When Big Dollars Are on the Line – An Audit Refresher

Mark Jacobs RPh
VP of Operations at PAAS National

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Disclosure

Mark Jacobs RPh, is the VP of Operations at PAAS National. The conflict of interest was resolved by peer review of the slide content.

Learning Objectives

• Review new developments in pharmacy audit recoveries
• Discuss red flags for pharmacy auditors and actions to ensure that procedures are followed to eliminate risk.
• Outline your audit rights and responsibilities
Plan Requirements

- Waste: OBQ, IDS
- Abuse: Overrides, Rx NPU, UAR, DID
- Fraud: Misbranding, duplicate billing or billing for fake prescriptions
- DID audits

New Developments

- CS Requirements
- Prescription Transfer Requirements
- Prescription Origin Code Audits
- Increase in Invoice Audits
- A surge in Desk Audits
Why the increased interest in audits?

- Big Money Recoveries
- Pharmacies continue to bill incorrectly
- New strategies are being developed – LAWF
- The Feds continue to discover fraud
- Auditors are reviewing invoices and terminating contracts for billing the wrong NDC

Huge Fraud Takedown – July 2017

- OIG along with state and federal law enforcement
- Largest health care fraud takedown in history
- More than 400 defendants in 41 federal districts charged in schemes involving about $1.3 billion in false billings to Medicare and Medicaid

Huge Fraud Takedown – July 2017

• OIG also issued exclusion notices to 295 doctors, nurses, and other providers based on conduct related to opioid diversion and abuse.
• The money spent fighting fraud is an excellent investment.
• For every $1.00 spent on health care related fraud and abuse investigations in the last three years, more than $5.00 has been recovered.


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Huge Fraud Takedown – July 2017

• In the Southern Louisiana Strike Force, operating in the Middle and Eastern Districts of Louisiana as well as the Southern District of Mississippi, seven defendants were charged in connection with health care fraud, wire fraud, and kickback schemes involving more than $207 million in fraudulent billing.
• One case involved a pharmacist who was charged with submitting and causing the submission of $192 million in false and fraudulent claims to TRICARE and other health care benefit programs for dispensing compounded medications that were not medically necessary and often based on prescriptions induced by illegal kickback payments.


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Exclusion Notices

- Bar participation in, or submitting claims to, All Federal health care programs, including Medicare and Medicaid
- 57 Doctors
- 162 Nurses
- 36 Pharmacists

OIG Concerns

- Medicare spending for Part D drugs has continued to rise by more than $10 billion a year
- By 2015 Part D spending on compounded drugs rose from $70.2 million in 2006 to $508.7 million
- Spending was highest for lidocaine/prilocaine, and diclofenac

HHS OIG Data Brief – June 2016 – OEI-02-16-00290
OIG Concerns

- Spending on commonly abused opioids exceeded $4 billion in 2015
- Spending for compounded topical drugs has risen more than 3,400 percent since 2006
- The extremely high rate of growth raises questions as to whether all of the drugs were medically necessary or even dispensed to the beneficiary.

HHS OIG Data Brief – June 2016 – OEI-02-16-00290

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www.ncpasonline.org/totenvironment
OIG Concerns

These concerns are reinforced by a growing number of fraud cases.

Together, the spending trends and cases involving compounded drugs signal the need for action.

The issues are not exclusive to Part D, but as the recent sharp increases attest, this opportunity should be seized so that spending and potential safety issues do not go unchecked in Part D.

HHS OIG Data Brief – June 2016 – OEI-02-16-00290

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OIG Concerns

- OIG is committed to continuing to conduct investigations and reviews to help address the ongoing problems created by opioid abuse and the emerging problems linked to compounded drugs.
- CMS has taken a number of steps to combat the multi-faceted problems associated with commonly abused opioids.
- For example, CMS now identifies both high-risk beneficiaries and outlier prescribers and shares that information with Part D plan sponsors.

_HHS OIG Data Brief – June 2016 – OEI-02-16-00290_

FWA

- Auditors claim to be looking for fraud, waste and abuse
- Estimates of the cost of fraud are as low as 3% of all health care billings to as high as 10% of all health care billings

_Criminal Fraud_

- Knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program
- 18 United States Code $1347
Fraud

• Billing for false claims
• Filling prescriptions which you know to be fraudulent
  • This includes prescriptions written by a doctor for the sole purpose of being sold or diverted
• Intentionally submitting false information to the government or a government contractor in order to get money or a benefit

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Fraud

• Billing for false claims
• Filling prescriptions which you know to be fraudulent
  • This includes prescriptions written by a doctor for the sole purpose of being sold or diverted
• Intentionally submitting false information to the government or a government contractor in order to get money or a benefit
• You can report fraud to: 800-581-1790 or 800-HHS-TIPS

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Waste and Abuse

• **Waste**: Overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare Program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

• **Abuse**: Includes actions that may, directly or indirectly, result in unnecessary costs to the Medicare Program. Abuse involves payment for items or services when there is not legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment.

- Waste might be submitting override codes to allow patients to receive a medication early, when they don’t really need it yet
- Waste is also mail-order prescriptions being sent to the patient in bulk when the patient is no longer using the product
- Abuse is submitting incorrect NDC numbers on MAC generics
Medicaid Fraud Data for Fiscal 2016

• In addition to Medicare Fraud Data, Medicaid Fraud is also escalating
• For all 50 states there were 18,730 investigations
• 1,721 persons were indicted, and 1,564 were charged with a crime
• Total recoveries were $1.88 billion

Notice from Prime Therapeutics

• As a result of the increase volume of compounded Rxs –
• Prime Therapeutics has sent out a letter to at least one provider that billing compounds or non-FDA approved drugs in excess of 10% of all claims do not comply with Prime’s network participation criteria
• Pharmacy provider was given 60 days to comply with the terms and conditions of network participation
Prime Therapeutics® “Unannounced” Audits

• CAUTION: Prime auditors have asked pharmacies for their complete book of business claims report. ***DO NOT SHOW THEM YOUR COMPLETE BOOK OF BUSINESS!***
• Prime Therapeutics auditors can only see Prime Therapeutics business!

Prime Therapeutics Provider Manual – September 2017

• Access to Pharmacy Records
• Participating Pharmacies must provide adequate access to their records related to Prescription Drug Services provided under the Agreement. This includes, but is not limited to:
  • Wholesaler invoices and pedigrees
  • Prescription orders
  • Signature log/delivery log
  • Licensing
  • Proof of insurance
  • Dispensing history
Prime Therapeutics Provider Manual – September 2017

• Wholesaler, manufacturer and/or return vendor invoices
• Pedigree invoices or documentation to support wholesaler(s) purchases to confirm traceability from the manufacturer
• Compound information including all ingredients with NDCs and quantities used to prepare the compound claim

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Prime Therapeutics Provider Manual – September 2017

Drug and Supply Requirements

• Participating Pharmacies must purchase all medications and supplies being dispensed to Covered Persons from authorized traders, in accordance with Federal law.
• The ordering of these medications and supplies must be tracked using verifiable invoices and pedigree invoices when required by applicable law.
• Prime reserves the right to not accept documentation from any authorized traders at any time when the invoice documentation cannot be verified.

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Drug and Supply Requirements

- Diabetes test strips are one class of items that have come under increased scrutiny due to unauthorized distributors potentially selling mis-branded unauthorized product.
- Authorized distributor lists exist on Abbott (Freestyle), Roche (Accu-check), and LifeScan (One Touch) websites.
- Here are links to the manufacturer websites:
  - Roche (Accu-Chek) [https://rxvp.accu-chek.com/welcome/adr_list](https://rxvp.accu-chek.com/welcome/adr_list)
  - LifeScan (One Touch) [http://www.lifescan.com/responsibility/counterfeit-products/authorized-distributers](http://www.lifescan.com/responsibility/counterfeit-products/authorized-distributers)

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Common Billing Errors

- **Quantity dispensed** — Overstating the days’ supply may affect future refills. Understating the days’ supply may exceed the Covered Person’s benefit, while assessing less Copays that are applicable.
- The Participating Pharmacy must submit the correct days’ supply, based on directions for use and benefit limitations to avoid an audit recovery (for example, incorrectly calculating the days’ supply of eye drops.
- Calculate eye drops days’ supply using 15 drops per mL for solutions and 12 drops per mL for suspensions).

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- (Other plans use different drops/mL for eye drops)
Common Billing Errors

- **Reversal of claims** — All prescriptions not received by the Covered Person within fourteen (14) days must be reversed through the electronic claims system.
- Claims not reversed after fourteen (14) days may be subject to audit recovery.

Some plans require that you reverse prescriptions that are not picked up within 10 days

- Rxs that are not reversed within the required time period may be subject to full recoupment

- **Use as directed** — The Participating Pharmacy must determine the specific dosing directions to accurately calculate the days’ supply and correctly submit the claim to Prime.
- The Participating Pharmacy must contact the Prescriber to clarify any ambiguous directions (such as “Use as Directed,” no directions documented or “As Needed”) and document them on the prescription hard copy.
- If the Prescriber is unavailable, communication with the Covered Person is acceptable and must be documented.
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Unacceptable Practices

• Submitting a claim with an NDC other than the NDC from the package from which the product was dispensed. (This can occur frequently on compound prescriptions because the formulas used to bill the compound are not updated when an NDC changes.)

• Overriding DUR rejects without properly resolving and documenting the resolution. (PAAS sees this occur when a prescription requires a prior auth and the pharmacy decreases the Rx quantity in order to circumvent the prior auth requirement. Fee splitting and price rolling are not allowed.)

• Misrepresenting the origin codes.

• Submitting a claim for a non-FDA approved drug (such as compound kits and patches).

• Pharmacies may not solicit Covered Persons or obtain a third party to solicit Covered Persons for prescription orders.

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Compound Rx Billing Guidelines

• Maintain a Compound Prescription log with documentation for each Compound Prescription dispensed.

• The log must document quantities and NDCs of the ingredients used to prepare the Compound Prescription. NDCs submitted for the Compound Prescription must be the exact formulation of what is dispensed. (Compounding logs are inadequate if they do not account for the weight of tablets or capsules used in the compound.)

• If a Compound Prescription claim rejects, the Participating Pharmacy must follow POS messaging to determine if the ingredients submitted require a PA. If a PA is required, the Participating Pharmacy must follow the POS messaging to obtain a PA. If a PA is not required and one or more ingredients is not covered by the Covered Person’s Benefit Plan, the Participating Pharmacy may submit a clarification code of “08” to receive payment for all covered ingredients. Not all benefit plans support the use of clarification “08.”

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Compound Rx Billing Guidelines

The following are examples of Compound Prescription drugs where benefit designs may vary:

• Any compound that contains active ingredients not approved by the FDA. (Examples: Diclofenac 3% gel is only approved for AK, and Lidocaine topical is not approved for pain.)
• A compound for which the stability is unknown at the time of dispensing or cannot be determined by reference of an USP-approved reference material.

Prime also considers the following to be additional unacceptable billing practices for Compound Prescription claims:

• Billing for a different NDC than what was used in the Compound Prescription.
• Billing for the full package size when only a partial amount was dispensed to the patient.
• Billing for a different dosage form than what was used in the Compound Prescription.
• Billing for a quantity other than what was actually used to prepare the Compound Prescription.
Prime also considers the following to be additional unacceptable billing practices for Compound Prescription claims:

- Any Compound Prescription to which active ingredients are added that were not part of the prescription order.
- Not following POS messaging, including but not limited to messaging for rejected claims.
- Obtaining changes to Compound Prescription orders to avoid POS messaging.
- Phishing for a drug that pays (i.e. Participating Pharmacy submits a claim for one drug, received a reject or reverses the claim and resubmits for a new drug within a short period of time.)

- Billing claims in a manner that bypasses system messaging requiring further review. Example: billing claims multiple times in a month to avoid obtaining a PA or reaching plan dollar thresholds.
- Billing claims for a new order prior to verifying the Prescriber/Covered Persons’ relationship.
- Billing Compound Prescription claims for a Covered Person: Where there is not literature that supports the clinical use
- If you have questions regarding compound drugs, please contact Prime’s Contact Center at 800.821.4795.
Key takeaways and other information:

• Medicare does not pay for bulk powders
• Medicare does not pay for off label uses of drugs
• Bill for the exact NDC#s used in the compound
• Paying physicians to write these Rxs is an illegal kickback
• Prescriptions for patients with no direct physician relationship may be invalid
• For Pharmacies – Expect more invoice audits*****

Prime Therapeutics® “Unannounced” Audits

• Prime Therapeutics is again performing unannounced onsite audits. Here’s what you can do to prepare yourself!
• CAUTION: Prime auditors have asked pharmacies for their complete book of business claims report. ***DO NOT SHOW THEM YOUR COMPLETE BOOK OF BUSINESS!***
• Prime Therapeutics auditors can only see Prime Therapeutics business!
Prime Therapeutics® “Unannounced” Audits

Known items they have reviewed:
- FWA compliance
- On-hand inventory evaluation – looking at expiration dates, lot numbers and how much in stock
- CMS 10147 adherence
- Refrigerator temperature
- License information for the pharmacy and staff
- Ownership of the pharmacy

Before the auditors leave they have been leaving an invoice audit with the pharmacy to forward to their wholesalers.

Based on the notice that the auditors bring, they could potentially look at all things covered in the Onsite Audit section of the provider manual as well.

Also, according to the provider manual, pharmacies are also expected to be adequately staffed during the audit and to have a representative (either pharmacist or technician) available to assist the auditor with questions and document retrieval as requested.
Prime Therapeutics® “Unannounced” Audits

**Recommendations:**

1. Verify that they are who they say they are. Request identification. Contact the phone number on their business cards, and attempt to get the information desk to verify they are who they say they are (employees of Prime Therapeutics for example).
2. Inquire why the audit is occurring and document their answer.
3. Ask how long they will be there and how many records they are auditing to determine if you can accommodate them at that time by getting extra help for the audit.
4. The auditors should allow you a couple hours to get extra help at the store if needed so your business doesn’t suffer.

5. Have questions directed to the pharmacy manager or the owner.
6. Make sure all staff is aware of your policies for partial fills, RxS that are not picked up, procedure when a drug isn’t covered by Medicare Part D (CMS 10147), in case questions are asked of them. This ensures consistency and that everyone is aware of your policies.
7. You should be there personally to assist the auditors.
8. Do not allow the auditors to roam the pharmacy unattended. If they need to check Rx outdates or fridge temperature, pharmacy license information or FWA Compliance, inventory counts for drugs on the shelf, then gather what they request and bring it to them.
Prime Therapeutics® “Unannounced” Audits

Recommendations:
9. If the auditors want to observe pharmacy staff pulling the records to make sure you are not defacing, altering or discarding any records it is reasonable for them to do so.
10. Verify all requests are for Rxs that were processed through the plan before handing PHI over to an auditor.

Audit Rights and Responsibilities

Recommendations:
• You have the right and responsibility to be present for all of your audits
• You have the right to only be audited on claims by the respective pharmacy benefits manager (PBM)
• You have the right to verify that the auditor is who they say they are
• You have the right to have the audit at a mutually agreeable time
• If the audit is unannounced, you have the right to bring in additional help so that your business does not suffer
So Much to Lose

- Legitimate Rx order
- Filled and billed correctly
- Member has benefits
- Member received medication
- Pharmacy should get paid

Auditors can also perform a compliance audit

The following Compliance elements may be reviewed during your audit:

- Licensure of Staff
- CMS 10/47 Adherence
- HIPAA Security
- Training, PVA Compliance
- OIG/GSA Validation
- Pharmacy Insurance Coverage
- State of Licensure
- DEA License
- Medfill Procedures
- Medication Recall Procedures
- Medication Expiration Procedures
- Return in Stock Procedures
- Patient Counseling practices
- Generic/Brand Price Disclosures
- Record Retention
## Audit Red Flags

- **Average Number of Prescriptions** (per patient or per prescriber)
- **Average Claim Amount** (*Sovaldi, Harvoni, Subsys*)
- **Billing Units** (gram-GM, each-EA, milliliter-ML)
- **Changes to Prescriptions** (such as quantity, day supply or refills)
- **Controlled Substance Dispensing**
- **Compounds**
- **DAW Code Usage** (*DAW-0, DAW-1, DAW-2, DAW-9*)
- **Generic vs. Brand dispensing rates**

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## Audit Red Flags

- **Override Codes** (to bypass Refill-too-soon edits)
- **Quantity dispensed vs. day supply, FDA Guidelines and Plan Limitations** (*instructions for use* field is NOT seen by PBMs as it is not standardized)
- **Patient attributes** (adherence, distance from prescriber or pharmacy)
- **Patient Residence Codes**
- **Prescriber attributes** (NPI, DATA 2000 waiver aka XDEA # prescriptions, scope of practice, distance from patient or pharmacy)
Audit Red Flags

• Prescription Origin Code
• Reversals
• Unit-of-use packages (multiple packages submitted or mismatched quantity – includes insulin, inhaler, eye drop, nasal sprays, topical products and migraine medications)
• Envision Rx, LDI and Medtrak require pharmacies to split boxes of insulin pens
• Usual and Customary Price
• Victoza – mg vs. ml
• Some auditors are looking at “Flex Pen” vs. “Flex Touch”

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Audit Red Flags

Audit Red Flags – Transmucosal Immediate Release Fentanyl
Audit Red Flags – Transmucosal Immediate Release Fentanyl

- Subsys prescriptions have caused headaches for some pharmacies this year on Humana for not having an indication of cancer pain
- Subsys is a REMS drug and is ONLY indicated for cancer pain
- Other issues with these products include improper use – proper use is SL or Buccally (between the cheek and gum)
- If you write on the label “On the tongue” or “By Mouth,” you might find yourself with an audit recovery

New and Continuing Developments in Pharmacy Audit Recoveries

- RTS – Return to Stock: Rxs not picked up 10-14 days
- Incomplete Rx Transfer information
- Complete Rx transfer information may include: name, address and phone number
  - Rx #
  - orig date
  - LF Date
  - orig of refills
  - RR
  - name of transferring in R.Ph. and out R.Ph.
  - AND WRITE RX TRANSFER ON THE FACE OF THE RX
- Humana is slamming some pharmacies for not having this information reduced to “hand” writing
- Insulin Rxs – RTS (refill Too Soon)
New and Continuing Developments in Pharmacy Audit Recoveries

• Changed or Altered Prescriptions

Name __________________________ Date 12/4/15
Address __________________________

Adderal 30%  
#60 Suby
TpoBID

Pill Nr 1-2-3-4-5 Void After __________

Preparation for an Audit

The groundwork for a successful audit
• Study the basics
• Know common discrepancies
• Evaluate filling and billing procedures
• Pre-Audit – Find and organize all hard copy prescriptions
• Masked list
  • Some SCIO Health Analytics Optum Rx auditors are not allowing enough time to complete on-site audits
Audit Prevention

The groundwork for a successful audit

- Basics: Patient name, date, drug, strength, dosage form, quantity to dispense (Insulin, Epi Pen, Z-pak), directions
- No SS or UUD
- Refill information – On fax back requests make sure you don’t exceed the number of refills authorized!
- Prescriber signature – NP or PA, don’t use the attending physician’s NPI#

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Audit prevention is a team effort

The groundwork for a successful audit includes pharmacy technicians and cashiers:

- **Intake Personnel**: Check allergy and demographic information every time! Weight for pediatric patients
- **Data Entry Techs**: Check for allergies, duplication of therapy, directions change
- **Filling Techs**: Check for right drug, right dosage form, right dose, right directions, right patient and right doctor
- **Packaging Technician**: Make sure the right drugs for the same patient or same patient family are being packaged together
- **Cashier**: Make sure the pharmacist is called over when required to counsel the patient, verify pt address or dob, make sure patient signs for prescriptions

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Audit Discrepancies - Valid Patient Residence codes at this time, include [Field #384-4X]: (Humana has audited these)

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Not specified (other patient residence not identified below)</td>
</tr>
<tr>
<td>1</td>
<td>Home</td>
</tr>
<tr>
<td>3</td>
<td>Nursing Home Facility</td>
</tr>
<tr>
<td>4</td>
<td>Assisted Living Facility</td>
</tr>
<tr>
<td>6</td>
<td>Group Home</td>
</tr>
<tr>
<td>9</td>
<td>Intermediate Care Facility/Mentally Disabled</td>
</tr>
<tr>
<td>11</td>
<td>Hospice</td>
</tr>
</tbody>
</table>

Humana also audits for prescription origin codes

### 3.1.3 PRESCRIPTION ORIGIN CODE (419-DJ)

For reference, this is the definition and valid values of the field.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø</td>
<td>Not Known</td>
</tr>
<tr>
<td>1</td>
<td>Written: Prescription obtained via paper.</td>
</tr>
<tr>
<td>2</td>
<td>Telephone: Prescription obtained via oral instructions or interactive voice response using a phone.</td>
</tr>
<tr>
<td>3</td>
<td>Electronic: Prescription obtained via SCRIPT or HL7 Standard transactions.</td>
</tr>
<tr>
<td>4</td>
<td>Facsimile: Prescription obtained via transmission using a fax machine.</td>
</tr>
<tr>
<td>5</td>
<td>Pharmacy: Any situation where a new Rx number needs to be created from an existing valid prescription</td>
</tr>
</tbody>
</table>

Source: NCPDP Telecommunication Version D and Above Questions, Answers and Editorial Updates – May 2012
Some pharmacies are unaware of the fact that there is a 5th Rx Origin Code

Rx Origin Code #5

- Any reason necessary to "give it a new number"
- This value is used to cover any situation where a new Rx number needs to be created from an existing valid prescription, such as traditional transfers, intra-chain transfers, file buys, software upgrades/migrations (NDC# change), established protocols, pharmacists authority to prescribe, etc.

Source: NCPDP Telecommunication Version D and Above Questions, Answers and Editorial Updates – May 2012

Rx origin codes do not change upon telephone clarification of the prescription

- The Prescription Origin Code (419-DJ) contains the value that represents the method in which the pharmacy originally received the prescription from the prescriber.
- Any subsequent changes or modifications to the original prescription do not change the Prescription Origin Code (419-DJ).
- Once a prescription is assigned an Origin Code, the Prescription Origin Code (419-DJ) value is retained for the life of that Prescription/Service Reference Number (4Ø2-D2).

Audit Protection:
1. Make Rx Origin Code a forced entry data field.
2. Post codes at each computer station.
3. Request a new Rx order (Phone, Fax, or E-Rx) for and changes authorized by the prescriber.

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www.ncpaval.org/statevention
All prescriptions require mathematically useful instructions

• Rxs where a physician prescribes more than what is required based upon the directions
• What about insulin 50 units every day #2 vials?
• What about Epi Pen - #2 dual paks?
• What about Dovonex 100 gram tube?
• What about 15ml of an eye drop with directions of 1 gtt ou qday?
Other Insulin Considerations: Days supply and dosage form

Insulin Issues:
• Levemir Insulin
• Flex Touch vs. Flex Pen
• Humulin R U-500 Insulin

Rx exceeds plan limits (IDS/EPL) and refill too soon (RTS) examples

**Amount Dispensed Exceeds Plan Limits:**
• Can occur with U.D. prescriptions
• For example: Insulin Rx
• Lantus
• Albuterol
• Symbicort
Other Insulin Considerations: Days supply and dosage form

Insulin Issues:

• Lantus 60 units hs #2 vials
• Lantus 40 units hs #2 vials
• Lantus 70 units at bedtime #3 vials
  Lantus 20 units at bedtime #1 vial
• What if Lantus Solostar Pens?

Other Considerations: Days supply

• Albuterol inhaler #2 – 1-2 puffs q4-6 h prn
• Symbicort #1 - 1 puff bid
Other Considerations: Exceeds plan limits and Days supply

Other Considerations: Excessive quantity billed
DAW Issues

DAW-0
• Generic or single source brand
• Only use DAW-0 unless otherwise indicated

DAW-1
• DAW-1 must be indicated by the prescriber

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DAW Issues – Pt requests brand name

• Which DAW code do you use?
• How do you document it?
• Other concerns?

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DAW Issues

**DAW-2**
- Patient requests brand
- Documentation on hard copy is key!
- Traps – Don’t fill as DAW-1!

**DAW-3**
- Pharmacist selected brand

**DAW-4**
- Generic not in stock in pharmacy
- Contrast to DAW-8 = Generic not available in marketplace

**DAW-5**
- Brand dispensed, priced as generic
- Example: Amoxil® for amoxicillin
- Typically, legacy brands that are now promoted as generic

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DAW Issues

DAW-6

• Currently not in use by most plans

DAW-7

• Brand mandated by law
• Examples: NTI range drugs, anticonvulsants, anticoagulants, hypothyroid drugs and Digoxin

DAW Issues

DAW-8

• Generic not available in marketplace
• May need proof for audit
• Be careful!

DAW-9

• Other
• Some plans use for formulary brand
  • Example: Xeloda® - Certain Medicaid plans require brand:
    • Use appropriate override code as instructed
DAW Issues – How do you handle the following?

• Doctor writes “DAW” on single-source brand Rx
• Pharmacist selects brand because generic is temporarily unavailable
• Doctor writes “Substitution permitted” on a brand with a generic. Patient has been on brand name previously
• Doctor writes for a brand name Rx that has a narrow therapeutic index

Considerations for Fax Back Rxs

• Is it dated?
• Is it signed? By whom?
• Is it a controlled substance?
• Are refills clearly indicated?
Considerations for use of Override Codes

Overrides:
• Does intervention require help desk?

What codes are available?
• 02 - High Dose
• 03 - Vacation
• 04 - Lost or spilled?
• 05 - Dosage Change

Considerations for use of Override Codes

• What documentation is required when using one of these override codes?
• Is it fraud waste or abuse to use the wrong override code to force a claim to go through? Would that be fraud waste or abuse?
  • If it happens once, it’s probably abuse.
  • If it happens multiple times, it could be fraud.
Considerations for use of Override Codes

Considerations for use of Override Codes

Network Pharmacy Weekly
September 17, 2015

More on Refill Too Soon Edits

As we have noted, if a pharmacist receives NCPDP Reject 79 with the error message “Refill Too Soon,” he/she should verify with the member the reason for the early fill. A call to the Express Scripts Pharmacy Services Help Desk is not necessary to obtain an override; applicable override codes are system supported using the Submission Clarification Code (SCC) Field 420 DX.

<table>
<thead>
<tr>
<th>SCC Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Vacation Supply: Indicates cardholder has requested a vacation supply of medication</td>
</tr>
<tr>
<td>4</td>
<td>Lost Prescription: Indicates cardholder has requested replacement of lost medication</td>
</tr>
<tr>
<td>5</td>
<td>Therapy Change: Indicates prescriber has determined a change in therapy is required; either the medication was used faster than expected or a different dosage form is needed, etc.</td>
</tr>
</tbody>
</table>

When one of the above codes is used to override a claim impacted by a reject 79 edit, it’s important to document both the code and reason for the override on the prescription. Failure to do so may result in identification of an audit discrepancy and possible recoupment.
Considerations for use of Override Codes and refill too soon discrepancies

**What are the circumstances?**

- Did directions change?
- Check refill history
- Justifiable?
- Think – cost control and medical
- Is an override or other intervention appropriate?

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Refill Too Soon Examples

- If a patient has a prescription for Atenolol 50mg one q day #30 and 7 days later the patient brings you a new Rx for Atenolol 50mg #60 one bid, what should you do?
- If a patient comes in to fill prescription one day early, but the patient is going on vacation next weekend, what should you do?
- If the patient received a prescription from their doctor for Ambien 10mg Sig: 1-2 qHS, and you receive a high dose rejection, what should you do?
- The patient spills his medication down the sink and just got it 2 days ago, what should you do?
Refill Too Soon Example

• The patient has a prescription for Atenolol 50mg one q day #30 and 7 days later the patient brings you a new Rx for Atenolol 50mg #60. What should you do?

DEA Requirements

21 CFR 1306.05a

• (a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.
DEA Requirements

- Suboxone Rx - What is required on this Rx in regard to the DEA registration number?
- How is Suboxone absorbed?
  - Buccally and SL
- On the tongue can = Full Audit recovery!

Other plan requirements

Waiving Copays can be a problem - Do Not waive patient copay amounts!
- Federal law requires collection of the full copay
- Some exceptions – unadvertised and non-routine manner
- State Medicaid may also have exceptions
- Generally not acceptable to waive copays for most plans

Audits:
- Some audits now verify copay collection
- Best process is to have POS system link to software
CMS Manual – Waiving Copays

- 30.4 – Pharmacy Waiver/Reduction of Cost-Sharing and Applicability Toward TrOOP
- (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)
- The Medicare Modernization Act (MMA) added a new exception to the anti-kickback statute under which pharmacies are permitted to waive or reduce Part D cost-sharing amounts, provided they do so in an unadvertised, non-routine manner after determining that the beneficiary is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts.

Waiving Copays

- If it happens once a month
- If it happens once a week
- If it happens every day
- If it happens several times a day...
CVS Caremark Proof of Copay Collection Requirements

• This is from a recent CVS Caremark audit notice: “Examples of acceptable evidence of copayment collection include credit card receipts, cash receipts and POS receipts with transaction numbers. Invoices to patients that still show balances on an account do not constitute acceptable evidence of copayment collection and further documentation will be requested.”

Proof of Copay Collection Requirements

• In order to protect your pharmacy from audit recoupments, it recommends that you collect all patient copays. The routine waiving of or not collecting copays is “steering” and a serious violation of the anti-kickback statute.
RXC – Prescription Changed or Altered

• What strategies exist to prevent this?
  1. Why did you call?
  2. Who did you speak to?
  3. What did prescriber say?
  4. Date + R.Ph. Initials

• What else could be considered?
  • Re-write the Rx as a telephone order

Examples of RXC

• Doctor crosses out Nexium 40mg #30 60 Sig: 1BID
• Doctor changes date from August 11 to August 12 by writing over the 1 and making it a 2
• Doctor changes the drug from Nexium to Pravacid by crossing out Nexium
When does RXC occur?

Was the prescription changed or altered?
- Cross-outs
- Write-overs
- Heavy pen
- Scratches
- Scribbles
- And Notations!

Topical creams and ointments

- Day Supply is becoming a larger audit risk
- Reasons:
  - Increased cost
  - Over-dispensing/Exceeds plan Limits
  - Previously little or no controls
  - Waste or abuse?
  - How much is the patient supposed to apply?
  - Where are they applying it?
Topical creams and ointments
Examples:

• Desonide cream 60 gms SIG: Apply to hand q day

• Fluocinonide cream #120 grams SIG: Apply to entire chest once daily

Sig Log Requirements

At a minimum:
• Date picked up
• Rx #
• Signature

Do not write “Delivery” or “Mailed” – these are not acceptable
Example of a costly sig log recovery

• Zytiga was delivered to the patient’s home. The elderly patient requests that his Rx be sent without signature required in case he cannot hear the doorbell.
• Pharmacy submitted the UPS Proof of Delivery without a signature.
• Adjustment: Full amount of the prescription

Express Scripts Sig Log Requirements

Network Provider Manual Audit Change

It is our process to notify pharmacies of changes or additions to the Network Provider Manual between official releases, and this is to alert you that the language below is being added to Section 5.3 Audit Guidelines.

The following two sentences will now be included at the end of the subsection titled “Appeal Documentation”:

In the event a signature log is missing or a submission clarification code was not noted correctly, Network Provider may gather a member/patient statement. Member/patient statements must clearly indicate the date of service of the claim in question, as well as medication, member address, member phone number and signature of patient.

An updated copy of the manual will be available soon on the Pharmacist Resource Center website, or you may request an electronic copy by email to ProviderOutreach@express-scripts.com.
DDB Examples:

Pharmacy dispenses different drug than ordered

- Illegal substitution – e.g. Albuterol
- Different drug – *Prevacid* for *Nexium* or *Novolog* for *Humalog*
- Formulary replacement
  - Do you have approval?
  - Did you document approval?
  - How did you document?

DDB Examples:

- Interaction with Gleevec
- Change to Pravachol 40mg
Avoiding audit recoveries

- Fill and bill exactly as written
- Always calculate a correct DS
- Fill within plan guidelines
- Obtain clear mathematically useful directions
- Monitor adherence and early refills
- Verify all changes
- Know how to write a good clinical note

Avoiding audit recoveries – Challenging is not always easy

1. Clinical Note
   - Hard Copy Rx vs. Computer
   - Be careful with scanned prescriptions

2. Prescriber Letter (PL)
   - Prescriber Letterhead vs. Replacement Rx
   - PL must be on prescriber letterhead
Helpful Information on the computer back tag

Software vendors may be able to turn on or activate certain features on the computer Rx fill sticker to help you avoid audit problems.

Examples:
- DS – Helps pharmacy staff monitor
- Rx OC
- DAW – Should be zero unless otherwise indicated
- LF – Helpful with adherence
- NPI#
- DEA# - Required on all CS Rxs, including Suboxone
- R.Ph. Initials
- Others?

Review new developments in pharmacy audit recoveries:
- Humana hitting pharmacies for incomplete Rx Transfers or
- For not reducing a transfer to “hand” writing
- Victoza prescriptions – Inject ml vs. mg
- Dispensing test strips from gray market (unauthorized) distributors
- Insulin Flex Pen vs. Flex Touch
Discuss red flags for pharmacy auditors and actions to ensure that procedures are followed to eliminate risk

- High Dollar claims
- Compounds
- DAW Code Usage (DAW-0, DAW-1, DAW-2, DAW-9)
- Generic vs. Brand dispensing rates
- Override Codes (to bypass Refill-too-soon edits)
- Quantity dispensed vs. day supply, FDA Guidelines and Plan Limitations
- Reversals

Outline your audit rights and responsibilities

- You have a right to be present for the audit
- You have the right to have an audit at a mutually agreeable time
- You have the right to bring in additional help for an unannounced audit
Mark Jacobs RPh
VP Of Operations at PAAS National
mjacobs@paasnational.com
Phone: 608-873-1342