

# Pharmacy Self-Auditing

Control Practices to Improve Medicaid Program Integrity  
and Quality Patient Care—Booklet 2: Controlled Substances





## Content Summary

This booklet is the second in a four-booklet series that discusses areas of pharmacy practice prone to triggering audits that pharmacy health care professionals should examine. This booklet focuses on controlled substance management. The other booklets examine provider prescribing practices, invoices and claims management, and billing practices. The four booklets may be used together or independently as a self-audit to identify areas of risk as well as opportunity for improvement.

The Affordable Care Act of 2010 expanded Medicaid eligibility in States that have adopted Medicaid expansion. In such States, Americans who earn less than 138 percent of the Federal poverty level, \$33,465 for a family of four in 2015, are eligible to enroll in Medicaid.[1] The National Health Expenditure Projections Forecast for 2014–2024 estimates Medicaid spending will grow by 5.8 percent on average annually from 2015 through 2024.[2]

The Medicaid expansion will impact Medicaid prescription drug utilization and expenditures. Private insurers lose about 1 to 1.5 percent of expenditures to fraud, while Medicaid may be closer to 10 to 15 percent.[3] Experts estimate another 20 to 30 percent of Medicaid dollars are lost to abuse or unnecessary services.[4]

According to the Kaiser Family Foundation, the Medicaid program paid for 520 million prescription claims and spent \$20.6 billion in total drug utilization expenditures in 2012, after recouping rebates.[5] The sheer volume of claims and expenditures requires Medicaid to protect itself from fraud, waste, and abuse.

Pharmacists' unique role in the health care system often allows for intervention before fraud, waste, or abuse occurs. Due to the high risk for improper payments, the Centers for Medicare & Medicaid Services (CMS) developed this toolkit to educate pharmacy providers on self-audit precautions related to invoice management, controlled substances management, proper billing practices, and proper prescribing practices. In addition, this toolkit addresses potential fraud, waste, and abuse related to pharmacy services and how to report them.

Pharmacy providers can identify areas of practice that require further scrutiny and can use these tools to educate staff about potential fraud, waste, and abuse.

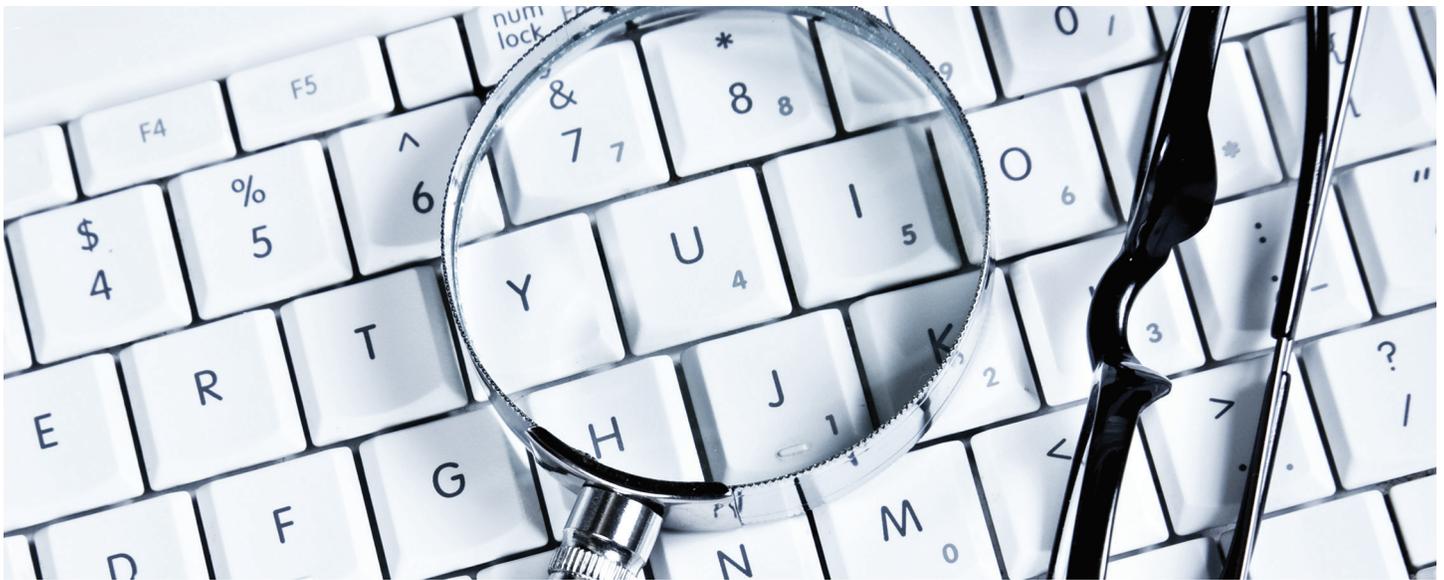
Title 18 of the United States Code defines health care fraud as knowingly and willfully executing, or attempting to execute, a scheme to defraud a health care program or obtain money or property from a health care program under false pretenses.[6] Medicaid fraud artists intentionally submit false claims or misrepresent facts to obtain funds to which they are not entitled.[7]

Federal Medicaid regulations do not define waste. Waste is similar to fraud, but it is not usually associated with criminal actions.[8] Think of waste as overutilization or misuse of services. Abuse may encompass waste and includes any action that may cost the Medicaid system unnecessary dollars. Abuse may include improper payment for services, payment for services that fail to meet professionally recognized standards of care, or payment for services that are medically unnecessary.[9] Abuse includes reimbursement for claims to which the provider is not entitled, but health care professionals guilty of abuse do not intentionally misrepresent facts to obtain payment. Like waste, abuse is not usually associated with criminal actions.

The Federal False Claims Act (FCA) is an important tool for combating fraud. In general, the FCA imposes civil liability on people who knowingly submit a false or fraudulent claim or engage in various types of misconduct involving Federal government money or property. From January 2009 through the end of the 2013 fiscal year, the Justice Department used the FCA to recover more than \$12.1 billion in health care fraud.[10]

A 2012 Office of Inspector General (OIG) report identified 2,637 retail pharmacies with questionable billing practices. The investigation found suspect pharmacies billed high dollar amounts per beneficiary, billed a high number of prescriptions per beneficiary, or billed for a high number of prescriptions per physician prescriber.[11] As a result, the OIG recommends CMS strengthen oversight of pharmacies and pharmacy audits.[12] Pharmacists can take the initiative to self-monitor practices within the pharmacy to prevent, identify, and correct potential fraud, waste, or abuse.

The audit process is a means of reviewing pharmacy practices to ensure staff members uphold operational procedures. State and Federal programs, such as Medicaid and Medicare Part D, State licensing boards, the



United States (U.S.) Drug Enforcement Administration (DEA), the U.S. Internal Revenue Service (IRS), and other third-party payers, conduct pharmacy audits. Through the pharmacy self-audit tool, pharmacy staff members can evaluate daily practices, pinpoint potential audit triggers, and proactively address vulnerabilities. Like any developing habit, a self-audit can become a part of daily, weekly, or monthly tasks.[13] Pharmacy managers can customize the pharmacy self-audit to ensure it addresses all pharmacy-specific compliance and operational procedures. When developing the blueprint for a customized pharmacy self-audit, consider the different forms of prescription drug fraud, waste or abuse that may occur in the particular pharmacy setting and focus on these vulnerabilities.

Managing controlled substances is a daunting task for all pharmacy personnel. Staff members must assess current processes and procedures in place and must mitigate vulnerabilities. Management and other staffers must consider the possibility of diversion, Federal and State record-keeping requirements, and the physical security of the pharmacy.

Pharmacists can help protect State Medicaid patients from harm and State Medicaid dollars from waste by taking steps to prevent internal diversion, maintaining adequate records, recognizing and impeding external diversion attempts, and maintaining the physical security of the pharmacy.

## **Controlled Substance Self-Audit**

This booklet (Booklet 2—Controlled Substances) contains 10 of the 50 steps to conduct a pharmacy self-audit and discusses how an evaluation of controlled substances practices can be incorporated into a pharmacy self-audit. Consider each step, answer the questions listed, and examine existing policies and procedures to identify any audit triggers related to controlled substances.

The three additional booklets in the “Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality” Toolkit (Booklet 1—Prescribing Practices, Booklet 3—Invoice Management, and Booklet 4—Billing Practices) contain the remaining steps, with audit questions and detailed information regarding each step. The steps in the four booklets correspond to the steps in the document titled “Pharmacy Auditing and Dispensing: The Self-Audit Control Practices to Improve Medicaid Program Integrity and Quality Patient Care Checklist.”

13. Ensure hiring procedures include adequate background checks.

- Visit <https://exclusions.oig.hhs.gov/> on the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG) website;
- Enter the first and last name of the potential employee to confirm the applicant is not excluded in the List of Excluded Individuals/Entities (LEIE), and use the potential employee's social security number to confirm any matches.[14]
- Check all staff and contractors monthly, and consider downloading the LEIE to do so more conveniently;
- Conduct a criminal background check after consulting with your State police agency or pharmacy association;
- Consult your State pharmacy board to determine whether any prior disciplinary action has been taken against the potential employee; and
- Conduct a financial background check.

Hiring trustworthy employees is an integral part of managing controlled substances in a pharmacy, not only to protect the pharmacy from potential vulnerabilities, but also to fairly assess the likelihood of an employee committing a drug security breach.[15]

The LEIE database lists individuals and entities currently excluded from participation in Medicare, Medicaid, and all other Federal health care programs.[16] Providers included on the list are not eligible to claim payment from these programs for items or services rendered.[17] The DEA restricts pharmacies from hiring employees who have a felony conviction related to controlled substances or who have had a controlled substance registration denied, revoked, or surrendered to the DEA for cause.[18] State pharmacy boards have access to the National Association of Boards of Pharmacy (NABP) Disciplinary Clearinghouse database. This national database maintains licensure and disciplinary information on pharmacies, pharmacy wholesalers, pharmacists, pharmacy technicians, and pharmacy interns.[19] A third party may be contracted to provide this service. When using a financial background report to make hiring decisions, the Fair Credit Reporting Act requires employers to take certain steps to comply with the law.[20] Consult this law for further guidance.

14. Determine whether vulnerabilities exist for internal diversion.

- Prohibit storing personal belongings in the pharmacy;
- Consider a policy on checking employees' personal bags;
- Require boxes be broken down inside the pharmacy;
- Dispose of all regular pharmacy trash in clear bags, and store all waste in secured trash bins;
- Promptly return drug inventory to the shelf or store in a secure area while awaiting return to stock at the time of claim reversal from the pharmacy billing system;
- Account for outdated drugs removed from the pharmacy shelf by inventory of outdates at the time the drug is pulled from the shelf;
- Store outdated prescription drugs in a secure location within the pharmacy;
- Use a tamper-evident or resistant receptacle for drugs awaiting transport;
- Fasten on-site collection receptacles to a permanent structure so as not to be removed;
- Lock containers securely;
- Select containers with a permanent outer container and a removable inner liner;



- Select containers that allow adding content while physically prohibiting removing existing contents; and
- Select containers that require at least two employees to install or remove the inner liner.

Be aware of the following diversion schemes: theft of stock medications or filled prescriptions prior to dispensing, theft of prescriptions declined by the patient but not returned to stock, theft of outdated prescription drugs, and theft of medications presented for disposal. Examine controls in place to prevent loss in trash containers, boxes, purses, lunchboxes, or briefcases. Adequate controls will help minimize loss from containers leaving the pharmacy.

Mitigate risks through controls that require unwanted filled prescriptions to be returned to stock in a timely manner. Minimize time between removal of unwanted filled prescriptions from pickup area and their return to stock.

Outdated prescription drug inventory may become an easy target for pilferage once removed from shelves. Mitigate this risk by taking steps to ensure outdated drug inventory is accounted for until removed from the premises for reverse distribution. Inventory all drugs held for reverse distribution, store outdated prescription drugs in a secure location, and use a tamper-evident receptacle for drugs awaiting transport.

In addition to external threats, there are many mechanisms by which internal theft of prescription drugs may occur in the pharmacy. According to the DEA, between January 1, 2010, and May 31, 2013, employee theft represented 46 percent of all reported pharmacy thefts nationwide.[21] Appropriately placed surveillance cameras provide protection and discourage pilferage. Ensure cameras are visible to customers and employees and are placed at entrances and exits, at the pharmacy counter, and within storage areas. Periodically inspect equipment and review footage to ensure the surveillance system is functioning properly.

15. Examine controlled substance inventory management. Verify pharmacy staff have taken the following steps to maintain accurate controlled substance inventory:

- Maintain perpetual inventory for all Controlled Substances Act (CSA) Schedule II controlled substances;
- Perform random inventory counts on CSA Schedule III through V controlled substances; and
- Document and witness all controlled substance inventory counts.

16. Examine documentation of a physical inventory that has taken place within the last 2 years. Verify the following inventory components:

- Date of the inventory;
- Indication of whether the inventory was taken at the beginning or close of business;
- Name of each controlled substance inventoried;
- Finished form of each of the substances inventoried (for example: 10 milligram tablet);
- Number of dose units of each finished form in the commercial container (for example: three 100 tablet bottles);
- Exact count for CSA Schedule II drugs;
- Estimated count for CSA Schedule III, IV, and V drugs unless the container holds more than 1,000 dosage units;
- Exact count for Schedule III, IV, and V drugs if the container holds more than 1,000 dosage units;
- Count on effective date of rule for previously non-controlled drugs that are reclassified as controlled substances;
- Count on effective date of rule for controlled substances that have a change in scheduling;
- Separate CSA Schedule II inventories and records; and
- Separate CSA Schedule III, IV, and V inventories and records (if not, controlled substance information must be readily retrievable from non-controlled substance pharmacy records).[22]

The DEA requires a physical inventory of all controlled substances every 2 years. Conduct the inventory count at the beginning or close of business on any date within 2 years of the previous inventory date.[23] Keep a copy of the inventory for at least 2 years from the date of inventory.[24] Keep in mind your State may have additional or more stringent pharmacy inventory requirements than the Federal requirements.

17. Ensure all staff members know what to do when a controlled substance loss takes place.

- Access an electronic version of the DEA Form 106, Report of Theft or Loss of Controlled Substances from [http://www.deadiversion.usdoj.gov/21cfr\\_reports/theft/](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/)[25] on the DEA's Office of Diversion Control website;
- Complete and submit the DEA Form 106 within 1 business day after discovery of the theft or loss; and
- Keep a copy of the submitted report for 2 years.[26]

18. Determine whether the pharmacist-in-charge (PIC) has met all legal and regulatory requirements and responsibilities. Whenever there is a change in PIC, perform the following checks:

- Perform a complete controlled substance inventory; and
- Complete State-specific requirements for the incoming and outgoing PIC.

The PIC must comply with all Federal and State laws and regulations, and the PIC is responsible for current licensure of pharmacy and pharmacy personnel, training, operational procedures, recordkeeping, security of the pharmacy department, and general site-specific compliance. Failure to adhere to the registration requirements of the CSA may subject a registrant to civil fines, imprisonment, or both.[27]

19. To address vulnerabilities for external diversion by patients, verify the pharmacy is complying with State Prescription Drug Monitoring Program (PDMP) regulations.



- Submit all State PDMP-required reporting elements;
- Report to the State PDMP in a timely manner if a process for real-time data collection is not implemented; and
- Perform periodic quality assurance to ensure data submission is accurate and complete.[28]

Forty-nine States have enacted legislation with regard to creating and operating PDMPs.[29] Consult your State-specific requirements to ensure compliance.

20. To address vulnerabilities for external diversion by patients, verify the pharmacy is complying with State Medicaid lock-in program requirements.

- Do not ignore insurance rejects and process Medicaid reimbursable prescriptions for cash or bypass insurance altogether; and
- Do not process early refill overrides for prescription drugs for any patient.
- State Medicaid patient lock-in programs, designed to promote safe and appropriate use of prescription drugs by enrollees exhibiting high-risk behaviors, restrict a beneficiary to a single prescriber, pharmacy, or both to obtain all Medicaid reimbursable prescriptions.[30] Behaviors may include using multiple doctors and pharmacies to obtain prescription drugs, requesting specific controlled substance drugs, and requesting early refills.

21. Determine whether vulnerabilities exist regarding physical security of the pharmacy.

- Restrict pharmacy access to authorized pharmacy personnel by key or key code;
- If feasible, assign a unique security alarm code for each pharmacist authorized to have access to the pharmacy;
- Periodically examine security logs to ensure personnel access the pharmacy only at appropriate times;
- Create only pharmacy keys that clearly state, “Do not duplicate”;
- Place any spare pharmacy key inside a container in a locked safe outside of the pharmacy, and affix a tamper-evident seal to the key container;

- Use a key log to document each time the spare key is accessed. Include the name and signature of the pharmacist, the date, and the name and signature of a witness; and
- Re-key the pharmacy in the event of a security breach.

Physical security must deter access to the pharmacy by unauthorized personnel. Entry before or after business hours and entry by unauthorized personnel are two physical security vulnerabilities. Placing a spare pharmacy key in a locked safe outside of the pharmacy may not be enough to ensure key security. Consider who may have access to the spare key.

22. Consider current procedures to communicate with other professionals—prescribers, other pharmacies, law enforcement, and State licensing boards.

- Document and disseminate information received from prescribers, between pharmacies in and around your local area, by State and local law enforcement, and by State licensing boards; and
- Create a notebook to store external communications received so pharmacy personnel can readily review the communications.

## Conclusion

CMS is committed to educating pharmacy providers about potential fraud, waste, and abuse related to pharmacy services. The four Pharmacy Self-Auditing booklets in the “Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality” Toolkit provide self-audit steps to identify potential audit triggers in a pharmacy practice. The booklets address areas prone to potential fraud, waste, and abuse related to pharmacy services, and provide instruction on how to report suspected fraud, waste, and abuse. Pharmacy providers can use audit findings to identify areas of practice that require further scrutiny as well as use these tools to educate pharmacy personnel about potential fraud, waste, and abuse.

This booklet discusses how an evaluation of controlled substances practices can be incorporated into a pharmacy self-audit. The booklet describes 10 of the 50 steps to examine hire employees, handle internal diversion, handle loss or theft, the responsibilities of a PIC, and best practices for controlled substances inventory management. The topics of PDMPs, lock-in programs, physical security, and communications were also discussed. A thorough review of these steps as they pertain to pharmacy practice will help pharmacies preserve State Medicaid program integrity and improve the quality of patient care for State Medicaid beneficiaries. Proceed to Booklet 3 for a detailed examination of how to perform a pharmacy self-audit of invoice management practices.

To see the electronic version of this booklet and the other products included in the “Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality” 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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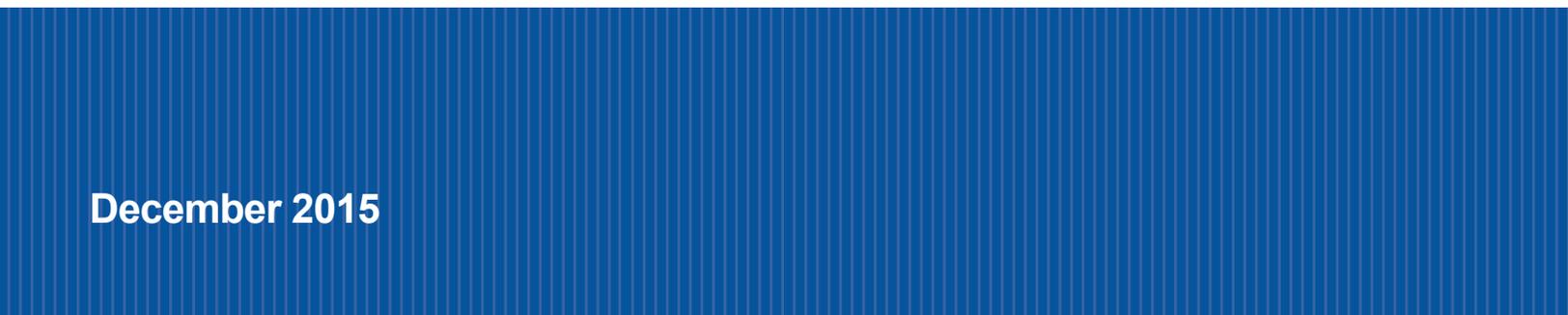
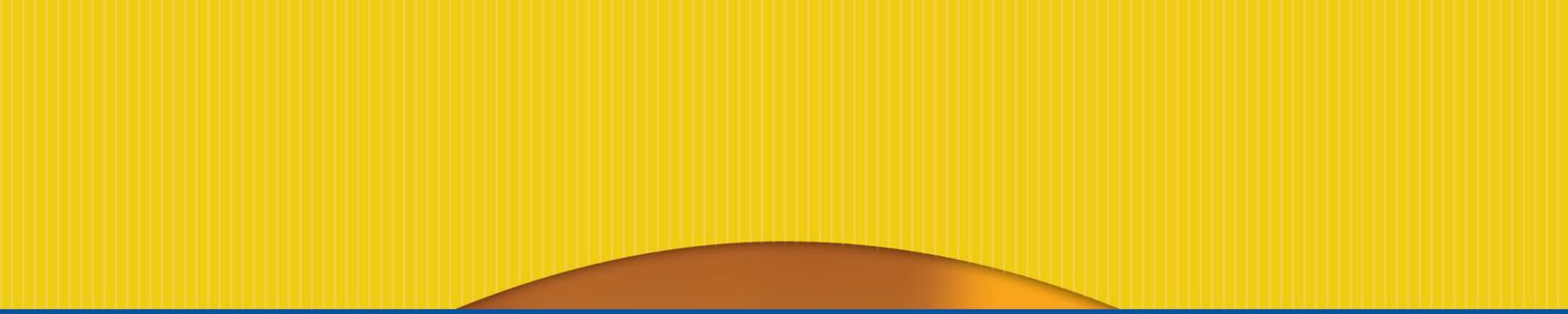
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