

Pharmacy Self-Auditing

Control Practices to Improve Medicaid Program Integrity and Quality Patient Care—Booklet 3: Invoice Management





Content Summary

This booklet is the third 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 invoice and claims management. The other booklets examine provider prescribing practices, controlled substance 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 5.9 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 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 State (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.

Fraud, waste, or abuse may occur as a result of inadvertent or inappropriate actions by pharmacy staff members. By comparing purchases to claims and sales, pharmacists can help protect State Medicaid patients from harm and State Medicaid dollars from waste or fraud. Taking steps to educate staff members about inappropriate practices—illegal sources, incentives, illegitimate prescriptions, and manipulation at the point of sale—will help prevent fraud, waste and abuse.

Invoice Management Self-Audit

This booklet (Booklet 3—Invoice Management) contains 13 of the 50 steps to conduct a pharmacy self-audit and examines invoice shortages, what to do if drug claims exceed purchases, what to do if drug claims exceed sales, and possible billing manipulation at the POS. Consider each step, answer the questions listed, and examine existing policies and procedures to identify any audit triggers related to prescribing practices.

The three additional booklets in the “Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality” Toolkit (Booklet 1—Prescribing Practices, Booklet 2—Controlled Substances 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.”

When considering invoices, perform the following steps:

23. Review amounts of medications that appear on purchased products from wholesale distributors and other applicable company invoices or receipts.

- Compare the number of units of medication purchased from wholesale distributors and other applicable companies to the corresponding number of claims for that drug; and
- Upon receipt of delivery, confirm the stock bottle of medication is sealed and has not been tampered with.

24. Pay particular attention to National Drug Codes (NDCs) of medications that appear on wholesale distributor and other applicable company invoices or receipts.

- Compare the NDCs of medications purchased from wholesale distributors and other applicable company invoices or receipts to the NDCs that appear on claims for that drug.

25. In an invoice shortage, payers may suspect you have billed them for drugs obtained from illegal sources, prescription drug samples, drugs returned to stock, or drugs returned from institutions or patients.

Drug claims will exceed purchases if the pharmacy is billing for more drug units than the pharmacy has purchased. This situation is considered an invoice shortage. Invoice shortages may occur if the pharmacy purchased an insufficient quantity or if no record exists of a specific NDC purchase.

26. Determine whether all wholesale distributors and other applicable companies with whom the pharmacy does business are reputable.

- Check wholesale distributors and other applicable company Verified-Accredited Wholesale Distributor (VAWD) status; and
- Ensure all wholesale distributors and other applicable companies are registered with the DEA and the appropriate State controlled substance agency if no VAWD accreditation is found.

The National Association of Boards of Pharmacy (NABP) accredits wholesale distributors and works in conjunction with State boards of pharmacy to help regulate the drug supply chain. VAWD accreditation, supported by the U.S. Food and Drug Administration (FDA), ensures compliance with State and Federal laws and helps prevent the introduction of counterfeit drugs into the U.S. market.[14]

Illegal sources include the black or gray market and foreign markets. Black market pharmaceuticals refer to pharmaceuticals that are traded illegally. Gray market pharmaceuticals refer to legal, non-counterfeit pharmaceuticals sold outside normal distribution channels by entities that may have no relationship with the producer of the pharmaceuticals.[15] Black, gray, and foreign market wholesalers may sell counterfeit or adulterated drugs.

27. Talk to pharmacy staff members about appropriate procedures with regard to medication samples.

- Store sample medications in a separate location to prevent inadvertent claims for sample medications if drug samples are maintained in the pharmacy for distribution by an on-site health care provider.

It is illegal to buy, sell, trade, or offer to buy, sell, or trade any prescription drug sample. A Kentucky physician who allowed several pharmacists to sell prescription samples he received was sentenced to 5 years' probation for his part in the scheme.[16]

28. Talk to pharmacy staff members about appropriate procedures to return medications to stock.

- Reverse any third-party insurance claims before returning a medication to stock.

Illegal sources include medications returned to stock without reversing billing. Pharmacies must reverse insurance claims if a patient fails to pick up a prescription. Claims reversal modifies the original prescription, the patient's medication history, and the patient's claims history and helps ensure an accurate inventory accounting.[17]

29. Talk to pharmacy staff members about appropriate procedures when accepting medications returned from institutions or patients.

- Modify the pharmacy's DEA registration to become an authorized collector if the pharmacy elects to accept medication returns; and
- Review and implement the DEA requirements to operate a secure collection receptacle.

Pharmacies may accept medication returns from institutions or patients for disposal, such as during drug take-back days. The DEA began hosting national prescription drug take-back events in 2010 because at the time the Controlled Substance Act (CSA) made no legal provision for patients and their caregivers to rid themselves of unwanted controlled substance prescription drugs except to give them to law enforcement. The new regulations authorize certain DEA registrants, including retail pharmacies, to modify their registration with the DEA to become authorized collectors.[18] To modify an existing registration, the pharmacy needs to access the DEA registration page, available at www.deadiversion.usdoj.gov/drugreg/ on the U.S. Department of Justice website. The registrant should select "Registration for Disposal of Controlled Substances" and complete the required fields.

When accepting medications for disposal, ensure on-site collection receptacles comply with DEA security requirements. For pharmacies that choose to maintain an on-site collection receptacle and serve as collectors for unwanted drugs, including controlled substances, the DEA has established security requirements for use of collection receptacles:

- Fasten on-site collection receptacles to a permanent structure so as not to be removed;
- Securely lock containers;
- 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.[19]

30. Talk to pharmacy staff members about prescription "shorting" (providing the patient with a quantity less than the prescriber has ordered).

Prescription shorting may occur if a pharmacist or technician purposefully "shorts" or provides less of a high-cost drug than was prescribed in order to increase inventory.

- Require the pharmacist who fills any controlled substance or high-dollar prescription and one other staff to double count the medication (whether manually or robotically) and initial the quantity filled; and
- Be proactive and alert staff that you monitor inventory.

31. Do not allow illegal incentives, illegitimate prescriptions, POS billing manipulations, coordination of benefits manipulations, or phantom claims.

Drug claims will exceed sales if the pharmacy bills for more than it sells. Claims that exceed sales may trigger audits and warrant further scrutiny of pharmacy practices.



32. Examine pharmacy practices related to pharmacy sales.

- Scrutinize gift cards given to customers;
- Require pharmacy staff to document and initial any prescription alterations; and
- Question unusually high quantities of prescriptions processed for controlled substances or high-dollar medications.

Providing incentives, such as gift cards or free products, to Medicaid beneficiaries to accept less than the labeled drug quantity or to return unused medications to the pharmacy is a type of illegal remuneration scheme.[20]

Altered prescriptions, expired prescriptions, forged prescriptions, and phony prescriptions are all types of illegitimate prescriptions. Pharmacy staff members complicit in prescription fraud schemes may create illegitimate prescriptions and process claims for reimbursement from Medicaid. Fraudulent practices include:

- Increasing the quantity on a prescription without prescriber consent;
- Adding refills to an expired prescription or renewing an expired prescription without prescriber consent;
- Forging prescriptions entirely, in written or verbal form; or
- Entering into an agreement with a complicit physician to create illegitimate prescriptions in exchange for pay.

Unusual drug utilization patterns may indicate diversion of prescription drugs. A recent report by the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG) indicated 1,578 Medicare Part D beneficiaries had questionable utilization patterns for human immunodeficiency virus (HIV) drugs in 2012. The majority of beneficiaries had no documented HIV diagnosis in their Medicare claims history, received a disproportionately large dose or quantity of medication, received drugs from multiple pharmacies or prescribers, or received contraindicated HIV drugs.[21]

In December 2014, a Federal jury convicted a pharmacist, two technicians, and other co-conspirators for their involvement in a scheme that cost taxpayers \$2.5 million in government insurance payments. Between 2007 and 2013, the defendants used names, insurance, and identification numbers of hundreds of patients



and automatically refilled prescriptions for expensive HIV and cancer medications that beneficiaries never requested. Defendants then returned the medications to the pharmacy shelves for resale. Investigators discovered falsified signature logs and many of the undelivered prescriptions at one of the homes owned by the pharmacist.[22]

33. Talk to pharmacy staff members about POS billing parameter manipulation.

- Do not dispense a generic drug while submitting a claim to a third-party payer for the brand name drug;
- Do not submit a claim for a contracted NDC product while dispensing a non-contracted NDC product; and
- Do not split prescriptions into multiple fills within 1 month unless the patient requests to fill only a partial quantity of the amount of drug prescribed.

Fraudulent pharmacy practices, such as billing for a brand name prescription drug while dispensing a less expensive generic one, as well as prescription splitting, continue to be areas of concern for CMS and third-party payers. In December 2014, a West Virginia pharmacy owner was charged with defrauding Medicare and Medicaid by dispensing both compounded drugs and generic drugs while billing for more costly brand name drugs.[23]

Consider the possibility of fraud associated with the following billing and dispensing practices. Educate staff that:

- Dispensing generic drugs while billing a third-party payer for the brand name constitutes billing fraud;
- It is fraudulent to bill for a contracted NDC product while dispensing a non-contracted NDC product;
- Periodic audits of filled prescriptions will occur to ensure the NDC billed corresponds to the NDC dispensed in the prescription container;
- It is inappropriate to split prescriptions (dispensing fee inflation through short day fills) to receive additional dispensing fees; and
- They must ensure prescription splitting complies with State pharmacy laws (when applicable); a notation is placed on the prescription hard copy.

34. Talk to pharmacy staff members about coordination of benefits billing procedure manipulation.

- Do not submit claims to multiple insurance providers without coordination of benefits;
- Do not list more than one health plan as the primary provider for coordination of benefit claims; and
- Do not submit a claim to a manufacturer’s assistance program as if a patient is uninsured and also submit a claim to a primary insurance provider.

Pharmacy information systems serve as the backbone to daily operations by providing pharmacy staff members with essential capabilities such as clinical decision support, inventory management, maintenance of electronic prescription records, and transmission of third-party claims. The system logic should support appropriate third-party claims transmission. Evaluate the pharmacy information system settings for susceptibility to potential fraudulent billing practices. Implement billing system logic that does not allow billing of:

- Multiple payers for the same prescription;
- More than one health plan as the primary provider for coordination of benefit claims; and
- Primary coverage as well as a manufacturer’s assistance program as if a patient is uninsured.

35. Talk to pharmacy staff members about phantom claims.

- Establish a procedure to reconcile prescription sales, claims, and inventory receipts for prescription drugs;
- Verify documentation for prescription claims most commonly associated with fraud (for example: large numbers of prescription claims per patient, high-dollar drugs, or high-volume prescribers); and
- Confirm each prescription claim is supported by corresponding documented verbal prescription order, electronically generated prescription, or prescription hard copy.

Consider the possibility of phantom claims. Phantom claims occur when pharmacies bill for drugs that have not been dispensed and no legitimate prescription is associated with the claim. A phantom claim fraud artist may create claims through identity theft. Phantom claims are also associated with criminal enterprises posing as pharmacies. In April 2015, a Nebraska pharmacist was accused of health care fraud for fraudulently submitting 399 claims for TOBI®, a drug to treat cystic fibrosis. The drug was never ordered or dispensed, resulting in a loss of nearly \$2.5 million to the Medicaid program.[24]

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 invoice management can be incorporated into a pharmacy self-audit. The booklet describes 13 of the 50 steps to examine invoice shortages, what to do if drug claims exceed purchases, what to do if drug claims exceed sales, and possible billing manipulation at the POS. 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 4—Billing Practices for a detailed examination of how to perform pharmacy self-audit of billing 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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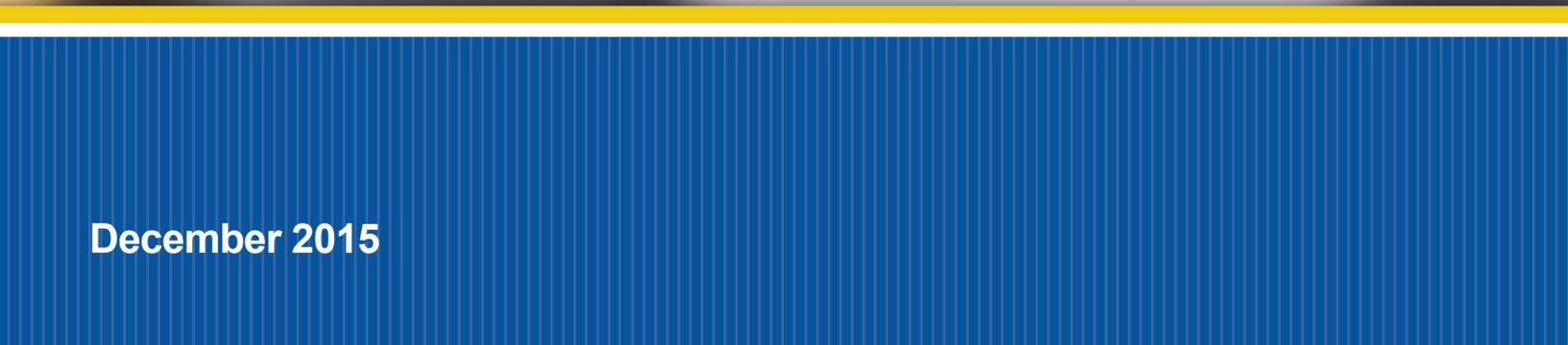
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