

Pharmacy Auditing and Dispensing: The Self-Audit Control Practices to Improve Medicaid Program Integrity and Quality Patient Care Checklist

The self-audit consists of 50 steps to help identify potential audit triggers in a pharmacy practice. The audit includes detailed information regarding each step and is divided into four sections that can be used separately or together as appropriate to meet the needs of the pharmacy practice: prescribing practices, controlled substances management, invoice management, and billing practices. The 50 steps below correspond to the steps found in the four accompanying booklets. Consider each step, answer the questions listed, and examine existing policies and procedures to identify any audit triggers related to prescribing practices, controlled substances management, invoice management, and billing practices.

Before using the self-audit checklist, gather the following information and review the documentation:

- Licenses—pharmacist, intern, and technician;
- Pre-hire screening and background check materials;
- United States (U.S.) Drug Enforcement Administration (DEA) Forms 106 and 222;
- Reverse distributor records;
- Spare key logs;
- Security camera and surveillance maintenance logs;
- Controlled substance inventory records;
- Law enforcement or State pharmacy board alerts;
- Purchase records;
- Invoices;
- Claim transaction records; and
- Signature logs.

Prescribing Practices Self-Audit

1. If a prescription presented for fill appears questionable or if the prescriber is unfamiliar, check to see if the prescriber appears on the Office of Inspector General (OIG) List of Excluded Individuals/Entities (LEIE) database. The OIG LEIE identifies prescribers currently excluded from participating in Medicare, Medicaid, and all other Federal health care programs.[1] If unsure about the status of an unfamiliar provider, complete the following:
 - 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 prescriber to confirm the prescriber does not appear on the LEIE database;[2] and
 - Download the LEIE and subsequent monthly updates.
2. Upon review of a prescription presented for fill, determine if the prescription is written for a legitimate medical purpose within the prescriber’s scope of practice.
 - Fill only prescriptions written for a legitimate medical purpose;
 - Know what “corresponding responsibility” means;
 - Fill only prescriptions written within the prescriber’s State-defined scope of practice limitations; and

- Fill only prescriptions written within professional and positional scope of practice limitations.
3. Use a combination of prescriber communication and patient counseling to confirm the prescription is written for a U.S. Food and Drug Administration (FDA)-labeled or approved compendial indication.
- Consult State-approved compendial sources, which vary by State, but may include the:
 - American Hospital Formulary Service (AHFS) Drug Information®;
 - Thomson Micromedex DrugDex® Information System;
 - National Comprehensive Cancer Network Drugs and Biologics Compendium® (NCCN Compendium); or
 - Elsevier Gold Standard's Clinical Pharmacology (Clinical Pharmacology).
 - Consider prescriptions written for drug classes often associated with inappropriate prescribing practices:
 - Transmucosal immediate-release fentanyl (TIRF) products;
 - Buprenorphine-naloxone products for opioid dependence;
 - Atypical (second-generation) antipsychotics;
 - Pediatric psychotropics;
 - Phosphodiesterase inhibitors (PDEIs);
 - Drug classes associated with cosmetic use: topical retinoids and injectable botulinum toxins;
 - Drug classes associated with weight loss: incretin mimetics; and
 - Drug classes associated with recreation use: amphetamines and cannabinoids.
4. Examine TIRF prescriptions carefully to determine if the patient will use the product for an FDA-labeled or compendial indication.
- To verify the patient understands the medication prescribed, counsel the patient using the Indian Health Service (IHS) counseling technique:
 - What did your prescriber tell you the medication is for?
 - How did your prescriber tell you to take the medication?
 - What did your prescriber tell you to expect?[3]
 - If the patient does not have a diagnosis of cancer, contact the prescriber to advise this medication is covered only for FDA-labeled indications. Discuss alternative options covered by Medicaid for the indication in question.
5. Examine buprenorphine-naloxone prescriptions carefully to determine if the patient will use the product for an FDA-labeled or compendial indication.
- Verify the prescription has been written by a prescriber who is in compliance with the Drug Addiction Treatment Act (DATA) requirements. Pharmacists can verify the validity of a prescriber's DATA 2000 waiver by consulting the Substance Abuse and Mental Health Services Administration's website at <http://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator> or by emailing info@buprenorphine.samhsa.gov or calling 1-866-BUP-CSAT (1-866-287-2728).[4] The prescription must contain both the prescriber's DEA registration number and the prescriber's unique identification number provided by DATA:[5]
 - Use the IHS counseling technique to verify the patient understands the medication prescribed; and
 - Contact the prescriber if the drug is used to treat pain or any indication other than opioid dependence maintenance. Advise the prescriber this medication is covered only for FDA-labeled indications. Discuss alternative Medicaid-covered options for the indication in question.
6. Examine atypical antipsychotic prescriptions carefully to determine if the patient will use the product for an FDA-labeled or compendial indication.

- Use the IHS counseling technique to verify the patient understands the medication prescribed; and
 - Contact the prescriber if the drug is being used for sedation to advise this medication is covered only for FDA-labeled indications. Suggest an alternative, including a benzodiazepine or another FDA-labeled sedative hypnotic, such as zolpidem, zaleplon, or ramelteon.[6, 7, 8]
7. Examine pediatric antipsychotic prescriptions carefully to determine if the patient will use the product for an FDA-labeled, compendial, or off-label indication.
8. Examine caregiver counseling procedures for pediatric second-generation antipsychotic prescriptions.
- Use the IHS counseling technique to verify the caregiver understands the medication prescribed;
 - The drug may be prescribed for off-label nonpsychotic indications, such as aggression, resistant attention deficit hyperactivity disorder, tic disorders, obsessive-compulsive disorder, eating disorders, depression, post-traumatic stress disorder, or insomnia, or for FDA-labeled or compendial indications, such as schizophrenia, bipolar disorder, and irritability associated with autism.[9, 10] Explain the medication's use, actions, and anticipated benefit;
 - Advise the caregiver of potential risks for common or severe side effects. Caregivers should monitor children for weight gain, metabolic changes (for example: diabetes or hyperlipidemia), cardiac abnormalities (for example: heart rate or blood pressure), prolactin elevation (for example: amenorrhea—absence of menstruation, galactorrhea—milk discharge from the breast unrelated to breastfeeding, in females or males, and gynecomastia—enlargement of breast tissue in males), extrapyramidal side effects (for example: akathisia—inability to sit still, dystonic reactions—sustained involuntary muscle contractions, or tardive dyskinesia—abnormal, involuntary movements), cataract formation, and increased risk of suicidal thinking;[11] and
 - Explain the importance of close monitoring and prescriber follow-up.
9. Examine PDEI prescriptions carefully to determine if the patient will use the product for an FDA-labeled or compendial indication.
- Use the IHS counseling technique to verify the patient understands the medication prescribed; and
 - If the drug is being used for erectile dysfunction (ER), explain the exclusion to the patient and offer a self-pay cash option for the prescription.
10. Examine topical retinoid and injectable botulinum toxin prescriptions carefully to determine if the patient will use the product for an FDA-labeled or compendial indication.
- Use the IHS counseling technique to verify the patient understands the medication prescribed; and
 - If the drug is being used for cosmetic purposes, explain the exclusion to the patient and offer a self-pay cash option for the prescription.
11. Examine incretin mimetic prescriptions carefully to determine if the patient will use the product for an FDA-labeled or compendial indication.
- Use the IHS counseling technique to verify the patient understands the medication prescribed; and
 - If the drug is being used for weight loss, explain the exclusion to the patient and offer a self-pay cash option for the prescription.
12. Examine amphetamine and cannabinoid prescriptions carefully to determine if the patient will use the product for an FDA-labeled or compendial indication.
- Use the IHS counseling technique to verify the patient understands the medication prescribed; and
 - If the drug is being used for an off-label use, such as to enhance academic performance,[12] treat depression, or enhance weight loss, explain the exclusion to the patient and offer a self-pay cash option for the prescription.

Controlled Substance Self-Audit

13. Ensure hiring procedures include adequate background checks.

- Visit <https://exclusions.oig.hhs.gov/> on the HHS-OIG website;
- Enter the first and last name of the potential employee to confirm the applicant is not excluded in the LEIE and use the potential employee's social security number to confirm any matches;[13]
- 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.

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

15. Examine controlled substance inventory management. Verify pharmacy staff take 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).[14]

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[15] 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.[16]

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.

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.[17]

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 patients.

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

- Restrict pharmacy access to authorized pharmacy personnel by key or key code;
- Assign, if feasible, a unique security alarm code for each pharmacist authorized to have access to the pharmacy;
- Examine, periodically, 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 in a container within 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.

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.

Invoice Management Self-Audit

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 invoice/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, on drugs returned from institutions or patients.
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.
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.
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.
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.
30. Talk to pharmacy staff members about prescription “shorting” (providing the patient with a quantity less than the prescriber ordered).
- Require the pharmacist who fills any controlled substance or high-dollar prescription and one other person 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, point of sale (POS) billing manipulations, coordination of benefits manipulations, or phantom claims.
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.
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.
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.
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.

Billing Practices Self-Audit

36. Discuss billing procedures with staff to determine if staff members correctly submit claims for drugs commonly submitted with improper billing units. Provide staff members with job aids associated with common types of quantity and/or days' supply miscalculations. The examples below are not comprehensive but suggest potential targets for job aids.
- Oral products;
 - Anti-migraine agents;
 - Bowel preparations;
 - Multi-drug/multi-month packs; and
 - Osteoporosis agents.
 - Other dosage forms;
 - Inhalers;
 - Ophthalmic products;
 - Topical products; and
 - Vaginal products.

- Injections; and
- Kits.

37. Review prescription requirements for non-controlled and controlled substances.[18, 19, 20]

- Date of issuance;
- Prescriber's signature;
- Prescriber's authority to prescribe (For example: mid-level prescribers versus physicians; State regulations versus Federal days' supply regulations; and authorization to prescribe specific controlled drug schedules);
- Drug name;
- Drug strength;
- Drug dosage form;
- Quantity of drug prescribed;
- Directions for use;
- Number of refills authorized by the prescriber (if any);
- "Brand name medically necessary" if no generic substitution is allowed;
- If hand written, controlled substance prescriptions must be written in ink or pencil that cannot be erased; and
- Prescribers must manually sign controlled substance prescriptions on the date issued.

38. Ensure staff members are able to correctly calculate a day's supply for prescriptions.

- Multiply the number of doses per day by the number of days of therapy to determine the correct quantity to dispense; and
- Reverse-verify by dividing the quantity dispensed by the number of doses per day to determine the number of days' supply.

39. Talk to pharmacy staff members about prescriptions written for odd quantities.

- Reduce the quantity dispensed to correspond to a number of days equal to or less than the plan-imposed maximum if the days' supply calculated by dividing the quantity dispensed by the number of doses per day exceeds the plan-imposed maximum allowable days' supply.

40. Talk to pharmacy staff members about prescriptions written for doses that exceed FDA labeling.

- Examine high doses with scrutiny;
- Consult the FDA label;
- Contact the prescriber to verify the dose if it exceeds FDA recommendations; and
- Document all communication on the hard copy.

41. Talk to pharmacy staff members about prescriptions that include the use-as-directed sig code for dispensed quantities more than one billing unit per month.

- Shampoos—Document frequency of use and size of area to be treated;
- Creams and ointments—Document frequency of use and size of area to be treated;
- Migraine medications—Document number of headaches treated per month;
- Insulin—Document exact regular dosage and maximum daily dosage for any sliding scale directions; and
- Diabetic syringes, test strips, or lancets—Document maximum use per day.

42. Talk to pharmacy staff members about refill practices.

- Do not push-bill or auto-refill without patient consent or request or when prohibited by State law;

- Do not refill and mail to patients without request or patient consent, and only perform patient outreach to initiate refills in attempts to improve medication adherence and clinical outcomes; and
 - Do not use financial incentives to influence beneficiary decisions about when or where to fill prescriptions paid by a federally funded program.
43. Consider possible patient-driven inappropriate refill practices.
- Counsel patients if stockpiling is suspected;
 - Be aware of red flags that may indicate diversion and require further scrutiny; and
 - If diversion is suspected, report concerns to the proper authorities.
44. Talk to pharmacy staff members about overrides at the POS.
- Submit claims with vacation supply override codes only if the patient is on vacation; and
 - Submit claims with known prior authorization (PA) override codes only if the patient meets the PA criteria.
45. Talk to pharmacy staff members about prescription origin codes.
- Do not alter prescription origin codes; and
 - Verify the prescriber DEA number and office telephone number for all controlled substances prescriptions received by telephone. If the caller or prescriber is unknown, confirm the contact information with a secondary source. If the contact information differs, call the prescriber's office at a published telephone number to confirm the prescription.
46. Talk to pharmacy staff members about product selection (dispense as written—DAW) codes.
- Only use the DAW 1 product selection code when the prescriber has indicated product substitution is not allowed on the prescription; and
 - Only use the DAW 2 product selection code when the patient has requested to receive the brand name drug rather than the generic equivalent.
47. Talk to pharmacy staff members about partial fill procedures.
- Adjudicate partial fills appropriately. Do not "owe" patients any drug quantity if the full quantity to be dispensed has already been billed;
 - Only use the partial fill functionality of the billing system when unable to fill the full quantity to be dispensed;
 - Do not bill the payer for the full amount of a partial refill; and
 - Do not bill the payer for a second dispensing fee when completing a partial refill.
48. Talk to pharmacy staff members about how they select package sizes when more than one size is available.
- Select the smallest commercially available package size to address the prescription requirements;
 - Ensure the NDC dispensed matches the NDC billed, particularly for generic and compounded medications;
 - Adhere to State-specific Medicaid compound prescription billing requirements;
 - Bill accurate quantities of medications used in compounded medications; and
 - Confirm that commercially available equivalents do not exist and that the compounded medications are treating a medically necessary indication.
49. Talk to pharmacy staff members about how they document beneficiary receipt of prescriptions.
- Always obtain signatures from patients or their agents at the time of prescription pickup.

50. If a Medicaid overpayment is identified, take one of the following steps:

- Reverse any claim within the last year;
- Send a check and an explanation for any older claim; or
- Self-disclose the overpayments to your SMA or the OIG.

To see the electronic version of this checklist 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 Centers for Medicare & Medicaid Services (CMS) website.

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