



**Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality**

**Module 1  
Prescribing Practices**



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**Cost of Pharmacy Services**

Pharmaceutical Expenditures

- 11.5 percent of total health care expenditures
- \$8,745 per capita

Health Care Expenditures

- 8 percent of the gross domestic product

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**Medicaid Expansion—  
Medicaid Spending**

Eligible: earnings less than 138 percent of Federal poverty level.



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### Definitions

**Fraud**

- 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

**Waste**

- The overutilization or misuse of services; not usually associated with criminal actions

**Abuse**

- Any action that may cost the Medicaid system unnecessary dollars; not usually associated with criminal actions

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### Self-Audit

Educate pharmacy providers on:

- Self-audit precautions related to:
  - Proper prescribing practices
  - Controlled substances management
  - Invoice management
  - Proper billing practices
- Reporting fraud, waste, and abuse

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### Objective

At the conclusion of "Module 1: Prescribing Practices," the learner will be able to:

- Recall five types of off-label uses a prescribing practice self-audit would help identify

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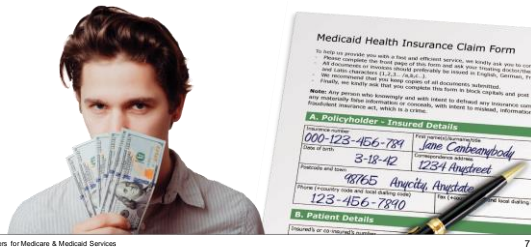
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## Pharmacy Self-Monitoring— The Self-Audit

Federal False Claims Act = Civil liability if a person knowingly submits a false or fraudulent claim.



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## Self-Audit Process

Use of the self-audit process allows pharmacy staff to:

- Evaluate daily practices
- Pinpoint audit triggers
- Address vulnerabilities

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## Prescribing Practices Self-Audit

- Office of Inspector General (OIG) List of Excluded Individuals/Entities (LEIE)
- Scope of practice
- Off-label indications



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## List of Excluded Individuals/Entities

Payment may be withheld if:

- A medication written by an excluded prescriber is dispensed
- An excluded pharmacist inputs prescription information for pharmacy billing
- An excluded pharmacist otherwise fills prescriptions billed to a Federal health care program

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## Legitimate Medical Purpose

- Corresponding responsibility
- Scope of practice includes:
  - State-defined
  - Profession and position-defined

“I would like to fill this prescription for my birth control please.”

“Well, it looks like this was prescribed by your podiatrist. Birth control isn't the type of drug a podiatrist prescribes. Let me give him a call.”

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## Types of Indications

- Labeled: approved by the FDA
- Compendial: recommended in a compendial source, but not approved by the FDA
- Off-label: neither FDA approved nor recommended in a compendial source

Drug classes often associated with inappropriate prescribing: transmucosal immediate-release fentanyl (TIRF), buprenorphine, antipsychotics, phosphodiesterase inhibitors (PDEIs), and drugs for cosmetic use, weight loss, and recreation.

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## Transmucosal Immediate-Release Fentanyl Medications

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?

Prescriber outreach: non-cancer pain alternatives.

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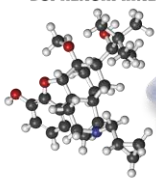
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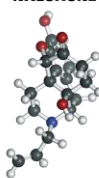
## Buprenorphine-Naloxone Products

Prescriber outreach: alternatives for indications other than opioid dependence (for example: pain).

**BUPRENORPHINE**



**NALOXONE**



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## Atypical Antipsychotics

Prescriber outreach: alternative options for use as a sedative-hypnotic.



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## 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%

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## Food and Drug Administration—Labeled Pediatric Indications

Brand/Generic Name	FDA Labeled Pediatric Indications
Ablify® Aripiprazole	<ul style="list-style-type: none"> <li>Bipolar I disorder</li> <li>Irritability associated with autistic disorder</li> <li>Schizophrenia</li> <li>Tourette syndrome</li> </ul>
Saphria® Asenapine	<ul style="list-style-type: none"> <li>Bipolar I disorder</li> </ul>
Zyprexa® Olanzapine	<ul style="list-style-type: none"> <li>Bipolar I disorder</li> <li>Depressive episodes associated with Bipolar I disorder</li> <li>Schizophrenia</li> </ul>
Invega® Paliperidone	<ul style="list-style-type: none"> <li>Schizophrenia</li> </ul>
Seroquel® Quetiapine	<ul style="list-style-type: none"> <li>Bipolar I disorder</li> <li>Schizophrenia</li> </ul>
Risperdal® Risperidone	<ul style="list-style-type: none"> <li>Bipolar I disorder</li> <li>Irritability associated with autistic disorder</li> <li>Schizophrenia</li> </ul>

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## Compendial Pediatric Indications

Generic Name	Compendial Pediatric Indications
Risperidone	<ul style="list-style-type: none"> <li>Behavioral syndrome-mental retardation</li> <li>Pervasive developmental disorder</li> <li>Tourette syndrome</li> </ul>

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## Off-Label Pediatric Uses

Generic Name	Off-Label Pediatric Uses
Aripiprazole	<ul style="list-style-type: none"> <li>• Conduct disorder (aggression)</li> <li>• Mania</li> <li>• Pervasive developmental disorder</li> </ul>
Clozapine	<ul style="list-style-type: none"> <li>• Refractory schizophrenia</li> <li>• Post-traumatic stress disorder</li> <li>• Treatment resistant autistic disorder</li> </ul>
Olanzapine	<ul style="list-style-type: none"> <li>• Anorexia and other eating disorders</li> <li>• Pervasive developmental disorder</li> <li>• Psychosis</li> <li>• Tourette syndrome (tic disorder)</li> </ul>
Quetiapine	<ul style="list-style-type: none"> <li>• Conduct disorder (aggression)</li> <li>• Obsessive-compulsive disorder</li> <li>• Pervasive developmental disorder</li> <li>• Psychosis</li> <li>• Tic disorders</li> </ul>

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## Off-Label Pediatric Uses

Generic Name	Off-Label Pediatric Uses
Risperidone	<ul style="list-style-type: none"> <li>• Anorexia nervosa</li> <li>• Conduct disorder (impulse aggression)</li> <li>• Attention deficit hyperactivity disorder with aggression</li> <li>• Disruptive behavior disorder</li> </ul>

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## Atypical Antipsychotics Pediatric Side Effects

Generic Name	Cataract Formation	Cardiovascular Changes	Extrapyramidal Effects	Metabolic Changes	Prolactin Elevation	Suicidal Thinking
Aripiprazole	N/A	Labeled	Labeled	Labeled	N/A	Black box warning
Asenapine	N/A	Labeled	Labeled	Labeled	Labeled	N/A
Clozapine	N/A	Guideline	N/A	Guideline	N/A	N/A
Olanzapine	N/A	Labeled	Labeled	Labeled	Labeled	Black box warning
Paliperidone	N/A	Labeled	Labeled	Labeled	Labeled	N/A
Quetiapine	Labeled	Labeled	Labeled	Labeled	Labeled	Black box warning
Risperidone	N/A	Labeled	Labeled	Labeled	Labeled	N/A
Ziprasidone	N/A	Guideline	N/A	Guideline	Guideline	N/A

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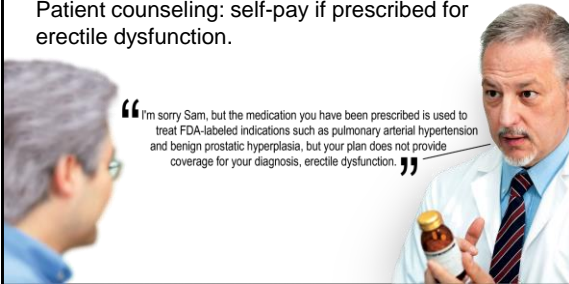
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## Phosphodiesterase Inhibitors

Patient counseling: self-pay if prescribed for erectile dysfunction.

“I'm sorry Sam, but the medication you have been prescribed is used to treat FDA-labeled indications such as pulmonary arterial hypertension and benign prostatic hyperplasia, but your plan does not provide coverage for your diagnosis, erectile dysfunction.”



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## Cosmetic Purposes

- Drugs prescribed off-label for cosmetic uses: tazarotene, tretinoin, or injectable botulinum toxins
- Patient counseling: self-pay if prescribed for cosmetic uses

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## Injectable Incretin Mimetic Medications

- IHS counseling technique
- Patient counseling: self-pay if prescribed for weight loss



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## Amphetamines and Cannabinoids

- IHS counseling technique
- Patient counseling: self-pay if prescribed for off-label use
- Exercise corresponding responsibility and do not fill if the drug is being used for illicit purposes

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## Knowledge Check

Review the following drug classes. Determine which of the off-label or excluded indications and appropriate covered use correspond from the options on the next slide.

1.  Atypical antipsychotics
2.  Amphetamines
3.  Injectable incretin mimetics
4.  Transmucosal immediate release fentanyl drugs
5.  Buprenorphine-naloxone containing drugs
6.  Retinoids
7.  Phosphodiesterase inhibitors

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## Knowledge Check

- A. Appropriate covered use: maintenance of opioid dependence; off-label or excluded indication: chronic pain
- B. Appropriate covered use: breakthrough cancer pain; off-label or excluded indication: non-cancer pain
- C. Appropriate covered use: psychiatric conditions including schizophrenia, bipolar disorder and depression; off-label or excluded indication: insomnia (sedation)
- D. Appropriate covered use: attention deficit hyperactivity disorder; off-label or excluded indication: enhance academic performance
- E. Appropriate covered use: acne; off-label or excluded indication: glabellar lines
- F. Appropriate covered use: pulmonary arterial hypertension or benign prostatic hyperplasia; off-label or excluded indication: erectile dysfunction
- G. Appropriate covered use: diabetes type II; off-label or excluded indication: weight loss

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### Correct Answers

- 1. C
- 2. D
- 3. G
- 4. B
- 5. A
- 6. E
- 7. F

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### Questions



Please direct questions or requests to: [MedicaidProviderEducation@cms.hhs.gov](mailto:MedicaidProviderEducation@cms.hhs.gov)  
 To see the electronic version of this presentation 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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