

# Drug Diversion Toolkit

## Prescription Opioids—An Overview for Prescribers and Pharmacists





## Content Summary

This booklet should inform prescribers and pharmacists about prescription opioids diverted for nonmedical use. This booklet identifies oral and transdermal opioids, discusses the mechanism of action of opioids, and highlights common reasons for abuse, side effects associated with use, and signs or symptoms that may indicate abuse. This booklet provides guidance regarding opioid regulatory requirements, including the Controlled Substances Act scheduling, verification of Drug Enforcement Administration registration numbers, the value of participating in State-managed prescription drug monitoring programs, and risk evaluation and mitigation strategies. The booklet also addresses recent extended-release and long-acting opioid labeling revisions and provides guidance regarding prescriber tactics that may reduce the likelihood that prescription opioids may be diverted for a nonmedical use.

The epidemic of nonmedical use of prescription opioids resonates worldwide. The United Nations Office on Drugs and Crime (UNODC) defines the nonmedical use of prescription drugs as “the taking of prescription drugs, whether obtained by prescription or otherwise, other than in the manner or for the reasons or time period prescribed or by a person for whom the drug was not prescribed.”[1] Prescribers and pharmacists should pay particular attention to the possible diversion of opioids because they are the most commonly diverted controlled prescription drugs and second only to marijuana in illicit drug use.[2] The Centers for Disease Control and Prevention estimates that insurer costs associated with nonmedical use of prescription opioids exceed \$72.5 billion annually.[3] Prescribers and pharmacists must be vigilant partners in the quest to combat the diversion of all prescription drugs—particularly opioids.

## Prescription Opioids

Although sometimes used interchangeably, the terms “opioid” and “opiate” are subtly distinct. Opioid literally means “opium-like” and includes all drugs derived in whole or in part from the opium poppy, as well as synthetic agents, derived wholly from other sources, that bind to opium receptors. Opiate more specifically refers to nonsynthetic derivatives of the opium poppy.[4] Thus, a drug may be an opioid, but not necessarily an opiate. Table 1 shows the different opioid types and whether they are available by prescription.

**Table 1. Types of Opioids and Their Derivatives and Availability by Prescription**

Opiates[5]	Semi-Synthetic[6, 7]	Synthetic[8, 9]
Opium	Buprenorphine*	Butorphanol*
Codeine*	Dihydrocodeine*	Fentanyl*
Morphine*	Heroin	Meperidine*
Papaverine	Hydrocodone*	Methadone*
Thebaine	Hydromorphone*	Pentazocine*
	Oxycodone*	Propoxyphene
	Oxymorphone*	Tapentadol*
		Tramadol*

\* Available in prescription form.



## Mechanism of Action of Prescription Opioids

Opium, naturally found in poppy seeds, exerts potent pain-relieving effects and generates euphoria.[10] Use of opium at one time was viewed favorably as an effective natural remedy to treat a wide variety of ailments. However, the addictive properties of this drug became readily apparent. The production of synthetic and semi-synthetic opioids began as an attempt to harness the therapeutic properties of opium without the addictive properties inherent in natural opiates.[11] However, attempts to create a nonaddictive opioid were unsuccessful. In the brain, opioids change the perception of pain rather than altering the pain threshold or interfering with conduction of pain in the nervous system.[12, 13] Both opiates and other opioids have chemical structures similar to naturally occurring opioid peptides (endorphins), and act on mu-, delta-, and kappa-opioid receptors.[14] Opioid receptors respond and react both to endogenous peptides, expressed in response to reward stimuli, and exogenous opiates and opioids.[15] Prescription opioids bind to and influence the same opioid receptors in the brain to which illegal opioids, such as heroin, bind to and influence.[16] As a result, prescribers and patients must consider use of prescription opioids cautiously.

## Reasons Prescription Opioids Are Abused

Most often, the initial use of a prescription opioid begins with the use of the medication for the legitimate medical purpose of short-term analgesia. Abuse may become a concern because patients often require prescription opioids over long periods to treat chronic pain, because opioids have addictive properties, and because prescription drugs are often easier to obtain than illicit opioids. Americans age 14 or older abuse prescription and over-the-counter drugs second only to alcohol and marijuana. Repeated abusers of prescription opioids attempt to re-create the surge of dopamine neurotransmitters in the brain, which flood reward pathways, leading to a sense of pleasure.[17] Abusers of prescription opioids seek the resulting euphoria (the rush) commonly associated with heroin. Often coined “chasing the dragon,” the pursuit of the high seen with first use of opioids is unattainable, but nevertheless, endlessly sought.

## Side Effects Associated With the Use of Prescription Opioids

Prescription opioids are safe and effective when used appropriately to alleviate pain, but no drug is without the potential for side effects, especially above a given dose threshold. Due to the relative ease of access, the addictive characteristics that trigger repetitive use, and tolerance that necessitates increasingly higher dosages, side effects of prescription opioids quickly can become major problems. Although often thought of as safe alternatives to illicit drug use, prescription drugs can cause addiction, and use of these drugs may lead to unintentional overdose, particularly when combined with other drugs or alcohol. Studies are now showing that opioid abusers are switching to heroin because the drug costs less and is more readily available.[18]

Some clinical effects of opioid receptor activation include respiratory depression, miosis, decreased gastrointestinal motility, nausea and vomiting, and euphoria, in addition to the desired effects of cough suppression or analgesia.[19] Minor resultant side effects of opioids include constipation and drowsiness. The most serious side effect from opioids is inadequate ventilation due to respiratory depression, particularly when the opioid is ingested in large quantities, snorted, injected or ingested with other drugs or alcohol. Deaths associated with overdose of prescription opioids surpass those attributed to overdose of all illegal drugs combined.[20]

## Signs of Opioid Diversion and Symptoms of Abuse

According to the UNODC, people obtain prescription drugs for nonmedical use in a variety of ways, including through:

- Family or friends;
- Prescriptions written in excess of the amount needed;
- Prescriptions rewritten or refilled when no legitimate need exists;
- Prescriptions that have been forged;
- Prescriptions obtained through illegitimate or illegal web-based pharmacies;
- Drugs obtained from stolen prescription products; or
- Illegal sale directly from corrupt health care professionals.[21]

Observers who examine these avenues to obtain prescription opioids often find clues that indicate potential diversion. Prescribers may observe patients who ask for extremely large quantities of medication; who complain the currently prescribed dose no longer works; who request a higher strength of the same medication; or who request a change to “something stronger.” In an Emergency Department setting, the patient may offer a vague or incomplete medical history or may fail to provide the name of a family doctor who provides ongoing care to the patient.[22]

Pharmacists may observe counterfeit or altered opioid prescriptions; patients who request to pay cash when insurance coverage exists or who refill too soon; or therapeutic duplication drug utilization review rejections when opioid claims are submitted. Prescribers, pharmacists, and other pharmacy personnel may be approached by patients who solicit prescriptions for opioids or the medications themselves in exchange for cash. Patients who abuse prescription opioids may complain of cravings for the next opioid dose or exhibit withdrawal symptoms, such as a runny nose, goose bumps, sweating, diarrhea, dilated pupils, nausea, or vomiting.[23] Being cognizant of the potential signs of diversion and symptoms of abuse may help providers detect and deter diversion attempts.



## Controlled Substances Act Schedules

One of the regulatory tools in effect to help prevent such consequences is the Controlled Substances Act (CSA) of 1970. The CSA, enacted to help curb drug abuse and diversion, established five drug schedules, differentiated by relative abuse and dependence potential, to help regulate the distribution of controlled substances.[24] To participate in this drug distribution closed system, prescribers and pharmacies must complete a registration process; maintain adequate security; comply with record-keeping requirements, including inventories and order forms; and submit to inspections by the Drug Enforcement Administration (DEA). Prescriptions for controlled substances must be written by registered prescribers for legitimate medical purposes within the course of their professional practice.[25] Prescription opioids appear in schedules II, III, IV, and V, as indicated in the following table.[26] Note, tramadol does not currently appear in a Federal controlled substance schedule; however, at least 10 States have included this opioid in State legislation regulating controlled substances.[27]

- Schedule I drugs have no medical use and are typically considered illegal. These would include heroin.
- Schedule II drugs have a high potential for abuse and severe psychological and physical dependence potential. Most opioids are classified in this schedule:
  - Codeine;
  - Fentanyl;
  - Hydrocodone;
  - Hydromorphone;
  - Methadone;
  - Morphine;
  - Oxycodone;
  - Oxycodone in combination with a nonopioid; and
  - Tapentadol.

- Schedule III drugs have less potential for abuse than Schedule II with high psychological and moderate/low physical dependence potential. The opioids in this Schedule include:
  - Buprenorphine
  - Codeine (1800 mg/100 ml or 90 mg/dosage unit) in combination with a nonopioid
  - Hydrocodone in combination with a nonopioid
- The Schedule IV opioid, pentazocine, has less potential for abuse than Schedule III.
- The Schedule V opioid, codeine 200 mg/100 ml, has low potential for abuse relative to Schedule IV.

## Verification of Drug Enforcement Administration Numbers

Prescribers and pharmacies registered with the DEA are assigned a DEA registration number. Scrutiny of the DEA number presented on a controlled substance prescription is an essential component of determining the validity of the prescription. Before 1985, all DEA numbers began with the letter A and the second letter was typically the first letter of the prescriber’s last name. After 1985, the DEA issued new registrants a DEA number that began with the letter B or F and issued mid-level practitioners a DEA number that began with the letter M. Recently, the Department of Defense began issuing DEA numbers beginning with “G” (preceding the A, B, or F of the standard number) to its personal service contractors.[28]

Pharmacists can perform a simple calculation to determine if the DEA number presented meets construction composition standards. To perform this check, add the sum of the first, third, and fifth digits to twice the sum of the second, fourth, and sixth digits. If the last digit of this sum is identical to the seventh digit of the DEA number, the DEA number conforms to the composition model. However, this is just a quick check; the number should still be validated through official sources like the DEA website or a call to the prescriber, especially if the prescription is presented under suspicious circumstances.[29] Table 2 gives examples of validating two numbers.

**Table 2. Steps to Validating the Conformity of a DEA Number**

Step	Provider A	Provider B
<b>DEA #</b>	AZ1234567	BA1424326
<b>Name</b>	Dr. Zahara	Dr. Abrahams
<b>Sum of first, third, fifth digits</b>	$1 + 3 + 5 = 9$	$1 + 2 + 3 = 6$
<b>Twice the sum of the second, fourth, sixth digits</b>	$2 + 4 + 6 = 12$ $12 \times 2 = 24$	$4 + 4 + 2 = 10$ $10 \times 2 = 20$
<b>Total of two sums</b>	$9 + 24 = 33$	$6 + 20 = 26$
<b>Compare final digits</b>	$7 \neq 3$	$6 = 6$
<b>Compare second initial</b>	$Z = Z$	$A = A$
<b>Potential Validity</b>	Fail	Pass



## Use of State-Managed Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMPs; also known as PMPs) provide another regulatory tool of use to prescribers and pharmacists. As of December 2015, 49 States and the District of Columbia had passed PDMP legislation to improve patient care and safety, and the one State without a program—Missouri—introduced legislation to establish a PDMP as well.[30, 31] PDMPs attempt to reduce prescription drug abuse and fraud through implementation of tools that help provide prescribers with validated, comprehensive information about all prescription products that have been prescribed to their patients. Through transmission of pertinent information to a central database, “patient and doctor behavior that gives rise to a reasonable suspicion that prescription drugs are being inappropriately obtained or prescribed” can be identified and acted upon appropriately.[32]

Several States participate in the National Association of Boards of Pharmacy’s PMP InterConnect. Through this service, providers in member States are able to search the PDMPs of other member States to determine if a patient is doctor shopping across State lines. This can serve as an additional deterrent to drug diversion. The implementation and use of State-overseen PDMPs can have a significant impact on diversion, misuse and abuse of controlled substances, especially when participation is mandatory. After Kentucky implemented a compliance-mandated PDMP, their ranking dropped from second to thirty-first place among States on nonmedical use of prescription opioids.[33] Florida’s PDMP has reduced doctor shopping by 65 percent and reduced oxycodone-related deaths.[34]

## Risk Evaluation and Mitigation Strategies

A Risk Evaluation and Mitigation Strategy (REMS) is a regulatory tool required by the Food and Drug Administration (FDA) to proactively manage risks known to be associated with an approved drug or biological product to ensure the benefits of use outweigh the known risks.[35] A REMS employs tactics outside the usual labeling, such as medication guides, communication plans, elements to assure safe use, or implementation systems to ensure the benefits of drugs or biological products with known risks outweigh the risks of use of these products.[36] Find REMS approved by the FDA specifically for opioids online at <http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemsDetails.page&REMS=17> on the FDA website.[37]

## Extended-Release and Long-Acting Opioid Labeling Revisions

In addition to REMS programs, the FDA has also mandated revisions to the labeling of extended-release and long-acting opioids. The revised labeling will emphasize the fact that patients selected for treatment should experience a degree of pain that warrants the use of these potentially addictive opioids. Labeling revisions will also remind prescribers to consider other less addictive, alternative treatment options, such as nonopioid analgesics or immediate-release opioids. Douglas Throckmorton, M.D., deputy director of regulatory programs in FDA's Center for Drug Evaluation and Research notes, "[The FDA] will continue supporting broader efforts to solve the serious public health problems associated with the misuse and abuse of opioids." [38]

### Key Points to Remember

Providers and pharmacists should consider the following tactics to reduce the likelihood that opioids may be diverted for a nonmedical use:

- Follow both Federal and State laws when prescribing opioid medications;
- Include the patient's full name and date of birth on the hard copy prescription;
- Write the quantity of medication dispensed in both numerical digits and spelled out;
- Dispense a 28 days' supply, rather than a 30 days' supply, to avoid the issue of patients running out of medication on a nonbusiness day;
- E-prescribe when reasonable and allowed by State law;
- Sign only completed prescriptions;
- Make a photocopy of any opioid prescription before the original is given to the patient so that a record of the unaltered copy is available for reference if alteration is suspected;
- Establish a patient-prescriber agreement that clearly defines expectations and emphasizes the risk-benefit analysis. Sample consent for chronic opioid therapy and medical agreement forms developed by the American Academy of Pain Medicine are available online at [http://www.jpain.org/article/S1526-5900\(08\)00831-6/pdf](http://www.jpain.org/article/S1526-5900(08)00831-6/pdf) in appendixes 6 and 7 [39]; and
- Clearly convey behaviors that may cause termination of the patient-prescriber agreement. This includes selling medication, obtaining additional medication from another legitimate or illegitimate source, use of illicit drugs, unapproved dose escalations, lost prescriptions, or use of prescribed opioid drugs to treat another condition without consent of the prescriber. [40]

To help tackle the surge in misuse of prescription opioids, the FDA also suggests prescribers and other health care professionals seek out opioid continuing education, familiarize themselves with the content of current opioid prescription labeling, and counsel and educate patients about risks versus benefits of prescription opioids. [41] If prescribers or pharmacists recognize the signs of potential opioid diversion or symptoms of opioid abuse, they should counsel the patient, offer referral for treatment, and report suspected diversion, if appropriate. Agencies that may be notified include:

- Local law enforcement;
- U.S. Drug Enforcement Administration (DEA);
- State Medicaid Fraud Control Unit; and
- State licensing board if a health care professional is involved.

You may also contact the U.S. Department of Health and Human Services, Office of Inspector General.

U.S. Department of Health and Human Services, Office of Inspector General

ATTN: Hotline

P.O. Box 23489

Washington, D.C. 20026

Phone: 1-800-HHS-TIPS (1-800-447-8477)

TTY: 1-800-377-4950

Fax: 1-800-223-8164

Email: [HHSTips@oig.hhs.gov](mailto:HHSTips@oig.hhs.gov)

Website: <https://forms.oig.hhs.gov/hotlineoperations/>

To see the electronic version of this booklet and the other products included in the “Drug Diversion” Toolkit, visit the Medicaid Program Integrity Education page at <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html> on the CMS website.

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