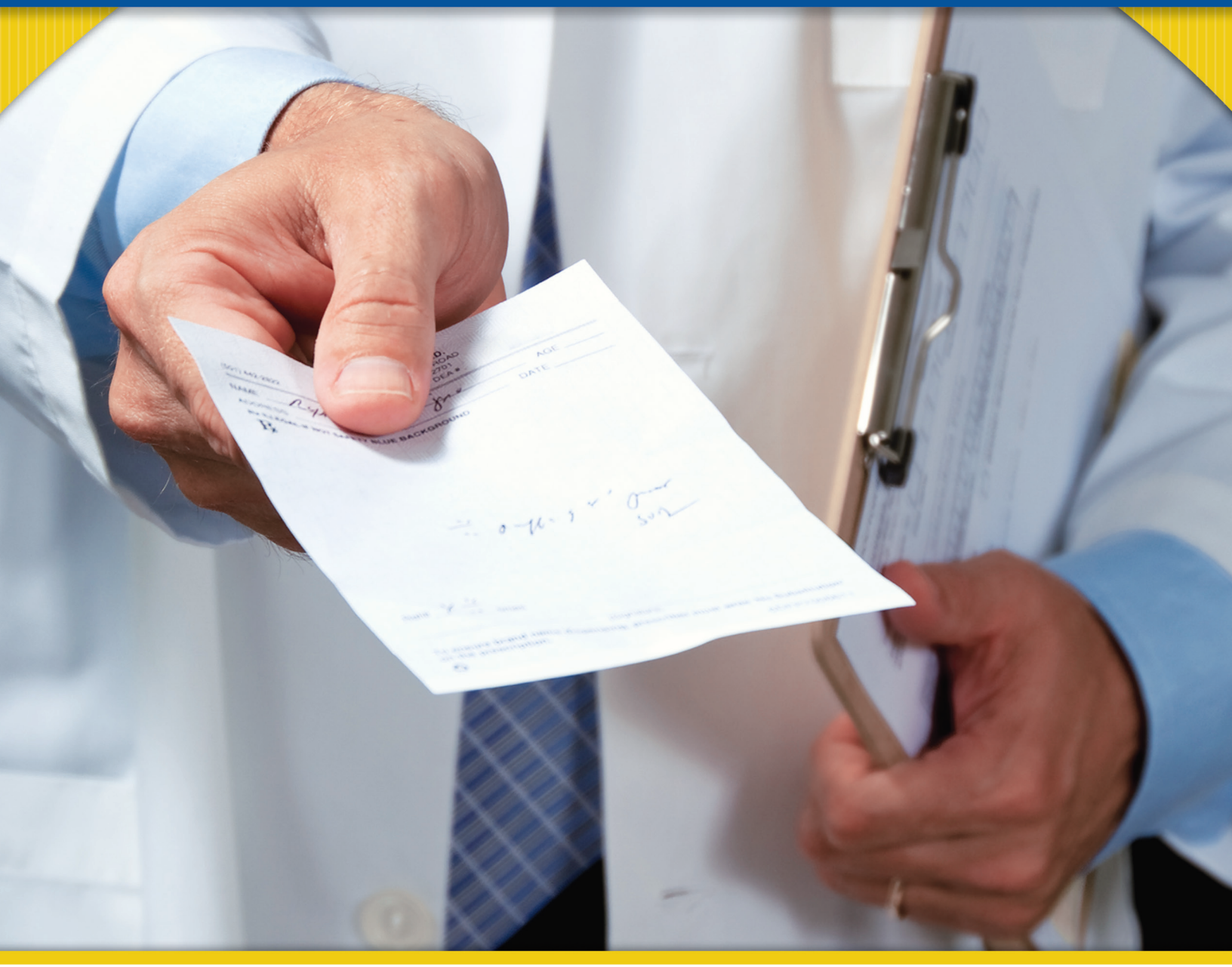
Pharmacy Self-Auditing

Control Practices to Improve Medicaid Program Integrity and Quality Patient Care—Booklet 1: Prescribing Practices



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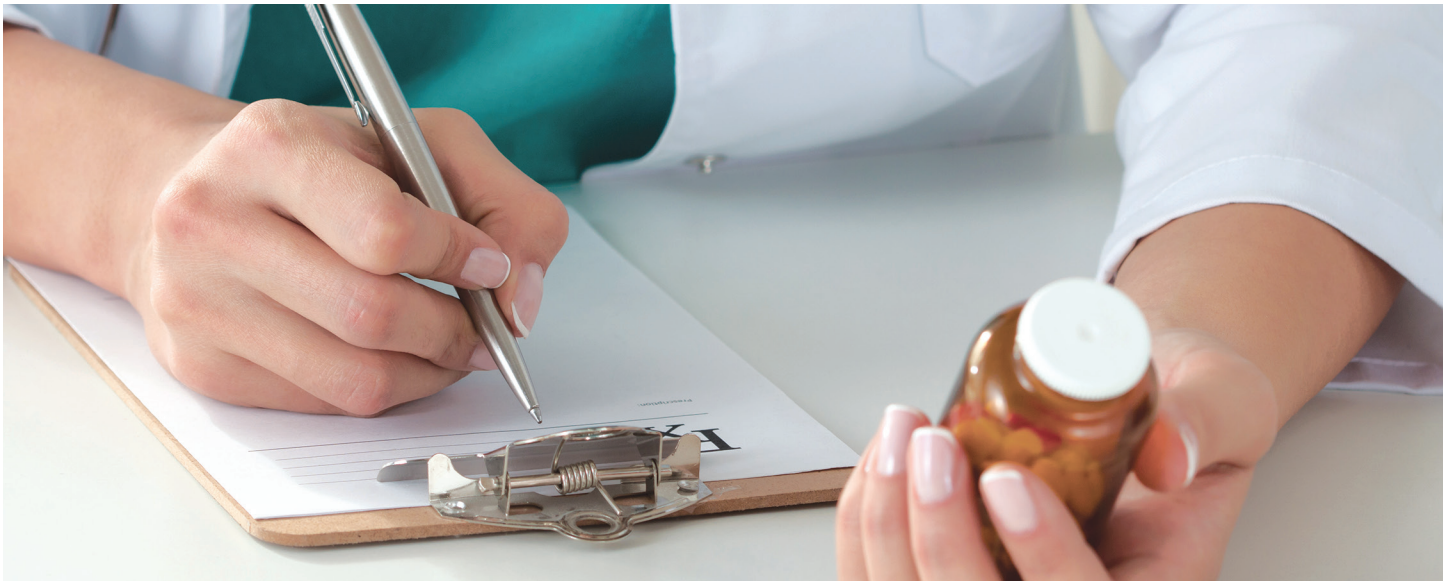


Content Summary

This booklet is the first 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 provider prescribing practices. The other booklets examine controlled substance management, 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 5.9 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 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.

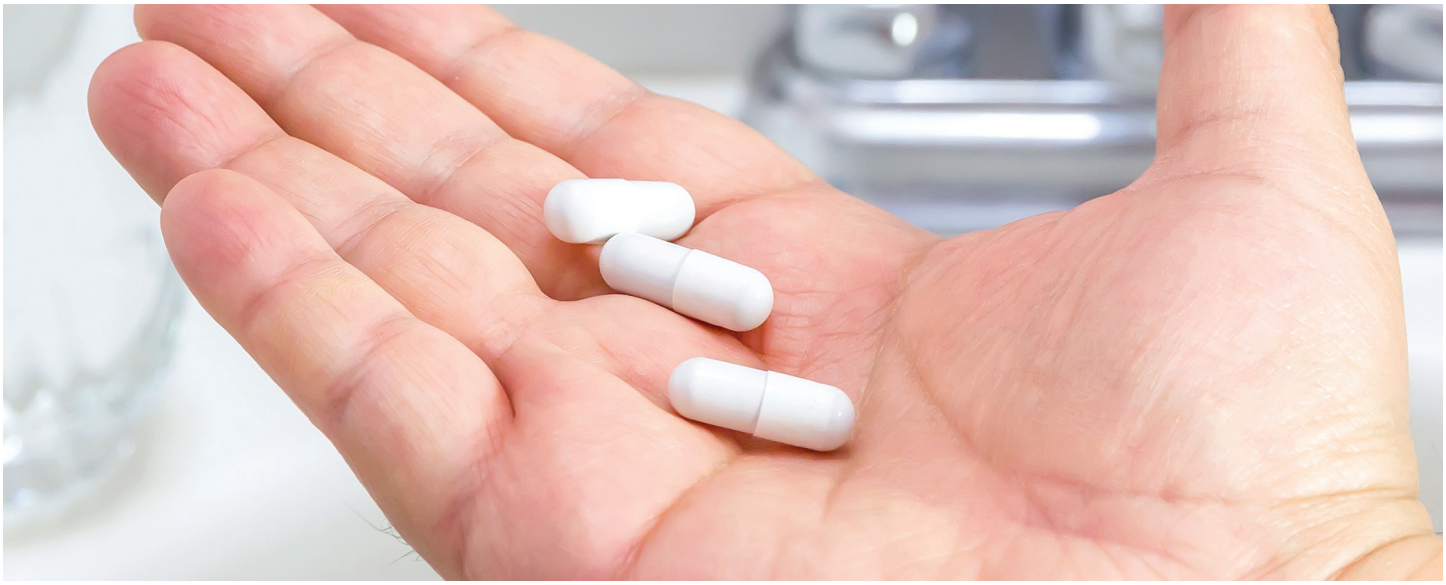
Title 18 of the United States Code defines health care fraud as knowingly and willfully executing, or attempting to execute, a scheme to defraud a health care program or obtain money or property from a health care program under false pretenses.[6] Medicaid fraud artists intentionally submit false claims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

Federal Medicaid regulations do not define waste, 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.

Off-label prescribing is a fundamental component of patient care. Off-label prescribing allows and encourages innovation, enables discovery of benefits not otherwise known, and is a tenet of care for patient populations not routinely included in clinical studies (for example: pediatric and geriatric populations). However, when off-label prescribing occurs in absence of therapeutic benefit, and, in some cases, when benefits do not outweigh risks, the possibility of peril to the health of the patient can occur. Therefore, judicious off-label use must be carefully considered.

Pharmacists can help protect State Medicaid patients from harm and State Medicaid dollars from waste by working in careful cooperation with prescribers to verify appropriate use of Medicaid prescription drugs. In addition, pharmacists can help identify excluded diagnoses for which payments through the Medicaid program are not allowed.

The Self-Audit

The self-audit consists of 50 steps to help identify potential audit triggers in a pharmacy practice. This booklet (Booklet 1—Prescribing Practices) contains 12 of the 50 steps. 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 2—Controlled Substances Management, Booklet 3—Invoice Management, and Booklet 4—Billing Practices) contain the remaining 38 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."

Prescribing Practices Self-Audit

Payment for medications prescribed for inappropriate uses may cost State Medicaid programs millions of dollars each year. A prescribing practice self-audit will help pharmacists identify prescriptions written by providers who appear on the OIG List of Excluded Individuals/Entities (LEIE), prescriptions written outside the prescriber's scope of practice, and prescriptions written for off-label indications. Pharmacists can perform prospective review on a continuing basis with little disruption to daily activities.[14] These self-audit practices will improve State Medicaid program integrity and improve the quality of patient care for State Medicaid beneficiaries.

1. If a prescription presented for fill appears questionable or if the prescriber is unfamiliar, check to see if the prescriber appears on the OIG LEIE. The OIG LEIE identifies prescribers currently excluded from participating in Medicare, Medicaid, and all other Federal health care programs.[15] 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[16] database; 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 profession- and position-appropriate scope of practice limitations.

   As the gatekeepers to controlled substances, pharmacists are obligated to exercise their corresponding responsibility to ensure each prescription has been issued to a patient for a legitimate medical purpose by an authorized prescriber acting in the usual course of professional practice. If the pharmacist believes a situation requires further investigation, steps must be taken. Failure to fulfill that corresponding responsibility violates the Controlled Substances Act (CSA), and pharmacists who fail to comply may be held liable for their actions.[17] To help prevent fraud, waste, and abuse, pharmacists should hold non-controlled prescriptions to the same standard. The Social Security Act says that States must "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan … as may be necessary to safeguard against unnecessary utilization of such care and services … ."[18] In 42 C.F.R. § 440.230(d), CMS says the State Medicaid agency (SMA) "may place appropriate limits on a service based on such criteria as medical necessity … ."[19]

   A prescriber should only write and a pharmacist should only dispense prescriptions that fall within the prescriber's scope of practice. Each State defines the scope of practice limitations that apply to a particular

health care profession.[20] Some States allow nurse practitioners and physician assistants to prescribe CSA Schedule II narcotics, while other States reserve this dispensing privilege for physicians. Pharmacists must consider State scope of practice prescribing limitations before filling prescriptions.

The pharmacist also has a responsibility to question prescriptions with an uncertain scope of practice. For example, it would be outside the scope of practice for an optometrist to write a prescription for birth control pills. Some scope of practice situations may require careful consideration. For example, a dentist may prescribe narcotic medications to treat dental pain, and to do so is within the dentist's scope of practice when prescribed to treat acute pain. However, the pharmacist should question a prescription written by a dentist for OxyContin® (oxycodone extended release) for appropriate scope of practice because OxyContin® is approved only for chronic pain.[21]

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.

   Labeled indications are indications that have been approved by the FDA for each drug. It is common for a drug to be prescribed for indications other than those shown in the label information. If the indication for which the drug is being prescribed is not an FDA-approved indication but can be found in an approved compendial source, then this is called compendial prescribing. Off-label prescribing occurs when the prescriber writes a prescription for a drug to treat an indication that is neither FDA-approved nor found in approved compendial sources.[22]

   ☐ 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).

   States usually consider NCCN and Clinical Pharmacology approved compendia when the drug in question is used in anti-cancer regimens.

   ☐ 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?[23]

☐ 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.

TIRF medicines contain fentanyl, an opioid agonist and a Schedule II controlled substance. These products are indicated only for managing breakthrough pain in adult cancer patients 18 and older (16 and older for Actiq® brand and generic equivalents) who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.[24] Prescribers and pharmacists must first enroll in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) program before the pharmacy's claim management system will adjudicate the claim for a TIRF medication.[25] If a patient presents a prescription for a TIRF medication (Abstral®, Actiq®, Fentora®, Lazanda®, Subsys®, or a fentanyl citrate generic product),[26] ensure appropriate prescribing.

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 emailing info@buprenorphine.samhsa.gov or calling 1-866-BUP-CSAT (1-866-287-2728).[27] The prescription must contain both the prescriber's DEA registration number and the prescriber's unique identification number provided by DATA.[28]

   ☐ 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.

   Medications indicated only for the treatment of opioid dependence are often prescribed inappropriately. Buprenorphine/naloxone-containing products are FDA-approved for the maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.[29] These products are partial opioid agonists, and their use is restricted under DATA.[30] They can only be prescribed by physicians who meet certain qualifying requirements, and who notify the Secretary of Health and Human Services of their intent to prescribe these products for the treatment of opioid dependence. These physicians are assigned a unique identification number that must be included on every prescription.[31] If a patient presents a prescription for a buprenorphine-naloxone medication (Bunavail™, Suboxone®, and Zubsolv®),[32] take steps to ensure appropriate prescribing.

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 such as a benzodiazepine or another FDA-labeled sedative hypnotic such as zolpidem, zaleplon, or ramelteon.[33, 34, 35]

Atypical antipsychotic medications are used to treat a variety of FDA-labeled psychiatric conditions. However, off-label use of atypical antipsychotics has increased rapidly since their introduction in the 1990s. Quetiapine and olanzapine are among the most common atypicals prescribed for off-label use.[36] Prescribing these medications for off-label uses is a worrying trend considering the significant potential for adverse effects.[37] These medications, commonly prescribed off-label for insomnia, offer low or very low efficacy and are an expensive treatment option for this use.[38] In addition, when used as a sedative, Medicaid beneficiaries are at risk for sudden cardiac death and cardiac arrest, and this risk is particularly dangerous in vulnerable pediatric and elderly populations.[39] If a patient presents a prescription for an atypical antipsychotic (Seroquel®, Zyprexa®),[40, 41] ensure appropriate prescribing.

7. Examine atypical antipsychotic prescriptions carefully to determine if the patient will use the product for an FDA-labeled or compendial indication.

   Antipsychotic medications prescribed for children is an issue confronting parents, other caregivers, health care professionals, and related organized health care agencies across the U.S.

   Due to the rising concerns of this prescribing practice, the OIG analyzed Medicaid claims in five states in 2014. The OIG identified quality-of-care concerns in 67 percent of claims for second generation antipsychotics that were prescribed for children.[42]

   See the breakdown in the table below:

Table 1. Quality of Care Concerns in Pediatric Antipsychotic Claims Analysis

Concern Identified	Percentage of Claims Affected
Poor monitoring	53%
Wrong treatment	41%
Too many drugs	37%
Taken too long	34%
Wrong dose	23%
Too young	17%
Side effects	7%

Many antipsychotic medications do not have FDA-approved labeling for use in children. The risk for a variety of significant side effects related to the use of antipsychotic medications appears to be significant for children and adolescents.[43] The FDA has approved five second-generation antipsychotics for use in children: Abilify® (aripiprazole), Invega® (paliperidone), Risperdal® (risperidone), Seroquel (quetiapine), and Zyprexa (olanzapine). Approved indications include schizophrenia, bipolar disorder, and irritability associated with autism.[44] However, off-label pediatric use is not necessarily excluded by SMAs because the drug manufacturer often does not seek FDA approval for use in children. The SMA may use the prior authorization approval process to ensure the drug is being prescribed for indications supported by current guidelines and literature.

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).[45, 46] 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;[47] and
- ☐ Explain the importance of close monitoring and prescriber follow-up.

If a pediatric caregiver presents a prescription for any atypical antipsychotic (Abilify, Clozaril®, Fanapt®, FazaClo®, Geodon®, Invega, Latuda®, Risperdal, Saphris®, Seroquel, Versacloz™, or Zyprexa),[48] help ensure the prescriber and caregiver are aware of labeling warnings that apply to children.

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.

   PDEIs are used to treat FDA-labeled indications that include pulmonary arterial hypertension (PAH),[49, 50] benign prostatic hyperplasia (BPH),[51] and ER (ED).[52, 53, 54] Federal law prohibits coverage of PDEIs, such as sildenafil or tadalafil, to treat sexual dysfunction.[55] Although States have measures in the pharmacy point-of-sale system to prevent inappropriate dispensing of these medications, the potential for fraud still

exists. If a patient presents a prescription for a PDEI (Adcirca®, Cialis®, and Revatio®),[56, 57, 58] ensure appropriate prescribing.

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.

    Topical retinoids, such as tazarotene and tretinoin, are FDA-labeled to treat acne and plaque psoriasis.[59, 60, 61, 62] Topical retinoid products are also FDA-labeled to treat facial wrinkling.[63] Injectable botulinum toxins are FDA-labeled to treat a variety of indications, including temporary improvement in the appearance of moderate to severe glabellar lines (also known as wrinkles).[64, 65, 66] States may opt to exclude drugs or drug classes used for a particular indication outlined in section 1927(d)(2) of the Social Security Act.[67] Because use of topical retinoids or injectable botulinum toxins to treat wrinkles is considered a cosmetic purpose, this particular indication is excluded from coverage.[68] If a patient presents a prescription for a topical retinoid (Fabior®, Tazorac®, Atralin®, Avita®, Retin-A®) or an injectable botulinum toxin (Xeomin®, Botox®, Dysport®), ensure appropriate prescribing.

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.

    Incretin mimetic drugs work by mimicking the incretin hormones that the body usually produces naturally to stimulate the release of insulin in response to a meal. They are used, along with diet and exercise, to lower blood sugar in adults with type 2 diabetes.[69] Studies have shown these products have a favorable side effect profile in that they enhance weight loss.[70, 71, 72] Products used for weight loss are excluded from drug coverage.[73] If a patient presents a prescription for an incretin mimetic (Victoza®, Byetta®, Bydureon®, and Tanzeum™),[74] ensure appropriate prescribing.

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,[75] treat depression, or enhance weight loss, explain the exclusion to the patient and offer a self-pay cash option for the prescription.

    Amphetamines are the prescription drugs most commonly abused and constitute a serious public health concern. Due to the highly addictive nature and street value of these drugs, the potential for fraud and abuse is substantial. If a patient presents a prescription for amphetamines (Adderall®, Concerta®, or Ritalin®)[76, 77, 78] or cannabinoids (Marinol®),[79] ensure appropriate prescribing.

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 prescribing practices can be incorporated into a pharmacy self-audit. The booklet describes the first 12 of 50 steps to identify potential audit triggers in a pharmacy practice and discusses excluded providers, prescriptions written outside a prescriber's scope of practice, and prescriptions written for off-label indications. A thorough review of these 12 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 2—Controlled Substances Management for a detailed examination of how to perform pharmacy self-audit of controlled substances 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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