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

Module 1
Prescribing Practices

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

Medicaid Expansion—Medicaid Spending

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

Self-Audit

Educate pharmacy providers on:
• Self-audit precautions related to:
  o Proper prescribing practices
  o Controlled substances management
  o Invoice management
  o Proper billing practices
• Reporting fraud, waste, and abuse

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
Pharmacy Self-Monitoring—The Self-Audit

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

Self-Audit Process

Use of the self-audit process allows pharmacy staff to:
• Evaluate daily practices
• Pinpoint audit triggers
• Address vulnerabilities

Prescribing Practices Self-Audit

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

Legitimate Medical Purpose

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

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.
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.

Buprenorphine-Naloxone Products

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

Atypical Antipsychotics

Prescriber outreach: alternative options for use as a sedative-hypnotic.
Quality of Care Concerns in Pediatric Antipsychotic Claims Analysis

<table>
<thead>
<tr>
<th>Concern Identified</th>
<th>Percentage of Claims Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor monitoring</td>
<td>53%</td>
</tr>
<tr>
<td>Wrong Treatment</td>
<td>41%</td>
</tr>
<tr>
<td>Too many drugs</td>
<td>37%</td>
</tr>
<tr>
<td>Taken too long</td>
<td>34%</td>
</tr>
<tr>
<td>Wrong dose</td>
<td>23%</td>
</tr>
<tr>
<td>Too young</td>
<td>17%</td>
</tr>
<tr>
<td>Side effects</td>
<td>7%</td>
</tr>
</tbody>
</table>

Food and Drug Administration—Labeled Pediatric Indications

<table>
<thead>
<tr>
<th>Brand/Generic Name</th>
<th>FDA Labeled Pediatric Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abilify®/Aripiprazole</td>
<td>Bipolar I disorder</td>
</tr>
<tr>
<td></td>
<td>Irritability associated with autistic disorder</td>
</tr>
<tr>
<td></td>
<td>Schizophrenia</td>
</tr>
<tr>
<td>Seroquel®/Olanzapine</td>
<td>Bipolar I disorder</td>
</tr>
<tr>
<td></td>
<td>Schizophrenia</td>
</tr>
<tr>
<td>Invokana®/Paliperidone</td>
<td>Schizophrenia</td>
</tr>
<tr>
<td>Seroquel®/Quetiapine</td>
<td>Bipolar I disorder</td>
</tr>
<tr>
<td></td>
<td>Schizophrenia</td>
</tr>
<tr>
<td>Risperidone®/Risperidone</td>
<td>Bipolar I disorder</td>
</tr>
<tr>
<td></td>
<td>Irritability associated with autistic disorder</td>
</tr>
<tr>
<td></td>
<td>Schizophrenia</td>
</tr>
</tbody>
</table>

Compendial Pediatric Indications

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Compendial Pediatric Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risperidone</td>
<td>Behavioral syndrome-mental retardation</td>
</tr>
<tr>
<td></td>
<td>Pervasive developmental disorder</td>
</tr>
<tr>
<td></td>
<td>Tourette syndrome</td>
</tr>
</tbody>
</table>
### Off-Label Pediatric Uses

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Off-Label Pediatric Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risperidone</td>
<td>- Anorexia nervosa</td>
</tr>
<tr>
<td></td>
<td>- Conduct disorder (impulse aggression)</td>
</tr>
<tr>
<td></td>
<td>- Attention deficit hyperactivity disorder with aggression</td>
</tr>
<tr>
<td></td>
<td>- Disruptive behavior disorder</td>
</tr>
</tbody>
</table>

### Atypical Antipsychotics Pediatric Side Effects

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Cognitive</th>
<th>Extrapyramidal</th>
<th>Metabolic</th>
<th>QT Interval</th>
<th>Suicide</th>
<th>Thinking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aripiprazole</td>
<td>N/A</td>
<td>Labeled</td>
<td>Labeled</td>
<td>N/A</td>
<td>Black-box warning</td>
<td></td>
</tr>
<tr>
<td>Asenapine</td>
<td>N/A</td>
<td>Labeled</td>
<td>Labeled</td>
<td>Labeled</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Clozapine</td>
<td>N/A</td>
<td>Guideline</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>Labeled</td>
<td>Labeled</td>
<td>Labeled</td>
<td>Labeled</td>
<td>Black-box warning</td>
<td></td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>N/A</td>
<td>Guideline</td>
<td>N/A</td>
<td>Guideline</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Phosphodiesterase Inhibitors

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

Cosmetic Purposes

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

Injectable Incretin Mimetic Medications

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

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

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
Correct Answers

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

Questions

Please direct questions or requests to: 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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