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# Drug diversion

## INTRODUCTION

The risks associated with drug diversion from a pharmacy and the obligations of the pharmacist to reduce drug diversion often are underappreciated. Despite the fact that prescription drug abuse is now the fastest-growing drug problem in the United States (more prevalent than illegal “street” drugs, such as cocaine and marijuana)<sup>1</sup>, pharmacists often are hesitant to address the need to increase protections against diversion of prescription drug products from within the pharmacy.

The public harm associated with drug abuse continues to make headlines and receive significant media attention.<sup>2</sup> As a result, pharmacists should expect increased focus and attention regarding their role in preventing drug diversion and curbing prescription drug abuse. Pharmacists should be aware of drug abuse trends in order to reduce the diversion of prescription drug products from pharmacies. The trend of increased abuse of prescription drugs,

particularly opioids and benzodiazepines, provides the pharmacist with a focus on targeted products for diversion.<sup>1</sup>

In April 2011, the Obama administration issued a report entitled “Epidemic: Responding to America’s Prescription Drug Abuse Crisis.”<sup>3</sup> The report drew attention to the country’s epidemic of prescription drug abuse and called for increased education, tracking and monitoring; proper medication disposal; and enforcement. The plan the administration set forth to address the crisis focused on measures to combat external drug diversion (e.g., doctor shopping, fraudulent prescriptions and the like). However, the internal diversion of prescription drugs is another form of diversion requiring the heightened awareness of pharmacists. Pharmacists, in particular pharmacists in charge, are responsible for both securing controlled substances within the pharmacy and overseeing the actions of technicians working in the pharmacy. Failure by the pharmacist to do so can result

in disciplinary and/or other legal actions against him or her. These may include, for example, suspension or loss of a pharmacist’s license; loss of a pharmacy Drug Enforcement Agency registration number; criminal liability, such as sentencing to jail time; and a variety of civil actions, including monetary fines.

This continuing education lesson highlights the trends in prescription drug diversion from inside retail pharmacies. The lesson addresses specific methods of internal drug diversion and strategies to be implemented by the pharmacist to protect against drug diversion. The initial sections of this lesson provide an overview of drug abuse trends and a review of the laws and regulations around controlled substances. The responsibilities of the pharmacist are discussed, including (1) identifying the dangers associated with drug diversion, (2) preventing drug diversion through the identification of common diversion scenarios and (3) reporting drug diversion occurrences.

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### Author Disclosures

Jill N. Link does not have any actual or potential conflicts of interest in relation to this lesson.

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### Target Audience

Pharmacists in community-based practice.

### Program Goal

To improve pharmacists’ awareness of methods of prescription drug diversion and steps to take to help safeguard against diversion, as well as procedures to follow if suspected or actual diversion occurs.

### Learning Objectives

Upon completion of this program, the pharmacist should be able to:

1. Identify trends in prescription drug diversion, as well as the most commonly diverted drugs.
2. Describe potential methods of internal drug diversion.
3. Specify strategies that can be implemented to help reduce drug diversion.
4. Recall pharmacists’ responsibilities regarding protecting against and reporting drug diversion as outlined in the Drug Enforcement Agency (DEA) Code of Federal Regulations and DEA Pharmacist’s Manual.
5. Explain how to handle potential drug diversion scenarios appropriately.

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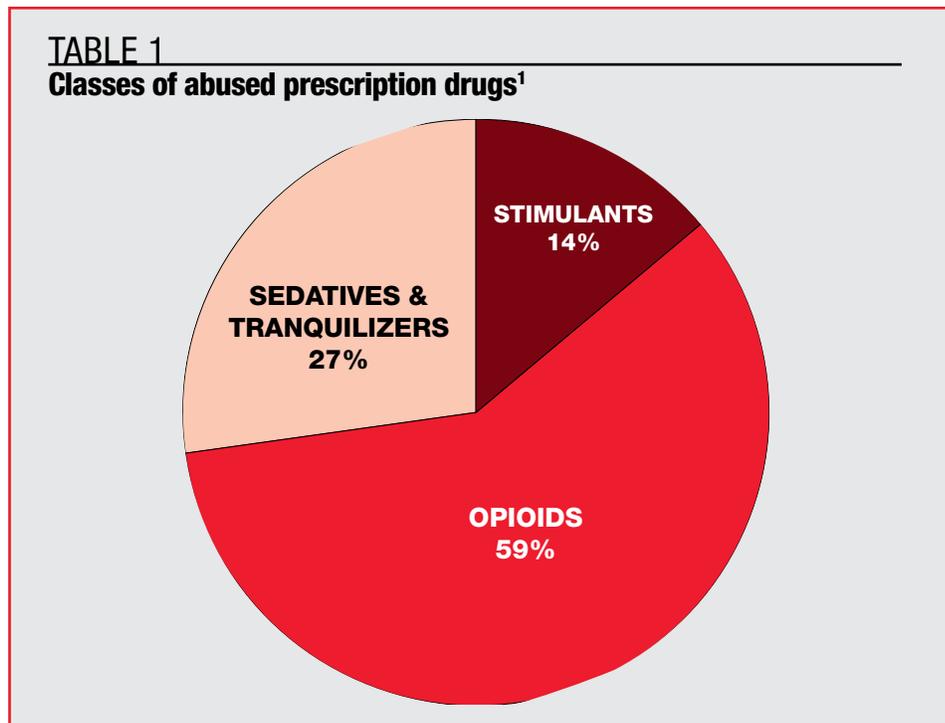
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### OVERVIEW OF DRUG ABUSE TRENDS TO IDENTIFY DRUG DIVERSION TARGETS FROM RETAIL PHARMACY

The abuse of prescription drugs has become a cultural phenomenon.<sup>4</sup> As discussed in this lesson, prescription drug abuse includes the use of medications that have not been prescribed or taking medications for reasons and/or in dosages other than as prescribed. Despite increased media attention paid to the abuse of prescription drugs, many health professionals, including pharmacists, retain the misconception that drug abuse predominates within the illegal drug markets. This dangerous misconception impedes pharmacists' ability to perform their key role in preventing drug diversion to decrease prescription drugs available for such abuse.

Nonmedical use of prescription drugs is the fastest-growing drug problem in the United States.<sup>5</sup> The 2009 National Survey on Drug Use and Health released in September 2010 estimated that more than 50 million Americans misuse or abuse prescription drugs (likely an underestimation), representing an 80% increase in prescription drug abuse between 2002 and 2009.<sup>6</sup> The increasing percentage of the population abusing prescription drugs represents a significant shift over the past 10 years, coinciding with the gradual decline in the abuse of illegal street drugs, including cocaine, marijuana and heroin, which previously topped the list of most commonly abused drugs.<sup>4</sup> Various sources suggest that prescription drug abuse (most often involving sedatives, opiates and stimulants) is more common than the abuse of illegal street drugs.<sup>7</sup>

The increased abuse of prescription drugs has further coincided with increased health risks and mortality. Abuse of prescription drugs ranked as the second-leading cause of death between 1999 and 2007 (exceeded only by motor vehicle accidents).<sup>8</sup> Centers for Disease Control and Prevention (CDC) statistics estimated an increased rate of unintentional drug overdose deaths of nearly 70% between 1999 and 2004, with more current figures expected to show further increases.<sup>9</sup> Equally troubling



are the increases in opioid analgesic unintentional overdose deaths (reported by the CDC in July 2010), which have surpassed both heroin and cocaine poisonings each year since 2000.<sup>8</sup>

In addition to increased mortality, the health risks associated with the abuse of prescription drugs can be just as dangerous as those associated with the abuse of illegal drugs.<sup>10</sup> There is little doubt that risks of addiction present significant health concerns, in addition to other health concerns associated with the abuse of prescription drugs. Increased reports of driving and operating heavy machinery under the influence of prescription drugs, namely opioids, represent a significant danger.<sup>11</sup> The pharmacist is directed to additional resources for further general information on the dangers associated with prescription drug abuse.<sup>12</sup>

The National Institute on Drug Abuse (NIDA) conducts research identifying the most commonly abused categories of drugs, including prescription drugs.<sup>13,14</sup> The 2009 National Survey on Drug Use and Health quantified more current statistics regarding the prevalence of prescription drug abuse, as summarized in Table 1, showing

the most commonly abused classes of prescription drugs to be psychotherapeutics (including opioid pain relievers, tranquilizers, stimulants and sedatives).<sup>1</sup>

As shown in Table 1, the most commonly abused class of prescription drug is opioids (i.e., for treatment of pain), followed by sedatives and tranquilizers, also known as central nervous system depressants (i.e., for anxiety and sleep disorders), and stimulants (i.e., for attention-deficit/hyperactivity disorder and narcolepsy).<sup>15</sup> The increase in abuse of those classes of drugs represents a significant increase in prevalence compared with the 1999 data, when only a few classes of prescription drugs were represented in the top 20 most commonly abused drugs, with benzodiazepines representing the only class of prescription drug in the top five most commonly abused drugs.<sup>16</sup> Today, almost one-third of new drug abusers report having an initial experience with a prescription drug (almost 20% identify abuse of an opioid).<sup>17</sup>

Opioids represent the most commonly abused class of prescription drug. Among the opioids, those most commonly abused include hydrocodone (Vicodin<sup>®</sup>, Lortab<sup>®</sup>) and oxycodone (OxyContin<sup>®</sup>). Significant

TABLE 2

Examples of abused prescription drugs and “cocktails”<sup>19,20,21,22</sup>

STREET NAMES	EXEMPLARY STREET PRICES	INGREDIENTS	INTENDED “HIGH”
Cocktail, Holy Trinity	Varies as a result of combination	Combination of:  Hydrocodone (Vicodin <sup>®</sup> , Lortab <sup>®</sup> , Lorcet <sup>®</sup> )  Carisoprodol (Soma <sup>®</sup> )  Alprazolam (Xanax <sup>®</sup> )	Exaggerated opioid effects; similar high to heroin
Hillbilly Heroin, Oxy, OC, Oxycotton, Percs, Happy Pills, Vikes	\$6 to \$10 per tablet  (Prices as high as \$20 to \$40 per tablet for OxyContin <sup>®</sup> )	Oxycodone (OxyContin <sup>®</sup> )  Hydrocodone (Vicodin <sup>®</sup> , Lortab <sup>®</sup> , Lorcet <sup>®</sup> )  Morphine (MS Contin <sup>®</sup> )	Exaggerated opioid effects
Vitamin R, Rits, West Coast	\$8 to \$15 per tablet	Methylphenidate (Ritalin <sup>®</sup> , Concerta <sup>®</sup> , etc.)  Dextroamphetamine (Dexedrine <sup>®</sup> , Adderall <sup>®</sup> )	Performance enhancer, including improved memory and concentration to “gain the edge”
Candy, Z-bar, Tranks	\$3 to \$4-plus per tablet	Alprazolam (Xanax <sup>®</sup> ) or other benzodiazepines	Rapid onset and longer duration
DMX, CCC, Triple C, Skittles, Robo, Poor Man’s PCP	Varies	Dextromethorphan	Euphoria; visual and auditory hallucinations

abuse of hydromorphone (Dilaudid<sup>®</sup>), methadone, meperidine (Demerol<sup>®</sup>), propoxyphene (Darvon<sup>®</sup>) and diphenoxylate (Lomotil<sup>®</sup>) also is reported. It is clear that hydrocodone and oxycodone are the most popular opioids among adolescents, second in frequency of abuse only to marijuana.<sup>17</sup> The increased use of opioids has led to increased street prices for the drugs. The price of hydrocodone (Vicodin<sup>®</sup>) ranges from \$2 to \$10 per tablet on the street, making the 1,000-count bottle on the pharmacy shelf worth up to \$10,000. The consumption of hydrocodone has been publicized widely within the United States, with 2004 data indicating that the United States consumes 99% of the world’s hydrocodone supply despite representing only 4.5% of the world’s population.<sup>18</sup> The abuse of oxycodone (OxyContin<sup>®</sup>) also is well-documented, and the drug has

acquired notoriety for producing a high similar to morphine (it’s often referred to as the “Hillbilly Heroin”). In addition to the abuse of individual prescription drugs, such as hydrocodone and oxycodone, abuse trends show increasing popularity of “cocktails” of various prescription drugs, including controlled substances. Table 2 shows examples of drug cocktails, along with the desired highs and examples of street prices for the drugs, demonstrating the significant demand for the various CIII-CV drugs.<sup>19,20,21,22</sup>

Among the depressants, benzodiazepines are by far the most commonly abused drugs, including diazepam (Valium<sup>®</sup>) and alprazolam (Xanax<sup>®</sup>). Barbiturates, such as pentobarbital sodium (Nembutal<sup>®</sup>), also are commonly abused depressants. The most commonly abused stimulants include methylphenidate (Ritalin<sup>®</sup>, Concerta<sup>®</sup>) and

amphetamines (Adderall<sup>®</sup>). Recent reports show a staggering increase in abuse of methylphenidate and other ADHD medications for “performance-enhancing” effects among students believing that the use will increase GPAs and test scores.<sup>17</sup> Additional information on prescription drugs of abuse, including street names, the intended intoxication effects and potential health consequences, is available for pharmacists through the NIDA.<sup>23</sup>

Over-the-counter medications also commonly are abused and diverted, including cough and cold products containing dextromethorphan.<sup>24</sup> The abuse of products containing dextromethorphan remains popular with adolescents, as they consume large quantities to obtain a high. Because this lesson focuses on the abuse and diversion of prescription drugs, pharmacists interested in learning more about

the abuse of OTC drugs, especially by adolescents, are directed to the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration Web site.<sup>25</sup>

In addition to the shift towards abuse of prescription drugs over street drugs, the “face” of the average prescription drug abuser may be unexpected to many pharmacists — the average abuser is between the ages of 18 and 25 years old.<sup>26,27</sup> Research through 2009 showed that over 16 million adolescent Americans had experimented with taking a prescription pain reliever, tranquilizer, stimulant or sedative.<sup>17</sup> The 2010 survey by the NIDA concluded that 2.7% of eighth graders, 7.7% of 10th graders, and 8.0% of 12th graders had abused hydrocodone and 2.1% of eighth graders, 4.6% of 10th graders and 5.1% of 12th graders had abused oxycodone on at least one occasion within the prior year.<sup>17</sup> These figures indicate that nearly one in 12 high school seniors have used hydrocodone and nearly one in 20 have used oxycodone for nonmedical purposes, further illustrating the cultural phenomenon of prescription drug abuse.

Within this adolescent age group (particularly ages 18 to 24), women appear more likely than men to abuse prescription drugs (as opposed to illegal drugs).<sup>26</sup> However, white men (of all age groups) remain the overall largest demographic of prescription drug abusers.<sup>26</sup> And the adolescent and young adult demographic group is not alone; even younger children, along with the middle-aged and the elderly, are affected by the phenomenon of prescription drug abuse.

The primary source or supply of the prescription medications also is surprising. Most adolescent users report obtaining prescription drugs for free from family or friends.<sup>17</sup> Youth are reporting the relative ease of obtaining prescription drugs in comparison with illegal drugs, with an estimated 40% of 12th graders reporting the ability to obtain painkillers easily.<sup>28</sup> In comparison, prescription drug abuse among college-aged students and other young adults demonstrates higher use rates of stimulants (such as amphetamines and dextroamphetamine) and

tranquilizers where the traditional “drug dealer” more often is involved.<sup>29</sup>

### PHARMACISTS' RESPONSIBILITIES

Pharmacists have a professional responsibility to assist patients and the community in the safe and effective use of prescription and OTC drug products. This professional responsibility extends to protecting patients from the dangers associated with drug abuse and curbing drug diversion.<sup>30</sup> The increase in abuse and diversion of prescription drugs invokes a myriad of dangers requiring the increased attention of pharmacists, as demonstrated by the fact that drug abuse is now the second-leading cause of accidental death in the United States.<sup>31</sup> In certain areas of the country, this risk is even greater. In an estimated 16 states, prescription drug overdoses have become the leading cause of accidental death, surpassing motor vehicle accidents.<sup>32</sup>

In addition to the professional responsibility of a pharmacist to protect patients and ensure the safe and effective use of prescription drug products, various authorities mandate the responsibilities of the pharmacist through state and federal laws and regulations. The U.S. Department of Justice and the Drug Enforcement Agency (DEA), specifically the DEA Office of Diversion Control, set forth various responsibilities for health professionals, including pharmacists, relating to the issues of drug abuse and drug diversion. These obligations are codified in the Code of Federal Regulations (CFR) and the Controlled Substance Act of 1970 (CSA).<sup>33</sup> In addition, the DEA Pharmacist's Manual provides an informational outline of the CSA for pharmacists.<sup>34</sup>

### Controlled Substance Act

The CSA is a federal law enforced by the DEA to establish a closed system of distribution for controlled substances. A closed system ensures the security and accountability of a controlled substance from its manufacturing to its consumption by an intended party (i.e., the patient). The CSA is the government's primary regulatory enactment aimed at fighting the abuse of drugs classified as controlled substances (including narcotics, stimulants, depressants,

hallucinogens, anabolic steroids and other chemicals used in the production of controlled substances).

The CSA sets forth various degrees of control for all participants in the system, including the manufacturer, distributor, wholesaler, prescriber, pharmacy and on to the patient. The limited access to controlled substances under the CSA establishes a majority of the safeguards against diversion of these types of prescription drugs. However, the closed system of distribution for controlled substances primarily focuses on safeguards up to the point of dispensing by the pharmacist to the patient. Once a controlled substance reaches the pharmacy, far fewer restrictions (excluding CIIIs) are in place as a result of the need for the pharmacist to have access to the controlled substances for the dispensing/counseling process.

The limited access to controlled substances begins with registration requirements, including DEA registration for all parties handling controlled substances. Pharmacists receive an exception to this registration requirement, wherein the registration obligation is limited to the pharmacy or institution where the pharmacist is employed.<sup>35</sup>

The CSA also establishes record-keeping requirements for tracking the transfer of controlled substances between registered, legitimate users and a client with a medical need for the controlled substance. In general, the transfer of controlled substances between registrants requires a record of transfer containing the name of the controlled substance, dosage, strength and number of units. In addition, records of receipt at a pharmacy require notation of the containers received, date, name, address and DEA registration of supplier, serving as a record of receipt for CIII-CV products.<sup>36</sup> The record-keeping requirements for CII products require use of the triplicate DEA form 222, wherein the controlled substances are shipped to the particular address on the form obtained from the DEA, which serves as the only acceptable record of the transfer.<sup>37</sup> The optional electronic ordering system known as the

**TABLE 3**  
**Potential indicators of forged or non-legitimate prescriptions<sup>30,31</sup>**

**THE FOLLOWING CRITERIA MAY INDICATE THAT A PRESCRIPTION WAS NOT ISSUED FOR A LEGITIMATE MEDICAL PURPOSE:**

- The prescriber writes significantly more prescriptions (or in larger quantities) compared with other practitioners in the area.
- The patient appears to be returning too frequently. A prescription that should last for a month in legitimate use is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for “uppers” and “downers” at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- People who are not regular patrons or residents of the community show up with prescriptions from the same physician.

**THE FOLLOWING CRITERIA MAY INDICATE A FORGED PRESCRIPTION:**

- The prescription looks “too good.” The prescriber’s handwriting is too legible.
- Quantities, directions or dosages differ from usual medical usage.
- The prescription does not comply with the acceptable standard abbreviations or appears to be textbook presentations.
- The prescription appears to be photocopied.
- Directions are written in full with no abbreviations.
- Prescription is written in different color inks or written in different handwriting.

Controlled Substance Ordering System also is available for a pharmacy’s ordering of controlled substances, providing an electronic equivalent with various benefits (e.g., decreased turnaround time and error rates in completing forms).<sup>34</sup> These and other restrictions at the wholesale level significantly deter diversion because of the limited access and various accountability measures. However, there remains significant diversion at the pharmacy level as a result of the more readily available access to controlled substances.

Most pharmacists are well aware of the CSA’s requirements for dispensing

a prescription for a controlled substance (as state dispensing laws closely mirror the CSA). The CSA requires: (1) a valid prescription (2) issued for a legitimate medical purpose.<sup>38</sup> The requirement for a valid prescription obligates pharmacists to ensure the legality of a prescription, including being on the lookout for fraudulent prescriptions (e.g., altered or forged prescriptions, stolen prescription pads, scanned duplicates of prescriptions).<sup>34</sup> Identifying fraudulent prescriptions often is difficult, as technology has made counterfeiting techniques harder to detect.<sup>31</sup> To assist pharmacists, the DEA

has published various indicators that help in determining whether a controlled substance prescription may be forged and/or issued for a non-legitimate medical purpose (Table 3).<sup>30,31</sup>

The requirement of confirming a legitimate medical purpose obligates the pharmacist to dispense controlled substances only for acceptable purposes. Here, the pharmacist must exercise sound professional judgment in determining the legitimacy of the purpose for the controlled substance. Many pharmacists are not aware that under the CSA, a legitimate purpose does *not* include dispensing a controlled substance to an addict to avoid withdrawal (unless the patient is enrolled in a licensed treatment program).<sup>34</sup> These distinctions under the CSA are important, as the act provides for both civil and criminal liability for pharmacists filling prescriptions not issued in the course of professional treatment.<sup>39</sup>

The CSA establishes various additional requirements for pharmacists and pharmacies in the handling of controlled substances. Further information is included in the discussion of the codification of the CSA *infra* (CFR).

#### **Pharmacist’s Manual**

The DEA publishes the Pharmacist’s Manual, a reference providing specific guidance and information on the requirements of the CSA. The Pharmacist’s Manual provides further guidance on how to implement the CSA regulations within a pharmacy. The manual is available online and provides a thorough reference for understanding, implementing and complying with the CSA.<sup>35</sup> Pertinent sections of the Pharmacist’s Manual affecting a pharmacist’s responsibility to protect against drug diversion are set forth in Table 4. Pharmacists are encouraged to be familiar with at least these sections of the manual. Most states require that this reference be available in a pharmacy’s reference library.

In particular, the Pharmacist’s Manual outlines the proper transfer and disposal of controlled substances for compliance with the CSA (as outlined

above), including the use of a reverse distributor. In addition, the manual establishes security requirements within a pharmacy, including that a pharmacy not employ people having certain felony convictions in any position having access to the controlled substances within the pharmacy, without an exemption granted by the DEA.<sup>40</sup>

### Code of Federal Regulations

The DEA Office of Diversion Control's authority is codified in the CFR Title 21, parts 1300-1399.<sup>41</sup> Similar to the guidance provided in the CSA and reiterated in the Pharmacist's Manual, the CFR provides specific guidance on protecting CII drugs. However, the requirements for non-CII drugs are vague, requiring "effective controls and procedures to guard against theft and diversion of controlled substances."<sup>42</sup> Therefore, in contrast to the explicit codified requirements for protecting CII drugs, there are fewer regulations controlling the protection of CIII-CV drugs, as they are viewed as presenting a less significant public risk.

Similar to the requirements under the CSA, parts 1305 (order forms), 1306 (prescriptions) and 1314 (retail sale and dispensing of scheduled listed chemical products) provide similar guidance for preventing drug diversion. The requirements for retail pharmacy's sale of scheduled products place additional security limitations on the scheduled drug products. For example, the pharmacist must ensure that scheduled drug products are not accessible by clients prior to the sale (dispensing).<sup>43</sup> The CFR requires that the products be placed behind the counter and may include the use of a locked storage cabinet.

The CFR provides additional diversion security measures through its regulation of various employment measures. The pharmacy is authorized to take "reasonable measures" to protect against employees presenting a risk for drug diversion, granting the pharmacy broad discretion in implementing internal security procedures.<sup>44</sup>

**TABLE 4**

### **Exemplary sections of Drug Enforcement Agency Pharmacist's Manual affecting drug diversion prevention<sup>35</sup>**

- Transfer or disposal of controlled substances (§IV)
- Security requirements (§V)
- Record-keeping requirements (§VI)
- Inventory requirements (§VII)
- Ordering controlled substances (§VIII)
- Valid prescription requirements (§IX)
- Dispensing requirements (§X)

More specific guidance regarding the reporting of diversion is set forth under the CFR. There is an explicit requirement for any employee having knowledge of drug diversion from his or her employer (pharmacy) by another employee to report the information to the employer.<sup>45</sup> There also are requirements for the regulated entity (pharmacy) to report to the DEA any "unusual or excessive loss or disappearance of a scheduled [product]."<sup>46</sup> The initial notice of significant loss must be submitted to the DEA within 24 hours of the entity (pharmacy) first becoming aware of the incident of diversion or loss. The pharmacist should be well aware of these requirements, as there are an estimated 6,500 pharmacy thefts occurring annually in the United States.<sup>47</sup> Of those thefts, an estimated 50% result from employee diversion, meaning there's a relatively high likelihood that the pharmacist may need to follow these reporting requirements at some point.

The pharmacist is obligated to ensure compliance with the various regulations and laws discussed herein, including the CSA and CFR (both as outlined and explained in the Pharmacist's Manual). In addition to the pharmacist's individual compliance, the actions of those working under the pharmacist's direction, including interns and technicians, also must comply with these regulations

and laws. A pharmacist's state licensure and the pharmacy's DEA registration (required for a pharmacy to dispense controlled substances) are dependent upon the actions of both the pharmacy technicians and the pharmacists to comply with the CSA and CFR. In addition, criminal liability (including jail time), along with civil monetary fines, can be levied against pharmacists, depending upon the actions of the pharmacist in failing to comply with the CSA and CFR. The pharmacist is therefore encouraged to take additional steps to ensure the compliance of all people within the pharmacy. And the pharmacist in charge has additional obligations to ensure the various regulations and laws are met by those within the pharmacy. As addressed in this lesson, an understanding of the specific methods of internal drug diversion will assist the pharmacist in establishing further strategies to protect against drug diversion and better comply with the various regulations and laws discussed.

In addition to the pharmacist's responsibilities under state and federal laws, trends in curbing the epidemic of prescription drug abuse and drug diversion suggest that state boards of pharmacy may weigh in on the matter. It is conceivable that in the future, pharmacy accreditations may further depend upon the specific measures for preventing

and/or reporting drug diversion incidents by pharmacies and pharmacists. As a result, the pharmacist's responsibility for the appropriate oversight of controlled substances and other prescription drugs is expected to increase beyond the CSA, CFR and other state-specific laws and regulations.

#### DRUG DIVERSION TECHNIQUES

Drug diversion has become an essential means to supply the demand for the abuse of prescription drugs. As a result, pharmacies have become a target for drug diversion, as they are an easily identifiable part of the supply chain. The trends in abuse outlined in this lesson provide the pharmacist with information about targeted drugs and populations of abusers who may seek to divert prescription and/or OTC medications from a pharmacy.

The diversion of prescription drugs may occur either internally (within a pharmacy) or externally (outside the pharmacy or after the dispensing of a prescription). Regardless of the type of diversion, the methods refer to the illegal removal of a prescription drug from its intended path beginning with a manufacturer and ending with the dispensing to a patient.

Internal diversion is the removal or loss of prescription drug products from within the pharmacy. Internal diversion often results from various types of employee theft or pilferage, which is made possible as a result of the significant access to prescription drug products afforded to pharmacy employees or others allowed in the pharmacy (whether authorized or not).<sup>11</sup> Internal drug diversion techniques may occur during all phases of pharmacy operations, including the ordering, inventorying, disposal and/or dispensing of medications. Internal diversion usually involves a relatively small group of potential suspects (depending upon the pharmacy size).

The inventorying of prescription drugs presents a unique opportunity for those with access to the pharmacy to divert prescription drug products. Inaccurate or forged inventories, along with a lack

of timely inventories, creates a break in the protocol of pharmacy operations such that a pharmacy employee could remove drug products from the pharmacy easily without having an accurate inventory to evidence the diversion of the product.

In addition to inventorying drug products within the pharmacy, the initial step of ordering the products presents an opportunity for internal drug diversion. For example, diversion may occur as a result of unauthorized people placing orders (including orders for controlled substances). Orders may be placed for excess quantities of the drug products, and in the event the same pharmacy employee conducts both the ordering (and acceptance of deliveries) and the inventorying, there is ample opportunity for discrepancies and falsification of records.

Diversion as a result of fraudulent record keeping also can occur at the time a drug product is disposed. People disposing of products from the pharmacy may document a product as outdated or contaminated, requiring disposal, and then take the product rather than actually disposing of it. Alternatively, another product could be substituted for the product documented as disposed in an effort to divert the product. More blatant techniques also may be employed, such as placing a bottle or other container in the garbage with product remaining in the container and later retrieving the remaining drug product from the garbage. This especially holds true if a pharmacy member knows that he or she will be taking out the garbage at closing of the pharmacy to a location where no one else would be able to see him or her take the containers back out of the bag.

Internal diversion also can occur as a result of the fabrication of prescription orders and/or the reuse of prescriptions in order to fill excess prescriptions that appear legitimate. These diversion techniques may or may not involve collusion with the patient and/or prescriber. In particular, the reuse of prescription orders gives the appearance that a prescription is filled for a legitimate

patient of the pharmacy; however, the prescription may never be dispensed (or sold). Instead the prescription may be taken by the pharmacy employee. Consider the scenario of a prescription that has already been filled and billed for a legitimate patient but that can't be located within the pharmacy. In the event the prescription has to be refilled, the pharmacist should look to see what products went missing, as it is possible that the full prescription was taken by a pharmacy member from the bins waiting for pickup, and then a new prescription is refilled for the actual patient. Alternatively, the pharmacy employee may actually dispense the prescription to a "patient" who is in collusion with the employee to make the transaction appear legitimate. Such methods may be extremely difficult to detect.

There are various other mechanisms of diversion from within the pharmacy. For example, during the filling of a prescription, a pharmacy employee may remove dosages from the prescription intentionally to "short fill" the prescription. As a result, a patient may receive 27 tablets instead of 30, with the pharmacy employee pocketing the remaining three tablets. Other diversion techniques may be employed to remove small or medium quantities of drug products from within the pharmacy consistently. For example, dosages may be placed into personal belongings, such as pockets or purses, throughout an employee's shift. Liquids may be poured into soda cans or water bottles kept by the employee within the pharmacy. These diversion techniques create difficulty, as there usually are no means to track the diversion because no retail transaction has occurred.

In addition, traditional theft and robbery of a pharmacy may be utilized to obtain larger quantities of drug products. Those employed within the pharmacy have intimate knowledge of the operation of the pharmacy and the levels of security employed, providing a myriad of opportunities to breach the systems of security established. This may include providing people outside

### CASE STUDY 1

A pharmacy staffing two pharmacists and three technicians is routinely very busy. In an effort to facilitate more efficient practices, the pharmacist in charge has discussed with the other pharmacist ways to have the technicians begin working as soon as they arrive and before the actual opening of the pharmacy. This allows the technicians to be in the pharmacy even if the pharmacist may be in and out for administrative reasons prior to opening. In addition, the technicians assist with ordering and the acceptance of orders. Oftentimes, there simply is not enough time for the pharmacist in charge or pharmacist colleague to complete all of those tasks on his or her own.

At the pharmacy, technicians routinely take the initiative to place and fill the orders for various prescription drug products, including controlled substances. One technician begins placing orders for additional bottles of alprazolam using the electronic ordering system. In addition, the same technician accepts the orders and restocks the bottles in the pharmacy. However, the technician routinely removes quantities of the alprazolam (often entire bottles), while not having to alter the documentation records for the amount of the controlled substance received in the shipments, as one of the pharmacists just signs the invoice after the alprazolam already has been placed on the shelf. As a result, the technician is able to divert relatively large quantities of the controlled substance from the pharmacy, with documented records showing that the pharmacist in charge and the other pharmacist were initialing the orders, creating significant liability for the pharmacist in charge.

#### CASE DISCUSSION

The pharmacy now is establishing revised controls to reduce the incidence and risks of internal drug diversion. In an effort to provide more limited access to controlled substances, the pharmacy's opening and closing process has been changed. The pharmacist does not leave the pharmacy at any time when it's closed and the technicians are still in the pharmacy. This ensures that the technicians are not in the pharmacy without supervision.

While the pharmacists do take lunch, leaving the technicians alone in the pharmacy, this only occurs during operating hours, when others have the capability to see into the pharmacy. In addition, security cameras can be utilized if any concerns or doubts about internal diversion arise.

In addition, the pharmacy is creating a system of "checks and balances" to ensure that the process of ordering controlled substances is not completed by any one individual (including a single pharmacist). A policy is created to ensure that a different person places the order, receives the order and shelves the order within the pharmacy. This is not done on a set rotational basis, as such a policy permits one person to know when and how to adjust to the schedule. The pharmacy also requires increased audits of all controlled substances to compare inventories against the purchase invoices for the controlled substances. And all the bottles for controlled substances now are placed with the invoice so the pharmacist who initials the inventory has an exact count of bottles.

Additional safeguards soon will be implemented within the pharmacy, including a rule prohibiting pharmacy employees from keeping personal belongings on or near the counters (including purses, backpacks and other containers). A further store policy has been implemented to allow the pharmacist in charge to check the personal belongings of the employees at the beginning and end of a shift (including jackets, purses, etc.) to look for stolen drugs.

the pharmacy with sufficient knowledge to orchestrate a theft or robbery of the pharmacy. For example, a pharmacy employee may work in tangent with another employee of the store (outside the pharmacy) and provide access codes to the pharmacy, along with instructions on where the desired prescription drug products are located.

External diversion involves the sourcing of prescription drugs through a variety of mechanisms outside the pharmacy. Often, external diversion includes a variety of patient pretenses, such as a patient's use of a fraudulent and/or altered prescription, doctor shopping, lack of a legitimate medical use, obtaining prescription drugs from friends or relatives, theft or

robbery of a pharmacy and/or acquiring products from unauthorized Internet sales or traditional drug dealing. Various key identifiers for high-risk diversion scenarios for a pharmacist are identified in Table 5.<sup>30</sup> As the focus of this lesson is on internal diversion of prescription drugs, the pharmacist is directed to additional resources for more information on external diversion methods.<sup>30</sup>

#### STRATEGIES TO REDUCE INTERNAL DRUG DIVERSION

Reducing drug diversion is a complex endeavor, as neither the supply nor the demand can ever be eliminated because it is essential to maintain access to prescription drug products for those with

legitimate medical needs. As a result, improved controls are necessary to reduce internal diversion, and the pharmacist is the key person to implement and oversee such controls. The pharmacist's access to prescription drug products and oversight of employees and pharmacy operations puts the pharmacist in the best position for improving strategies to reduce diversion.

#### Reduction of internal diversion

Reducing internal diversion begins with a pharmacist's appreciation of the trends of the most commonly targeted drugs of abuse, along with the key demographics for prescription drug abuse. An understanding of the trends of prescription drug abuse will allow for the implementation of

**TABLE 5**  
**High-risk drug diversion scenarios: patient characteristics<sup>30</sup>**

- Client requesting brand-name controlled substance
- Prescription written with apparent irregularities
- Client's lack of familiarity with the prescribing physician
- Client and/or prescribing physician from out of town
- Suspicious client demeanor (overly friendly, nervous or aberrant)
- Client trying to pay in cash instead of using insurance
- Client triggers "gut" instinct of pharmacist

increased security measures for those most commonly targeted drugs (opiates, including hydrocodone, oxycodone and methadone; stimulants, including amphetamine, dextroamphetamine and methylphenidate; and sedatives and tranquilizers). Although CII drugs may appear to be the most likely target of diversion, this generally is not the case because of the established precautions for monitoring (such as a perpetual inventory). As a result, more attention should be placed on the targeted diversion of CIII-CV drugs, which often can be taken between inventory periods with greater ease. The increased focus on CIII-CIVs is particularly important, as this is where both hydrocodone and benzodiazepines are classified — the most frequently targeted drugs for internal diversion.

In addition, a greater awareness as to those employed within the pharmacy, along with any people having access to the pharmacy, is required. This includes the pharmacists, technicians, sales associates, backup technicians and other store personnel entering the pharmacy (e.g., for maintenance or garbage removal). No pharmacy personnel are immune to the risk of internal drug diversion. A culture of responsibility and accountability for the security of the prescription drug products of the pharmacy is essential. Commitment to standard processes for monitoring and controlling the inventory within a pharmacy will assist in curbing internal diversion.

The prevention of unauthorized access to the pharmacy is essential in the reduction of internal diversion. Pharmacists and those working in the pharmacy do not have the same physical restrictions limiting access to controlled substances and other targeted prescription drug products, as access is an essential element to dispensing such drugs. This is distinct from the limited access given to other DEA registrations, wherein there may be extensive background and eligibility limitations and security measures (e.g., extensive vaults, alarms and even caged security systems). As a result, any person having access behind the counter should be under direct supervision, and the "visits" should be kept to a minimum. This includes all members of the pharmacy team, as well as those granted occasional access to the pharmacy (e.g., pharmacy maintenance, computer repair, store manager, other store team members, etc.).

Changes to dispensing practices are recommended to reduce internal diversion. Further limitations on employee access to controlled substances are recommended to provide additional safeguards. Limited access to controlled substances often is sacrificed for convenience, which is detrimental to the goals of deterring drug diversion. Controlled substances at highest risk of diversion (e.g., hydrocodone and benzodiazepines) also could be stored under lock and key and require the supervision of a pharmacist to remove for dispensing. These should include CIII-CV

medications, rather than only CII medications. Enhanced security measures around CIII-CV medications are essential within the pharmacy, as the more relaxed standards required under the CSA and state regulations make these medications an easier target for internal drug diversion. Pharmacists should review their own current practices about who opens the CII cabinet, especially if the highly sought-after medications also are stored in this area — leaving the cabinet unlocked when a product is out only provides greater temptation for internal diversion.

Record-keeping and inventory requirements also can be enhanced to reduce internal diversion. Inventories upon the transfer, disposal and/or dispensing of all controlled substances significantly would decrease the opportunities for pharmacy employees to remove drugs without the detection of others in the pharmacy. In addition, the pharmacist should consider increasing the frequency of inventories, including requiring the perpetual inventory of non-CII drugs. This significantly would decrease the opportunities for technicians and other pharmacy employees to remove drugs without prompt detection. Some states recommend keeping perpetual inventories of high-risk drugs, such as hydrocodone or alprazolam, to ensure that accurate records are maintained.<sup>48</sup> Ensuring that the same person does not always conduct the inventories provides further safeguards.

Review of the pharmacy's salvage process also can be an efficient means of reducing diversion. Oftentimes, the pharmacy's salvage bin is a staging area for drug diversion. As with other control limitations, it is preferred that more than one person oversees this process. For example, the same technician should not be responsible for documenting damages or expired products, placing the containers in a salvage bin and then transporting the drugs for disposal or return. Additional red flags within the salvage process should be monitored, including the regular use of large amounts of a controlled substance requiring wasting of a portion of the controlled substance

when a smaller dose is available that would generate less waste. In addition, any increase in damaged or broken vials, spills, etc., requiring the discarding of controlled substances should be monitored. There should always be appropriate witness documentation for any waste or discarding of a controlled substance, and the witness actually should see the discarding of the product.

A review of the existing security measures within the pharmacy in terms of storage and access may identify the need for adding security cameras, mirrors or other means of ensuring that pharmacy technicians or those having access to the pharmacy do not remove drug products through the various techniques discussed in this lesson. Other measures may include storing the personal belongings of pharmacy employees (e.g., purses, coats) in an appropriately defined area that is not accessible during the work shift and/or having a pharmacy manager inspect these items before the end of a shift to ensure that no theft has taken place.

In addition, an overall increase in the vigilance to what is happening within the pharmacy is a critical element of reducing drug diversion. The pharmacist should be aware of the behavior of technicians, interns and other pharmacists to identify signs of potential misuse or abuse of drug products, which might indicate the person also is diverting drugs from the pharmacy. For example, employees exhibiting sluggish behavior or indications of sleep disturbances, frequent flu-like symptoms, bloodshot eyes, changes in mood or mental state, or indications they need treatment by drugs or have exaggerated medical problems may be signals that the person is at risk and in need of additional monitoring or intervention. Each of these are ways the pharmacist can take a proactive role in identifying signs of potential drug diversion from the pharmacy rather than looking the other way.

### Reduction of external diversion

The reduction of external diversion also is a responsibility of the pharmacist and requires the pharmacist's understanding

## CASE STUDY 2

A pharmacist receives an oral prescription for a CIV. The prescription is received from a practitioner's office that the pharmacist is not familiar with, and the number on caller ID has been blocked. The pharmacist determines that the legitimacy of this prescription order should be confirmed prior to dispensing to the patient.

### CASE DISCUSSION

The pharmacist should verify all prescriber information, including calling the prescriber's office back and verifying the DEA registration number. Just calling the number provided without verifying the DEA registration number is not enough. Fraud groups have set up operations that include phone numbers that are directed back to them or a partner and not the true physician's office. Any person answering the call-back number should be asked a variety of questions to ensure the legitimacy of the prescriber and the DEA registration number. If the pharmacist is still in doubt over the legitimacy of the prescriber, the pharmacist should use the Internet to find the actual number of the prescriber and compare it with the information provided from the oral prescription.

Prior to dispensing the prescription, the pharmacist also should verify the patient's information. The pharmacist also may request that the patient confirm the identity of the prescribing physician. The pharmacist is encouraged to pay particular attention to the patient for any additional suspicious behavior and should not dispense the prescription if the legitimacy of the prescription and its medical use are not confirmed.

of drug abuse trends. The pharmacist should continue to verify all suspicious prescriptions and client behavior vigilantly before dispensing a prescription. In addition, patient education regarding the proper usage of medications and the dangers of drug misuse and abuse (including allowing others to use one's medication) should be included in discussions with patients. Drug utilization review and medication therapy management services also should be tools utilized by the pharmacist to assess whether drug abuse and/or diversion is occurring.

### Participation in prescription drug monitoring programs

National and/or local prescription drug monitoring program (PDMP) participation may provide further opportunities to minimize the diversion of prescription drugs. Both national and local PDMPs have been formed to try to detect suspicious patterns of drug use, particularly controlled substance use.<sup>49</sup> PDMPs seek to identify prescribers and patients at risk for both addiction and diversion and

provide for methods of professional and law enforcement intervention. A pharmacist's participation in such programs often requires reporting certain dispensing information, such as patient name, date and quantity of the drug dispensed, refills, practitioner and dispenser information. All programs require the tracking of information related to CII drugs. However, programs differ on the requirements with regard to CIII-CV drugs. As the design and requirements of your state programs may differ, pharmacists are directed to the DEA for further information on state requirements.<sup>50</sup>

### Reporting drug diversion

In the event of an actual drug diversion occurrence, check with your organization for specific reporting obligations and protocol (including reporting the loss to the DEA Office of Diversion Control and local law enforcement). The reporting of issues through appropriate law enforcement, regulatory and compliance channels not only will assist with compliance with applicable laws, but also will assist

in establishing additional safeguards for preventing future drug diversion.

## CONCLUSION

Pharmacists' understanding of their responsibilities to protect against drug diversion should be heightened after review of this lesson. It is clear that pharmacists

have a professional responsibility, along with legal obligations, to both deter and report incidences of drug diversion from the pharmacy. These professional responsibilities obligate the pharmacist to be aware of potential scenarios for possible drug diversion. In addition, the CSA and other regulations require that certain security

measures be taken to protect the ordering, inventorying, disposal and dispensing of controlled substances. These and other regulated efforts will assist in preventing drug diversion. However, additional security measures and pharmacist awareness are required to curb the incidence of internal pharmacy diversion.

## PRACTICE POINTS

1. Pharmacists must understand the trends in drug abuse to identify targeted prescription drugs for diversion from the pharmacy.
2. The pharmacist is responsible for the activities of all people within the pharmacy, including technicians and interns.
3. Increased vigilance is required for CIII-CV drugs in the pharmacy.
4. Increased diligence is needed in enforcing all corporate policies and procedures around controlled substance security.
5. Personal belongings in the pharmacy need to be screened carefully to prevent diversion.

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### Learning Assessment

Successful completion of "Drug diversion" (lesson 401-000-11-304-H04-P) is worth two contact hours of credit. To answer questions, visit our Web site at [www.cedrugstorenews.com](http://www.cedrugstorenews.com).

1. **Which of the following statements regarding the Controlled Substances Act is true?**
    - a. The federal law establishes a closed system for controlled substances up to the point of a wholesaler or manufacturer selling the controlled substance to a pharmacy.
    - b. A pharmacy DEA registration for handling controlled substances may be revoked as a result of a pharmacist's or technician's failure to comply with the Controlled Substances Act.
    - c. Pharmacists have increased regulation under the closed system of the Controlled Substances Act as a result of the direct contact with the intended party (i.e., the patient).
    - d. Pharmacists are exempt from the requirements of the Controlled Substances Act because they do not have a DEA registration number.
  2. **A controlled substance prescription under federal law (Controlled Substances Act) must be a valid prescription issued for a legitimate medical purpose. Which of the following is an indicator of a forged prescription and/or a non-legitimate purpose?**
    - a. The prescription is written for antagonistic drugs at the same time.
    - b. Directions are written in full with no abbreviations.
    - c. The prescription appears to be a photocopy.
    - d. All of the above
  3. **The Code of Federal Regulations codifies the following requirements for non-CII drugs:**
    - a. Effective controls and procedures to guard against theft and diversion
    - b. Locked in a storage cabinet prior to dispensing
    - c. Use of DEA 222 forms (and equivalent electronic prescribing system)
    - d. Perpetual inventories
  4. **The classes of prescription drugs most commonly abused include:**
    - a. Tranquilizers, opioids and steroids
    - b. Opioids, sedatives and tranquilizers, and stimulants
    - c. Opioids, stimulants and steroids
    - d. Opioids, stimulants and benzodiazepines
  5. **Death from prescription drug overdose:**
    - a. Is more common than deaths attributed to overdose of heroin and cocaine combined
    - b. Rarely occurs as an accidental cause of death
    - c. Is the second-leading cause of accidental death in the United States
    - d. Has not been documented
  6. **The pharmacist in charge should consider whether which of the following methods of internal diversion is occurring within the pharmacy:**
    - a. Employee theft
    - b. Forged inventories, including orders, disposals/wastes and transfers
    - c. Short filling prescriptions
    - d. All of the above
- The following scenario is provided for Questions 6 to 9 below.
- A pharmacist in charge oversees three pharmacists (as well as a variety of PRN pharmacists who frequently fill in shifts as needed) and five technicians. Although the pharmacist in charge has known many of the pharmacy employees for years, the PRN pharmacists and two of the technicians are new members of the pharmacy team, and the pharmacist in charge has not had an opportunity to work closely with them. There was a break-in at the pharmacy a few months earlier, and security measures were enhanced to minimize access to the pharmacy to any people other than the pharmacists and technicians. Since the break-in, the pharmacist in charge has monitored the controlled substances in the pharmacy more vigilantly and has noticed an increase in discrepancies in controlled substance inventories, particularly hydrocodone and alprazolam. The other pharmacists also have informed the pharmacist in charge of incidents when filled prescriptions have had to be refilled as a result of the prescription being misplaced prior to dispensing to the patient. However, no other "suspicious behavior" has been identified.

## Learning Assessment

7. Which statement is false based upon the scenario?
- The pharmacist in charge has an ethical and legal obligation to establish safeguards and controls to prevent drug diversion.
  - To ensure controlled substance inventories are accurate, only the pharmacist in charge should be allowed to place orders, accept orders, stock all controlled substances and inventory controlled substances.
  - The pharmacist in charge should implement a perpetual inventory for the hydrocodone and alprazolam.
  - The increase in the number of pharmacists working at the pharmacy, along with the new hiring of technicians, should trigger the pharmacist in charge to be more vigilant of the behaviors and work tactics of the employees to monitor for employee theft.
8. Methods of reducing internal diversion according to the scenario may include:
- Increased supervision of any new member of the pharmacy team and considering whether the employee fits within recognized demographics for current trends of drug abuse and diversion
  - Increased scrutiny and awareness of employee behavior, including occasional double checks on filled prescriptions for hydrocodone and alprazolam (e.g., ensuring no undercounting or “shorting” of prescriptions)
  - Perpetual inventories for targeted CIII-CV drugs, including hydrocodone and alprazolam
  - All of the above
9. Which statement regarding internal drug diversion according to the scenario is true?
- Each member of the pharmacy team is solely responsible for his or her actions, and pharmacists are not responsible for the actions of technicians.
  - Failure of the pharmacist in charge to supervise employees and implement securities against internal diversion may result in loss of license and/or other board of pharmacy or legal action.
  - As a result of the robbery from the pharmacy, it is expected that inventories will be inaccurate for a period of time until the complete extent of the theft has been identified.
  - All of the above
10. Methods of reducing diversion with improved record keeping can be achieved by the following:
- Inventorizing only CII drugs
  - Increasing the frequency of inventories, including non-CII drugs
  - Maintaining perpetual inventories of CII drugs
  - Using the same pharmacy personnel to inventory to maintain consistency