Pharmacy Audits
Unstacking the Deck!

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Types of Pharmacy Auditors
and Auditors

• Medicaid
  – Inventory Analysis
  – Records Audits
  – Managed Care Audits
  – Cross-over Audits
• Third Party Audits

Overview

• Define common audit types
• Review common “triggers”
• Discuss documentation needs and collection
• Medicaid audits
• Third party audits
• Review of appeal submission and documentation collection
Industry Status

- Revenue source for Medicaid and third party payors
- Outsourcing auditors - incentivized
- Fraud is on the increase
- South Florida is Fraud Capitol of the U.S.
- Increase in contractual audit requirements
  - Med D, Managed Medicaid, Private employers
- RAC program – Recovery Audit Contractors
  - Outside parties paid on contingency - incentivized
  - $250 million to chase Medicare fraud 2011-2016
  - Expanded scope of liability for fraud
- 48 out of 50 states face funding issues

The Rules are Changing

- Traditional recoupment
- Extrapolation is making a comeback and may have never left
- HR new penalties: Establishes civil monetary penalties of $50,000 per violation for providers, suppliers, Part D, or Medicare Advantage plans that knowingly make false statements or misrepresentation of material fact on enrollment applications for any federal health care program.
- Potential for jail or prison time
- Medicaid Sanctions
- Termination as a provider

Audit Types

- **On-Site** – prior notice is required for Medicaid
- **Desk Audits** – call for copies – reasonable response time should be given
  - **Algorithms**
    - Compare geographic dispensings
    - Fill Rates
    - City
    - Generic vs. Brand
    - Brand vs. SS Brand
    - Quantities – Inhalers, Ophthalmics, Test Strips, Insulin
    - Your store vs. the community average
    - Compounds – uncommon items or quantities
    - Odd quantities – i.e., 100
Basis for Audit

• CH. 465 (Pharmacy Practice Act)
• CH. 64B16-27 and 28 (Board of Pharmacy Rules)
• CH. 409 (Medicaid)
• Medicaid Handbooks
• CH. 499 (Drugs, Devices and Cosmetics)
• Payor Handbooks or Manuals

Top Discrepancies

• Overbilled quantity
• Missing prescription (usually oral)
• Use as directed
• Refilled too soon
• Invalid prescription
• Compound Rx - excessive quantity billed
• Unauthorized refill
• No signature on signature log
• Exceeds plan limits

Audit Triggers

• Quantity Dispensed vs. Day Supply
  – (100 ct vs. 90-day supply)
• Query your system to determine potential issues
• Staff training
Audit Triggers

Oral Prescriptions

- Documentation
- Rule 64B16-27.103
- Only a pharmacist may prepare a copy of prescription
- It should contain all information that should be on a written prescription
- Make a note of
  - who you spoke to at the prescriber’s office
  - their position there
  - the date of the conversation

Audit Triggers

Invalid Prescriptions

- Requirements for a written prescription:
  - legibly printed or typed
  - name of the prescribing practitioner
  - name and strength of drug
  - quantity of the drug
  - adequate directions for use
  - signed by the prescriber on the date issued

Use as Directed (PRN)

- Staff Training
- Prescriber Training
- If PRN, there should be a maximum number or amount of the drug

“Provider must obtain more concise directions, as to accurately represent the days supply.”
  – Caremark Provider Manual
Use as Directed (PRN)

- DOCUMENT ON THE FRONT OF THE HARDCOPY
  - Who authorized, date of the authorization, and the pharmacy staff who took the authorization
  - Shampoos
    - Frequency and size of area
  - Creams and Ointments
    - Frequency and size of area
  - Migraine Medications
    - Number of headaches per month
  - Insulin syringes
    - Document dosage

• Note: Prime Therapeutics does not accept post audit documentation for “Use as Directed” unless documented directions were present prior to dispensing.

Audit Triggers

Instructions outside FDA Guidelines

ICD9 Trigger – Off-Label Usage
(But how will you know?)
Additional Triggers

- Unauthorized Refills
  - Phone Orders, E-Prescriptions – refills must be put on new prescription
  - Documenting in the computer will not suffice
  - Document:
    - To whom you spoke
    - Their title
    - The date

Transfers

- Florida requires the following:
  - Patient Name and DOB
  - Drug Name and Strength
  - Dosage Instructions
  - Prescriber
  - Transfer Date
  - Original Prescription Date
  - Number of Authorized Refills Remaining
  - Name, DEA#, and Phone Number of Transferring Pharmacy
  - Name of Transferring Pharmacist
  - Initials of Pharmacist/Pharmacy Intern Taking Prescription

Medications to Watch

- HIV Medications
  - High dollar, monitored by payors
  - Diversion issues: ADAP inventory dispensed for retail patients

- Compounds
  - Be reasonable - time, equipment cost, capsules, process
  - Payors will reimburse for level of effort
Medications to Watch

- Schedules 2’s (CII’s)
  - Check ID
  - Counterfeit proof forms
  - Written and numerical quantity
  - Month in abbrev. form
  - No refills
  - No phone orders
  - Quantity
- Suboxone/Subutex/Buprenorphine
  - Prescriber DEA# and ID#

Medications to Watch

- Schedules 3’s (CIII’s)
  - Verify that prescription is valid
  - One 30-day supply on oral prescription
  - Oral prescriptions reduced to writing
  - 5 refills within 6 months

Medications to Watch

- Insulin Pens
  - Dosage and days must coincide
  - If outside limitations process, allow to reject and call for a prior authorizations
  - Document any changes
- Lovenox
  - Pharmacies submitting number of syringes dispensed rather than total ml’s, .4/.6
- Eye Drops
  - Know standard drops per ml per PBM
  - Caremark = 15 drops per ml
On-Site Audits

- Assign your best people person to work with auditor
- Try not to agitate the auditor
- If it is easier to agree, then agree
- Have records ready
- Make a record of anything that they take with them
- Unless required by contract, do not give away original records
- Spoonfeed the documents

Discrepancy Review, Documentation Collection, and Submission

- Review the findings from an audit and establish a plan to best challenge the discrepancies from the audit
- If any organization provides audit support - utilize it
- Place the response date on your calendar - ensure your appeal is submitted on time!
- Contact doctors ASAP if documentation or replacement scripts are required
- Submit your appeal in an organized manner (i.e., spoon feed)
- Create a cover sheet listing the Rx's that correlate to the audit findings
- Make a copy of your final response for your files
  - When mailing your response in, send it with a proof of delivery request - file the receipt with the audit

Medicare D Requirements

- Medicare D contracts require you to provide prescription history for 10 years or the length of the contract
- Do you have a system in place to provide an original or front/back copy of a prescription?
- Will you be able to supply signature logs 10 years from now?
- False Claims Act goes back 11 years
Medicaid Audit Rights

- Florida spells out a pharmacy’s rights (465.188, FS)
  - One week prior notice
  - Can’t be over one calendar year
  - Must be conducted by a Florida licensed pharmacist
  - Must be uniform procedures
  - Pharmacies allowed at least 10 days to produce records
  - Can’t be conducted during the first 5 days of the month
  - Audit report must be provided to the pharmacy within 90 days after the conclusion of the audit (the Preliminary Audit Report, or “PAR”)
  - Final audit report (“FAR”) must be delivered within 6 months of the Preliminary Audit Report

Medicaid Audit Rights

- A clerical, recordkeeping, typographical or scrivener’s error, or computer error does not constitute a willful violation and is not subject to criminal penalties without proof to commit fraud.
- A pharmacist may use the physician’s record or other order for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.

Medicaid Audit Rights

- Extrapolation
  - A finding of an overpayment or underpayment must be based on the actual overpayment or underpayment and may not be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.
  - Notwithstanding any other provision in this section, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating penalties for Medicaid audits.
Medicaid Audit Rights

- The Agency for Health Care Administration ("AHCA") shall establish a process under which a pharmacist may obtain a preliminary review of an audit report and may appeal an unfavorable audit report without the necessity of obtaining legal counsel.

- The preliminary review and appeal may be conducted by an ad hoc peer review panel, appointed by the agency, which consists of pharmacists who maintain an active practice. If, following the preliminary review, the agency or review panel finds that an unfavorable audit report is unsubstantiated, the agency shall dismiss the audit report without the necessity of any further proceedings.

- Exceptions:
  - Investigative audits conducted by the Medicaid Fraud Control Unit
  - Any investigative audit conducted by the Agency for Health Care Administration when the agency has reliable evidence that the claim that is the subject of the audit involves fraud, willful misrepresentation, or abuse under the Medicaid program

Discovering an Overpayment without an Audit

- Reverse any claims within the last year
- Send a check and an explanation for any older claims
- If more involved, ask for a meeting
- Can result in adverse action by AHCA including:
  - Fines and penalties
  - Termination from the Medicaid program
    - without cause
    - with cause
Medicaid Audits

- Usually inventory audit and record audit
- Medicaid takes whichever is greater - the records audit is usually subsumed in the invoice audit
- Can’t add together
- Preliminary Audit Report – Can’t challenge
- Final Audit Report – Must challenge if overpayment

Medicaid Invoice Audits

- Invoice audits have been used since 1980’s
- Used to be called Aggregate Analysis – Theory is “If you did not buy the drugs, you did not dispense the drugs”. Now allowed by statute.
- What is wrong with this theory:
  - Assumes equal inventory at the start & close of the audit period
  - Assumes no large purchases
  - Assumes no “off the grid” purchases
  - Doesn’t always consider return-to-stock and claim reversals
  - Pharmacy may have been cheating a private payor
  - Assumes pharmacies and wholesalers keep good records
- Be prepared to coordinate with your wholesaler

Medicaid Invoice Audits

- How they work:
  - Take a subset of your top drugs dispensed
  - For each drug calculate total dispensed during audit period
  - For each drug calculate the average reimbursement per unit
  - For each drug calculate total dispensed to Medicaid
  - Divide the amount dispensed to Medicaid by total dispensed to get the Medicaid percentage
  - Multiply the Medicaid Percentage times total units purchased to get amount to be billed to Medicaid
  - Subtract this amount from dollar amount of units billed to Medicaid to get the overpayment
Medicaid Invoice Audits – Example

- Purchased 100 units of drug A
- Dispersed 200 units of Drug A all patients at an average reimbursement of $2 per unit
- Dispersed 50 units of drug A to Medicaid patients
- Medicaid percentage is 50/200 = 25%
- 25% of 100 units = 25 units of Drug A available for Medicaid use
- Medicaid paid for 50 units minus 25 units available = a 25 unit overpayment @ $2 per unit = $50

Medicaid Invoice Audits – Example

<table>
<thead>
<tr>
<th>Amount Purchased</th>
<th>Total Dispensed</th>
<th>Medicaid Percentage</th>
<th>Shortage Dispensed</th>
<th>Paraphernalia</th>
<th>Overpayment</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>200</td>
<td>50/200=25%</td>
<td>25/200=12.5%</td>
<td>25</td>
<td>$50</td>
</tr>
</tbody>
</table>

Responding to Medicaid Invoice Audits

- Start immediately!
- Very important to respond to the PAR
- Consider hiring a lawyer for a bad PAR
- PARs are easier to resolve than FARs!
- Ask for an extension of time to provide records and ask for more time than you will need
- Assign your best staff person to find all of these records
- Maintain a separate file for each wholesaler and manufacturer
- Ask each wholesaler and manufacturer for records during the audit period and 6 months before
Responding to Medicaid Invoice Audits

• Check for any large purchases before the audit period
• Rank the overpayments by dollar amount and start with the largest overpayments
• If you have both invoice audit and record audit, ignore the smaller one ... ie, don't bother with $35,000 worth of prescription records if you have a $500,000 invoice audit
• Ask your PDM or business partner if they remember any large purchases or purchases from non-regular sources

Responding to Medicaid Invoice Audits

• Review Pharmacy’s checkbook
  – Look for any purchases from names that sound like drug wholesalers or manufacturers
  – Look for any large purchases
• Eyeball or check the audit numbers
• Does the total number of Medicaid prescriptions include reversed claims?
• Has the pharmacy taken an inventory or does it have an ongoing inventory?

Records Audits

• Common Problems:
  – Unauthorized Refills
  – Missing Prescription
  – Physician not a Medicaid Provider
  – Day's Supply
  – Refill too Soon
Responding to Records Audits

• Check for reversed claims
• Ask doctor for copy of missing prescription records
• HIPAA issues
• Show pattern of prescriptions
• Check if prior authorized
• Check records for refills
• Check electronic records

Medicaid Managed Care Audits

• Patient was fee for service and joined managed care program
• Pharmacy may or may not be in the managed care network
• Audit seeks overpayment of fees paid to pharmacy
• Redress is usually against the managed care payor
• Small Claims Court

Medicaid Crossover Claim Audits

• Medicaid is a payor of last resort
• Other payor is billed before Medicaid
• If Medicaid is billed first, then overpayment results
• Try to re-bill the primary payor if possible
Challenging Medicaid Audits

- If a bad PAR, get counsel engaged early
- Find a lawyer that handles Medicaid pharmacy audits and isn’t afraid of math
  - Not much a lawyer can do with small audit amounts - lawyer fees eat into the recovery
  - $5,000+ may be able to help you handle
  - $25,000+ may do a simple challenge
  - $50,000+ may do a more involved challenge
- Note date of receipt of FAR
- 21 days to file a Petition for Formal Administrative Hearing
- Do not request an informal hearing

Challenging Medicaid Audits

- Do all of the things discussed under Responding to Medicaid Audits
- Other Arguments
  - AHCA can’t use lack of drug pedigree as a basis for the audit
  - Ask for a peer review of claims prior to hearing
  - Application of Medicaid Rebates
  - Any reasons that opening and closing inventory are not equal
  - Any factor not considered by AHCA
  - Challenge the Sanction

Medicaid Hearing “Gotchas”

- Venue for the case is Leon County [409.913(28)]
- All records must be provided to AHCA 14 days before hearing or excluded from consideration [409.913(22)]
- Pharmacy can’t present witnesses or cross-examine AHCA’s witnesses about any purchases or sales of drugs if not supported by written evidence [409.913(22)]
- Using statistics to prove overpayment is specifically allowed [409.913(20)]
- AHCA may recover all investigative, legal, and expert witness costs if findings not contested or if AHCA prevails
- The FAR is prima facie evidence of an overpayment [409.913(28)]
- Upon 2 days notice, AHCA has authority to inspect any pharmacy, wholesaler, or drug manufacturer [409.913(32)]
Medicaid Audit “Gotchas”

- AHCA may review non-Medicaid related records
- Sanctions
- Once a PAR is issued, AHCA can immediately withhold any money due to the pharmacy unless the pharmacy:
  - pays in full
  - enters into a payment plan
  - Interest on the payment plan is 10% a year
- AHCA may terminate a provider from the Medicaid program immediately for cause or without cause upon 30 days notice
- Termination without cause can’t be challenged
- Pharmacy can be placed on pre-payment review

Hearings on Medicaid Audits

- Formal Administrative Hearing
- Judge, depositions, discovery, witnesses, evidence, etc.
- Proposed Recommended Order
- Recommended Order
- Final Order
- Appeal

Medicaid Audit “Gotchas”

<table>
<thead>
<tr>
<th>Sanctions</th>
<th>Penalties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to make records available</td>
<td>$2,500 ($1,000/day after 10 days)</td>
</tr>
<tr>
<td>2nd Violation</td>
<td>$5,000 ($2,000/day after 10 days)</td>
</tr>
<tr>
<td>3rd Violation</td>
<td>Termination</td>
</tr>
<tr>
<td>Failure to make reimbursement records available</td>
<td>$2,500 ($1,000/day after 10 days)</td>
</tr>
<tr>
<td>2nd Violation</td>
<td>$5,000 ($2,000/day after 10 days)</td>
</tr>
<tr>
<td>3rd Violation</td>
<td>Termination</td>
</tr>
<tr>
<td>Failure to maintain records</td>
<td>$250 up to $2,500 per patient</td>
</tr>
<tr>
<td>Failure to comply with Medicaid laws</td>
<td>$1,000 per claim</td>
</tr>
<tr>
<td>2nd Violation</td>
<td>Termination</td>
</tr>
</tbody>
</table>
Medicaid Audit “Gotchas”

<table>
<thead>
<tr>
<th>Sanctions</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Violation</td>
<td>20% of overpayment</td>
</tr>
<tr>
<td>2nd Violation</td>
<td>40% of overpayment</td>
</tr>
<tr>
<td>3rd Violation</td>
<td>50% of overpayment</td>
</tr>
</tbody>
</table>

Responding to Private Audits

- Usually record audits and not invoice audits
- Like Medicaid, looking for a reason not to pay you
- Same steps as with a Medicaid audit
- Appeal process is usually informal
  - Usually just submit a written appeal
  - Not usually granted
- Can be terminated as a provider

Recourse if Terminated by a Health Plan

- Florida is not an “any willing provider” state
- The pharmacy has the termination rights in the provider agreement (usually 30-90 days notice)
- Ask to be reinstated
- Contact local and state politicians
- Contact employer groups that use the Health Plan
- Don’t waste money on lawyers
Future Medicaid Managed Care and Audits

- By 2014, Florida Medicaid will be all Medicaid Managed Care
- Audits will likely be private audits
- Not clear what Medicaid Program Integrity will do
- Try to get legislation passed that sets procedures and rights for audits
- Get to know your legislators!

Assessment Questions

Question 1
Can you name and describe two types of Medicaid audits?

Assessment Questions

Question 2
Which of the following are pharmacy claim discrepancies or audit triggers?

- Overbilled quantity
- Missing prescription (usually oral)
- Use as directed
- Refilled too soon
- Invalid prescription
- Compound Rx - excessive quantity billed
- Unauthorized refill
- No signature on signature log
- Exceeds plan limits
Assessment Questions

Question 3
Which of the following have to be on a written prescription in Florida?
• Legibly printed or typed
• Name of the prescribing practitioner
• Name, strength, and quantity of drug
• Adequate directions for use
• Signed by the prescriber on the date issued
• All of the above

Questions.....