability to move and carry out physical activities, such as walking, dressing, and attending to personal hygiene.
- Psychological: The ability to cope with illness, pain, and limitations.
- Social: The ability to interact with others and carry out normal social functions, including school, work, and entertainment activities.

A **functional capacity assessment** should include assessment of the following limitations:

- Postural: Ability to sit, stand, walk, bend, climb, reach, squat, crawl, and kneel.
- Physical exertion: Ability to lift, carry, and push various weights.
- Manipulative: Ability to use fine and gross motor skills and assessment of feeling.
- Mental: Ability to remember, concentrate, follow directions, make decisions, respond appropriate, receive supervision, and relate to others.
- Visual/Communicative: Ability to see, hear, and speak.
- Non-physical: Effects of pain, environmental restrictions, rest, and medication side effects.

Each method of pain control should be clearly tied to functioning. Thus, if the goal of pain control is a 50% reduction in pain (as assessed on a 1-10 pain scale), then functional goals may be that the patient is able to dress herself, prepare breakfast, and walk up to 4 blocks.

Healthcare practitioners in West Virginia must follow a number of steps when prescribing controlled substances for chronic non-malignant pain for those not suffering from a terminal illness.

Prescription of controlled substances for chronic non-malignant pain (West Virginia)

- Prior to initial prescription for a patient, the practitioner must access the CSMP database to determine if the patient has received prescriptions for controlled substances from any other practitioner during the preceding 12 months.
- The practitioner must document any report to the CSMP of the patient's
 use of controlled substances within the preceding 12 months as well as
 rationale for the prescribing further controlled substances. The
 practitioner must also maintain a paper or electronic copy of the patient's
 CSMP report in the patient's record.
- If the practitioner continues to provide controlled substances to the
 patient, the practitioner, or the practitioner's authorized agent, must
 access the CSMP database at least annually to determine if the patient is
 acquired controlled substances from any other practitioner. The
 practitioner must document any report to the CSMP of the patient's
 acquisition of controlled substances from other practitioners as well as
 rationale for the prescribing further controlled substances. The
 practitioner must also maintain a paper or electronic copy of the patient's

CSMP report in the patient's record.

■ NOTE: If there is a power outage, a disaster, or some other cause that prevents the practitioner from accessing the CSMP database and the provision of controlled substances is medically-necessary, then the practitioner may document the medical necessity and prescribe a limited amount of drugs. The reason for failing to access the CSMP database must be documented in the patient's record and the CSMP database accessed as soon as possible.

Dispensing agency (Pharmacist, pharmacy, hospital or other health care facility for outpatient use, or pharmacy or pharmacist licensed by the Board of Pharmacy but operating outside of the state for delivery to people residing in WV) must report the following information to the CSMP with 24 hours:

- (1) The name, address, pharmacy prescription number and DEA registration number of the dispensing pharmacy;
- (2) The name, address and birth date of the person for whom the prescription is written;
- (3) The name, address and DEA 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 dispensed;
- (5) The quantity and dosage of the Schedule II, III and IV controlled substance dispensed;
- (6) The date the prescription was filled; and
- (7) The number of refills, if any, authorized by the prescription.
- (8) The full name, birth date, and address of a person picking up a prescription if other than the patient.
- (9) The manner of payment.

NOTE: Reporting is not required for a drug administered directly to a patient or a drug dispensed by a practitioner at a facility licensed by the state: *Provided,* That the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of seventy-two hours with no greater than two seventy-two-hour cycles in any fifteen-day period of time.

Treatment contract Once a healthcare practitioner has determined that controlled substances are appropriate for a patient, then the healthcare practitioner and the patient should discuss use of medications and the responsibilities that both have and should complete a treatment contract that outlines expectations.

Sample Treatment Contract
I,, am being treated by Dr. Jones with opioid
(pain) medications to control my pain condition. I agree to the following
conditions:
 I will not seek opioid medications from any other physician or prescriber, and only Dr. Jones will prescribe opioids to treat my pain.
I will take prescribed opioids only in the dosage and frequency prescribed and will not take larger amounts or more frequently.
3. I will store my medications where others do not have easy access to them.
I will not share my medications with any other person, including friends and family members.
5. I will not take any opioid medications that were not prescribed for me.
6. I will take supplementary over-the-counter pain medications (such as acetaminophen and ibuprofen) only as directed by Dr. Jones.
7. I understand that if I lose or misplace my medications, I will not receive another prescription until the next prescription is due.
8. I will keep a record of drug use, including time and dosage, and bring this record and the remaining pain medications with me to follow-up visits to allow for pill counts.
 I understand that my use of and need for pain medications will be reassessed every 30 days.
10.I agree to submit to random drug testing.
11.I understand that if I break the conditions of this contract, that Dr. Jones may choose to stop writing opioid prescriptions to control my pain.
Patient's signature
Prescriber's signature
Date

According to West Virginia guidelines, the healthcare practitioner should clearly state and include in the contract, provisions for monitoring the patient's use of controlled substances as well as the frequency. Methods should include:

- Pill counts: Checking the date of prescription and the number of pills used, as well as ascertaining that the pills have not been replaced with non-narcotic substitutes.
- Periodic random drug testing (especially important for those with a history of drug abuse), usually urine testing.
- A single patient-designated pharmacy.
- Duty of the patient to disclose outside medications.
- Use of the CSMP.
- Patient re-evaluation at appropriate intervals.

Prescription

DEA requirements for prescribers include:

- Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use.
- Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.
- Use prescription blanks only for writing a prescription order and not for notes.
- Never sign prescription blanks in advance.
- Assist the pharmacist when they telephone to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription.
- Contact the nearest DEA field office (see Appendix E) to obtain or to furnish information regarding suspicious prescription activities.
- Use tamper-resistant prescription pads.

Additional requirements for all prescriptions of controlled substances include

- Patient's full name and address and practitioner's full name, address, and DEA registration number. □ Drug name, strength, dose □ Quantity prescribed.
- · Directions for use.
- Number of refills if any authorized.

The DEA requires that prescriptions be written in ink, indelible pencil, or typewritten and manually signed by the practitioner on the date issued. Prescriptions may be transmitted by FAX to expedite filling the prescription but the original must be presented prior to dispensing the drug except is special circumstances, such as for hospice patients.

The DEA allows multiple prescriptions that allow a patient to receive a 90-day supply of schedule II controlled substances if each prescription is written for a legitimate medical purpose, each prescription contains written directions and the earliest date by which a pharmacy may fill the prescription, there is no increased risk of diversion, state law allows, and the practitioner complies with all regulations.

The DEA allows prescriptions for schedules III, IV, and V to be communicated orally, in writing or by FAX. Schedule II and IV drugs may be refilled if authorized on the prescription but only 5 times within 6 months after the initial date. After 5 refills or 6 months, a new prescription is required.

Prescriptions in West Virginia must be written on tamper-proof stateissued, serially-numbered prescription forms. Practitioners are required to immediately report to the Board of Pharmacy any unauthorized use, theft, or destruction of authorized state prescription paper.

Documentation, counts, and disposal

Prompt documentation of controlled substances, with accurate time of

administration, is essential to avoid patient's receiving a second dose too soon as well as to evaluate patient's response to the medications.

When patients are taking controlled substances in the home, they should be advised to keep a record of the medication, dose, and time and to take this record along with the prescription bottle to the prescribing practitioner at any follow-up visit and to have the record and prescription bottle available for home health nurses to evaluate if under the care of a home health agency.

Documentation for controlled substances

- Reason for administration (site of pain).
- Degree of pain (using 1-10 or appropriate pain scale).
- Patient, medication, dosage, route, and time (immediately after administration).
- Response to medication (evaluated at expected onset of action and at expected peak performance).
- · Adverse effects.

In a medical facility, when drugs must be disposed of, this disposal should be witnessed by at least two healthcare providers who are licensed to dispense drugs and this disposal documented and signed by both witnesses. Disposal, such as when only 1 mL is given from a 2mL vial, must be done immediately rather than carrying the medication to be disposed of in a pocket or storing for later disposal as this practice increases the risk of diversion.

Under no circumstances should a healthcare provider agree to sign for unwitnessed disposal of narcotics after the fact. Doing so could make the healthcare provider complicit in diversion or arouse suspicion of unprofessional conduct.

Each facility should have protocols in place for the disposal of medications, and these protocols should be followed carefully. In many cases, medications (such as unused but securely stored drugs) are returned to the pharmacy for disposal.

Disposal methods

Flushing (All forms of drugs)	Flushing of excess drugs into the sewer system is a common practice but has environmental implications although this is one method recommended by the FDA over fears about diversion and substance abuse. However, the EPA has classified pharmaceutical wastes as an area of concern. States may regulate flushing. For example, after widespread pharmaceutical contamination of watershed was found in New York, hospitals were fined and agreed to stop flushing medications. In medical institutions, flushing should be done in a clean area in a sink or flushing unit designated specifically for this purpose. In a flushing unit, the nurse should verify that all solid narcotics (pills, tablets, capsules) have flushed. If disposed of under running water, the water should run for at least 30 seconds after the medications go down the drain to
Placing in sharps containers	trap. In the home, pills are usually flushed down the toilet because they are less likely to cause blockage and are less easily retrieved. Patients should be advised to flush unused controlled substances when no longer needed or to return to designated places, such as a pharmacy, that is willing and able to dispose of the drugs. Wasted injectable narcotics are often disposed of in sharps containers. However, because sharps containers are not secured adequately for controlled substances, disposal into a sharps container is a poor practice. If this practice is used, then the drug should be injected directly into the container and not left inside of a syringe or vial, which may be more easily retrieved.

(Injectables only)	
Incinerating	Incinerating involves placing materials in hazardous waste containers for incineration and is the preferred method of disposal but is more expensive than flushing and not always available. Additionally, not all hazardous waste containers are adequately secured or tamper proof. In some facilities, liquid waste is injected or poured into small plastic bags containing kitty litter, coffee grounds, or other absorbant material so it is absorbed prior to disposal in a hazardous waste container. Some automatic dispensing carts have secure hazardous waste containers lined with absorbant material into which both liquid and solid narcotic
	wastes may be disposed of for later incineration.
Transferring to reverse distributers	Some pharmacies contract to dispose of out-ofdate, damaged, or otherwise unusable controlled substances with reverse distributors. These are companies that are licensed to recycle and/or destroy controlled substances.

Note that West Virginia is participating in National Take Back programs for prescription drugs. In 2011, more than 100 sites throughout the state accepted expired, unused, and unwanted medications.

Conclusion

Drug diversion cannot be controlled without rigorous compliance with regulations and guidelines regarding the prescription of controlled

substances. Healthcare practitioners must be diligent in observing patients, co-workers, and others for indications of diversion and must be proactive in taking steps to prevent further diversion.

Healthcare practitioners must carry out adequate pain assessment and evaluate patient's needs on an individual basis, making appropriate referrals and consultations if necessary. Patients should be active participants in determining the plan of care and should be educated about the use, storage, and disposal of controlled substances.

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Appendix A:



West Virginia **Controlled Substances Monitoring Program**



106 Capital Street Charleston, 200 (304) 558-8411 | (304) 558-0474 (jan)

Monitoring Program Online User Request Form – Practitioner ALL REQUESTS WILL BE RETURNED IF THE INFORMATION IS NOT LEGIBLE PLEASE PRINT OR TYPE ALL INFORMATION. Please fill out completely! You password and user name will be e-mailed back to you.

City	State	Zip Code
Phone Number	Fax Number	E-mail Address
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