

Drug Diversion Toolkit

Controlled Substance Integrity—Documentation From Drop-Off to Pickup





Content Summary

This booklet discusses procedures to ensure the appropriate handling and documentation of prescriptions for controlled substances. Methods the pharmacist or pharmacy technician may use to verify the identity of the patient, the validity of the prescription, and the scope of practice of the prescriber are provided. This booklet also reviews methods to record the quantity of drug dispensed and emphasizes proper documentation on the prescription blank. Finally, the booklet discusses the importance of making the offer to counsel the patient about the proper use of the medication, documenting the offer, and maintaining signature logs.

Introduction

The abuse of controlled substances in the United States and their diversion into the hands of individuals for whom they were not prescribed is a seemingly uphill battle for health care professionals, law enforcement, and policymakers alike. The crisis extends beyond our country's borders. The Global Burden of Disease Study 2010 is the first of its kind to assess the worldwide burden of disease attributable to illicit drug use and dependence and was published in "The Lancet" in August 2013[1]. The study demonstrated that opioid dependence was the primary contributor to illicit drug-related deaths worldwide. In addition, the United States was one of the top four countries in the world with the highest rate of burden.[2] From 1999-2010, opioid-related deaths in the United States dramatically increased in number, according to the Centers for Disease Control and Prevention (CDC). The number of deaths parallels the 300 percent increase in sales of opioid prescriptions during that same time frame.[3]

While pharmacists routinely use their professional judgment when determining whether to fill prescriptions for controlled substances, added scrutiny is required to prevent diversion to the illicit drug market. Pharmacists are responsible for ensuring that prescription drugs are dispensed appropriately while intercepting prescriptions that are not issued by authorized prescribers for lawful medicinal purposes. As the primary gatekeepers between prescriptions and access to controlled substances, pharmacists are strategically positioned to ensure that all requirements are met in order to be in compliance with State and Federal regulations. This booklet provides pharmacists, interns, and pharmacy technicians with information that assists with compliance, appropriate validation, and documentation of a prescription for a controlled substance as well as the corresponding recordkeeping requirements related to distribution from the time the prescription is dropped off to the time it is picked up.

Drop-Off

Patient Identification

Verification that a prescription has been issued to a valid patient is one of the first steps to ensure the integrity of a prescription for a controlled substance. Patient identification is an important dispensing consideration, so identification issues may occur at drop-off, at pickup, or both. It is considered good practice for a patient to provide identification when the patient is not known to the pharmacy staff. This practice will help prevent fraud, waste, and abuse in the pharmacy, including, for example, the fraudulent use of another's identity to obtain drugs under a false claim for a Federal benefit. Medicaid law requires that a reasonable effort be made by the pharmacist to obtain, record, and maintain identifying information on individuals receiving prescription drug benefits under the program.[4] The Drug Enforcement Administration's (DEA) Office of Diversion Control explains that pharmacists must require "every purchaser of a controlled substance ... not known to him or her to furnish suitable identification" when dispensing controlled substances that are not prescription drugs.[5] Nearly half of all States go a step further—as of August 31, 2010, 22 States required patient identification prior to dispensing a prescription for any controlled substance.[6] Individual pharmacies may choose to establish a policy requiring photo identification as well. Examples of forms of identification that are typically acceptable include a valid driver's license or similar State-issued photo identification card, a military identification card, or a passport.

In addition, some States that require verification of a patient's identity require the pharmacy to record a patient's identifiable information in the State's Prescription Drug Monitoring Program (PDMP).[7] PDMPs are State-sponsored prescription drug databases that provide a unified system for sharing patients' prescription information between health care practitioners, pharmacists, and members of law enforcement who are authorized to use the system. How PDMPs are utilized, when they must be queried, what information is recorded, and who may access

the information varies from State to State as do the reporting requirements. For additional details on PDMPs, visit <http://www.namsdl.org/prescription-monitoring-programs.cfm> on the National Alliance for Model State Drug Laws website.

In addition to verification of a patient's identity, pharmacy personnel should exercise professional judgment regarding the type of information provided by the patient prior to filling the prescription. According to the DEA, common characteristics of a drug abuser include:

- Patient provides suspect answers for medical history or allergies;
- Patient claims to be from out of town;
- Patient claims to have no regular doctor;
- Patient claims to have no health insurance;
- Patient has an unusually high level of knowledge of controlled substances; and
- Patient claims that only a particular medication is effective.[8]

Pharmacy technicians and interns should document any of the above information on the prescription hard copy when the prescription is dropped off. Pharmacists should review this information to determine if further investigation is warranted.

Prescription Requirements

Performing a thorough inspection of the prescription hard copy is essential to ensure controlled substance integrity. This step may help identify a prescription that has been photocopied or altered. Since October 1, 2008, Federal law has required that printed prescriptions issued to Medicaid patients comply with three characteristics to be considered tamper-resistant.[9] Prescriptions must have:

1. One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.
2. One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber.
3. One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

In addition to ensuring that a prescription is issued on a tamper-resistant prescription blank for Medicaid patients and that the prescription has not been altered or tampered with, pharmacy personnel should ensure that the prescription contains all required information.



A valid prescription for a controlled substance must contain all of the following (21 C.F.R. 1306.05[a]):

- Patient’s full name and address;
- Drug name, strength, dosage form;
- Quantity or amount prescribed;
- Number of refills authorized (if any);
- Directions for use;
- Practitioner’s name and address; and
- Practitioner’s DEA registration number.[10]

Federal law mandates that a prescription for a controlled substance be signed and dated on the day it is issued by the prescriber.[11]

Prescribing Authority

In addition to verifying that the prescription blank appears valid and contains all required information, the pharmacist should recognize whether the practitioner has authority to prescribe the controlled substance in the State where the prescription was written. A June 2013 report released by the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG) found that in 2009, tens of thousands of prescriptions (including 29,212 prescriptions for controlled substances) were inappropriately ordered nationwide by individuals who did not have the authority to prescribe medications and were paid for under Medicare Part D.[12] This finding was based on a comparison of prescriptions found in CMS’ prescription drug event (PDE) database with the qualifications of prescribers as reflected in CMS’ National Plan and Provider Enumeration System (NPPES) database.[13] Using this data, HHS-OIG identified the top four types of providers that had prescribed Part D drugs without authority: dietitians and nutritionists; audiologists or other hearing- and speech-related service providers; massage therapists; and athletic trainers.[14] In its comments on the report, CMS noted that “the instances identified by OIG ... are likely due to administrative data input and maintenance issues affecting database accuracy and reliability.”[15] While there is some question about the extent of prescribing without authority, CMS and HHS-OIG are in agreement that guidance is needed to identify and investigate apparent instances of prescribing without authority.[16]

Effective June 1, 2010, mid-level practitioners were granted Federal prescribing authority. Mid-level practitioners provide care to patients while working under the supervision of a physician and may include physician assistants, nurse practitioners, and nurse anesthetists just to name a few. A mid-level practitioner may be authorized to prescribe controlled substances depending on the regulations of the State in which he or she practices.[17] To ensure that a practitioner is prescribing within the scope of practice designated by Federal and State law, pharmacy technicians and pharmacists should be familiar with the prescribing scope of all practitioners, including mid-level practitioners in their State. A table representing the prescribing authority of various mid-level practitioners by State can be found at http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf on the U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control website.[18]

Pharmacy personnel should be familiar with the Code of Federal Regulations (21 C.F.R. § 1304.06), which states that a pharmacist has the corresponding responsibility to ensure that a prescription for a controlled substance is issued in the “usual course” of business for the prescriber and for a “legitimate medical purpose.”[19]

Electronic Prescribing

A Federal rule to allow for e-prescribing of controlled substances became effective June 1, 2010. Prescribers have the choice of writing prescriptions for controlled substances manually or electronically, and pharmacies may receive, dispense, and store electronic prescriptions electronically; however e-prescribing of controlled substances is not permitted in any State. Pharmacists and technicians should be familiar with their State's e-prescribing regulatory requirements. The DEA requires registrants to be in compliance with all State and Federal laws. When State laws are more restrictive than Federal laws, registrants must comply with the more stringent State requirements.

Multiple Schedule II Prescriptions

In certain instances, a prescriber may determine that it is appropriate to issue multiple prescriptions for Schedule II (C-II) substances to a patient. Federal law permits a prescriber to issue "multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply." [20] The prescriber must date and sign each sequential prescription on the day it is issued and must indicate the earliest date that each prescription may be filled by annotating a "dispense after" date on each prescription blank. [21] To ensure compliance, pharmacy personnel should make certain that any prescription that contains a "dispense after" notation is not filled until the date designated on the C-II prescription. Additional regulatory information on this subject can be found in the Practitioner's Manual and in the Questions and Answers section at http://www.deadiversion.usdoj.gov/faq/mult_rx_faq.htm on the U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control website. [22]

The November 2007 Final Rule related to the issuance of multiple C-II prescriptions conflicted with previous regulations with respect to permissible changes to C-II prescriptions by pharmacists. [23] Until this matter is resolved by the DEA, pharmacists should exercise professional judgment and comply with State and Federal regulations regarding changes that may be made to C-II prescriptions. [24]

Changes to Controlled Substance Prescriptions by Pharmacists

Perform a careful inspection of the controlled substance prescription to ensure it does not contain any errors or require further clarification prior to filling. Only the following information may be changed on a Schedule III–V controlled substance prescription after consultation with the prescriber:

- Patient's address;
- Drug strength;
- Quantity to be dispensed;
- Directions for use;
- Issue date;
- Dosage form; and
- Generic substitution. [25]

Pharmacists are prohibited from making any changes to the patient's name, the controlled substance prescribed (except for generic substitution), or the prescriber's signature. If any of the required information for a controlled substance is missing, or if the prescriber must be contacted to obtain or clarify any information prior to filling the prescription, the information should be documented on the prescription hard copy. A good practice is to record the date the information was obtained, the name of the prescriber or authorized agent (if applicable) who provided the required information, and the initials of the dispensing pharmacist on the prescription hard copy. When clarifying an electronic prescription for a controlled substance, pharmacists should print a hard copy on which to record the required information, re-scan the prescription, and store the hard copy in a manner that complies with Federal requirements.

Drug Utilization Review

Prior to dispensing any prescription, a pharmacist should perform a drug utilization review of the patient's medication history. Pay particular attention to duplicate therapies, early refills, recent filling of drugs with antagonistic effects, and multiple prescribers for controlled substances. Also be aware of drugs commonly misused for "bridging." In the outpatient setting, bridging may involve the inappropriate use of prescription drugs by an abuser to reduce the severity of physiologic withdrawal symptoms associated with the abused substance of choice until the next high can be achieved.[26] Although bridging is more traditionally associated with the pharmaceutical management of patients residing in substance abuse treatment centers, bridging in the outpatient setting may be considered misuse. Substances commonly involved in bridging may include methadone, buprenorphine, buprenorphine/naloxone, gabapentin, and tramadol.[27] In addition, performing a routine review of previously documented patient notes and a review of the patient's medication history may alert the pharmacist to prior suspicious activity. This may include things such as a history of frequent early refill requests, lost or spilled medication, or corresponding follow-up communication notes with prescribers.

Controlled Substance Inventory Records and Dispensing

The Pharmacist's Manual states, "Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user." [28] In addition, Schedule II controlled substance records and inventories must be maintained separately from all other records.[29] Many pharmacies maintain a separate perpetual inventory system for Schedule II controlled substances. To ensure accuracy and accountability of those drugs, use a log book to record each time inventory is received, dispensed, recalled, or outdated and sent to a third party reverse distributor for destruction. Although the laws do not require every pharmacy to follow an identical process to manage controlled substance inventory and records, pharmacy personnel must ensure that the processes in place are in compliance with all Federal and State requirements.

For purposes of accuracy and safety, implement a process to double count all controlled substance prescriptions prior to dispensing. The filling technician or pharmacist should verify the quantity to be dispensed, double count the medication to ensure accuracy, circle the quantity verified, and document his or her initials on the prescription label.

Partial Fills

Partial filling of Schedule III, IV, and V controlled substance prescriptions is permitted by Federal law. In addition, the number of times the prescription is refilled



may exceed the originally authorized number of refills so long as the total quantity of medication dispensed does not exceed the total quantity authorized on the original prescription.[30] Partial filling of C-II controlled substances is also permitted in certain situations.[31] For example, a partial filling is permissible if the pharmacy is unable to supply the full quantity to the patient at the time the prescription is presented or called in for an emergency situation. The dispensing pharmacist must document the date, time, and partial quantity dispensed on the original C-II prescription hard copy. Federal law stipulates that any unfilled balance of the C-II prescription may be dispensed to the patient only within 72 hours of the first partial filling.[32] If the remaining balance is either not filled or unable to be filled, the pharmacist must notify the prescriber, and the remaining balance must be forfeited.[33]

A partial filling of a C-II prescription is also permitted when the patient either resides in a long-term care facility or has been medically diagnosed with a terminal illness. A prescription that meets either of these criteria is valid for a maximum of 60 days from the date it was issued by the prescriber, and the medication may be dispensed in single units.[34] To be in compliance, ensure that evidence of terminal illness or residency in a long-term care facility is documented on the original prescription hard copy. Documentation of each partial filling of a Schedule II, III, IV, and V prescription should be recorded in the same manner as a refill. According to the Code of Federal Regulations: “For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.”[35]

Controlled Substance Refill Requests

In 2012, the DEA issued a letter of clarification to the legal counsel for Omnicare, Inc., (Omnicare) regarding the practice of sending refill reminders to prescribers on behalf of a patient for a controlled substance. The DEA determined that Omnicare was not in compliance with the Controlled Substances Act (CSA) because it was utilizing refill reminder notification forms that were pre-populated with all information, and only a prescriber’s signature was required to make the prescription valid. In the letter, the DEA explicitly states

that the intent of the CSA is to ensure that “every prescription for a controlled substance must be predicated on a determination by an individual practitioner that the dispensing of the controlled substance is for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.”[36] In this instance, the DEA determined that Omnicare had acted as an unauthorized “agent” for the physician and the subsequent submission of such requests was a violation of the CSA.[37] Although the Federal law has not changed, the \$50 million settlement agreement that Omnicare reached with the DEA for this and other violations[38] caught the attention of pharmacists, pharmacies, State pharmacy boards, and pharmacy associations nationwide. Retail and long-term care pharmacies may not submit a refill request to a practitioner for a controlled substance prescription that is in the format of a partially or fully pre-populated prescription template because the pharmacy is not an authorized “agent” of the prescriber.[39] A reminder notification that contains a blank prescription template that must be completed by the prescriber is considered acceptable. Pharmacy personnel should assess controlled substance refill request procedures to ensure that the process and any associated forms are in compliance with the CSA.



Pickup

Patient Counseling

Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) dramatically impacted the delivery of pharmaceutical care and the interaction between patient and pharmacist. OBRA '90 was initially established to improve therapeutic outcomes of Medicaid recipients and includes three key pharmaceutical components:[40]

1. A prospective drug review of the patient's profile.
2. Maintenance of essential patient and drug therapy information.
3. Provision of medication counseling for all Medicaid patients.

To ensure compliance and as a condition of receiving Federal Medicaid funds, each State was required to establish standards. According to the National Health Law Program (NHeLP), as of 2010, 48 States had enacted laws that require patient counseling or an offer to counsel.[41] Although OBRA '90 was initially established to improve the therapeutic outcomes of Medicaid patients, the application of State-mandated patient counseling requirements extends to non-Medicaid patients. All patients are entitled to the same standard of care with regard to patient counseling.

OBRA '90 patient counseling standards include:

- Name of the drug (brand name, generic, or other descriptive information);
- Intended use and expected action;
- Route, dosage form, dosage, and administration schedule;
- Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including how to avoid them and the action required if they occur;
- Techniques for self-monitoring of drug therapy;
- Proper storage;
- Potential drug-drug[42] interactions or drug-disease contraindications;
- Prescription refill information; and
- Action to be taken in the event of a missed dose.[43]

According to NHeLP, 34 States have established laws with different patient counseling requirements depending on the type of prescription, while 14 States have the same requirements for new and refilled prescriptions.[44] Many States have unique requirements for: counseling when the patient is not in the pharmacy, the distribution of supplemental written materials, and notification to the patient when a generic substitution has been made.[45] Pharmacy personnel are responsible for compliance with all patient counseling regulations in the State(s) in which they practice.

Documentation at the time a prescription is picked up is an important final step to ensure integrity when prescriptions for controlled substances are dispensed. Pharmacists and pharmacy technicians have a responsibility to ensure positive patient identification when prescriptions for a controlled substance are picked up. This measure helps prevent fraud, waste, and abuse, such as identity theft for the purpose of obtaining drugs under a false claim for a Federal benefit. State identification requirements and PDMP reporting requirements may vary. Pharmacists and pharmacy technicians should familiarize themselves with the regulations established by the State and corresponding compliance.

Signature Logs

Signature logs serve an important purpose in retail pharmacy. From the billing standpoint, they provide documentation of the delivery and receipt of services to patients. From the patient counseling standpoint, signature logs aid pharmacies with documenting that patient counseling was offered. A “yes” or “no” checkbox next to the signature can be marked by the patient or patient’s agent when the prescription is picked up to document whether counseling was accepted or declined. A process must be established to ensure that prescriptions that are not picked up in the store (in other words, delivered or mailed) also comply with documentation requirements. Because signature logs are tools that may be utilized to demonstrate a pharmacy’s compliance with billing, dispensing, and patient counseling requirements, they should be retained and stored in an organized manner in a secure location to facilitate retrieval in the event of a pharmacy audit.

Key Points

Pharmacists, pharmacy interns, and pharmacy technicians should integrate the following aspects when handling prescriptions for controlled substances:

- Confirm the patient’s identity;
- Verify that the prescription contains all required information;
- Confirm the prescriber has authority to prescribe the medication;
- Document any changes made to the original prescription as permitted by law;
- Perform a drug utilization review;
- Properly document full or partial dispensing(s);
- Verify that refill request forms comply with Federal and State requirements;
- Comply with patient counseling requirements;
- Collect patient signature to record the pickup of the medication; and
- Report required information to the State PDMP.



Conclusion

To ensure the integrity of the controlled substance dispensing practice, pharmacy personnel must use special care when working with prescriptions for controlled substances and the patients who present them. The process starts when the prescription for a controlled substance is received or dropped off and concludes when the prescription is picked up. Documentation of an offer to counsel and proof of delivery to the patient are also critical components to demonstrate compliance. Pharmacists, pharmacy interns, and pharmacy technicians are responsible for complying with all policies, procedures, and State and Federal laws related to dispensing and documenting delivery of controlled substances to patients. For more information on handling prescriptions for controlled substances, review the additional resources section.

To report potential fraud, waste, or abuse, contact the State Medicaid agency, the State's Medicaid Fraud Control Unit, or HHS-OIG. Contact information is as follows:

- Visit http://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/fraudabuseforconsumers/report_fraud_and_suspected_fraud.html for a link to a list of State by State Fraud and Abuse Reporting Contacts
- HHS-OIG
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
Website: <https://forms.oig.hhs.gov/hotlineoperations/>

Additional Resources

Practitioner's Manual: An Informational Outline of the Controlled Substances Act. (2006).
http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

Pharmacist's Manual: An Informational Outline of the Controlled Substances Act. (2010).
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