



GPS



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PHARMACISTS ASSOCIATION

Growth. Performance. Success.

2024 ANNUAL CONVENTION



Equipping Your Team for Typical and Atypical PBM Audit Scenarios

NCPA 2024 Annual Convention and Expo
Columbus, Ohio

Speaker



Trenton Thiede PharmD, MBA

President

PAAS National®

Disclosure Statement

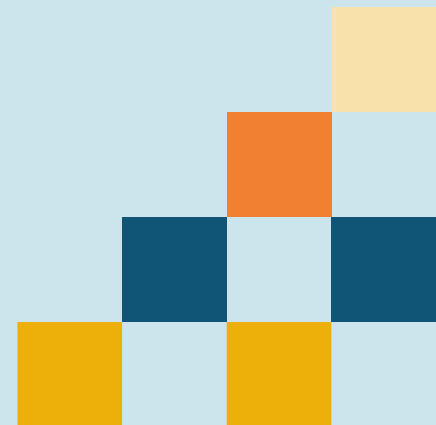
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Pharmacist and Technician Learning Objectives

1. Review four common PBM audit issues.
2. Discuss invoice audits. LS0
3. Summarize common drug substitution issues that can result in an audit.
4. Outline strategies for pharmacy team members to prevent and respond to audit scenarios.



Why So Many Audits



Escalating Healthcare Costs



Opioid Epidemic



Contractual Requirements



Fraud, Waste & Abuse



Common Billing Errors



Data Analytics/Outliers



PBM Revenue Source = \$\$\$

Audit Penalties



Financial Recovery



Corrective Action Plans



Network Termination



Reputation



License



OIG Exclusion



Fines



Prison

Audit Penalties

The screenshot displays the official website of the Office of Public Affairs, U.S. Department of Justice. The header includes the department's logo, name, and navigation links for 'Our Offices', 'Find Help', and 'Contact Us'. A search bar is also present. Below the header is a menu with categories: 'About', 'News', 'Documents', 'Internships', 'FOIA', 'Contact', and 'Information for Journalists'. The main content area features a breadcrumb trail: 'Justice.gov > Office of Public Affairs > News > Press Releases > Pharmacists Convicted of \$13M Medicare, Medicaid, and Private Insurer Fraud Scheme'. On the left, a 'News' sidebar lists 'All News', 'Blogs', 'Photo Galleries', 'Podcasts', and 'Press Releases' (which is highlighted). The main article is titled 'Pharmacists Convicted of \$13M Medicare, Medicaid, and Private Insurer Fraud Scheme' and is labeled as a 'PRESS RELEASE'. It is dated 'Friday, September 6, 2024' and includes a 'Share' button. A 'For Immediate Release' box from the 'Office of Public Affairs' is also visible.

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PRESS RELEASE

Pharmacists Convicted of \$13M Medicare, Medicaid, and Private Insurer Fraud Scheme

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Office of Public Affairs

Audit Penalties



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PRESS RELEASE

Walgreens Agrees to Pay \$106.8M to Resolve Allegations It Billed the Government for Prescriptions Never Dispensed

Friday, September 13, 2024

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U.S. Attorney's Office, Middle District of Florida



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PRESS RELEASE

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SEC Charges Three Former Executives of Pharmacy Startup with Defrauding Investors

Now-defunct digital pharmacy raised over \$170 million based on fake prescriptions and fraudulently inflated revenue



Audit Trends 2019 – 2023*

- 17% increase in audits over last year
- Many invoice audits are in tandem with desk/onsite or credentialing audits

	Desk	Rx Validation Requests	Virtual	Onsite	Stand Alone Invoice Audits
2019	64%	21%		13%	2%
2020	62%	23%	7%	6%	2%
2021	67%	20%	11%	0%	2%
2022	67%	21%	5%	5%	2%
2023	51%	37%	1%	9%	2%

*Based on PAAS Audit Statistics

4^{LSO} Common Audit Issues

Prescription

1. Is the prescription legal/valid per state and federal laws?

Data Entry & Filling

2. Is the prescription filled and billed accurately?

Dispensing

3. Is there proof of dispensing?
4. Is there proof of copay collection?

Common Discrepancies

Prescription

Missing Elements (e.g., controlled substance requirements)
Mid-level Practitioners (do they need supervising MD, license #, etc.)

Data Entry & Filling

Days' Supply Calculations
Overbilled Quantity
Refill Too Soon

Dispensing

Missing/Invalid Signature Log
Dispensed outside PBM return to stock window
Mail/Delivery Restrictions
Unable to prove copay collection

LSO

Invoice Audit Fundamentals

- PBMs/payors want to validate that pharmacies purchased more than (or equal to) what they billed in claims
 - Defined date range (typically 12 months)
- Some PBMs require the pharmacy to submit a full dispensing history to validate purchases against all claims

Invoice Audit Fundamentals

- Why do PBMs conduct invoice audits?
 - Ensure pharmacies are purchasing from ‘PBM approved’ sources LSO
 - Identify false/phantom claims
 - Billing for medications that are never dispensed, including failure to reverse claims not picked up
 - Identify billing discrepancies (e.g., billing for brand - dispensing generic, NDC swaps, etc)

Invoice Audit Fundamentals

“The alleged cornerstone of the scheme was a code used by the pharmacy employees in their internal computer system: “BBDF” or Bill But Don’t Fill.”

United States Attorney's Office Eastern District of Pennsylvania

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Justice.gov > U.S. Attorneys > Eastern District of Pennsylvania > Press Releases > Philadelphia Pharmacy Criminal Pleas and Civil Resolutions Result in Multiple Criminal Convictions and Over \$4 Million Recovered

PRESS RELEASE

Philadelphia Pharmacy Criminal Pleas and Civil Resolutions Result in Multiple Criminal Convictions and Over \$4 Million Recovered

Wednesday, March 20, 2024

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U.S. Attorney's Office, Eastern District of Pennsylvania

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Invoice Audit Fundamentals

“conspired to charge Medicaid for a particular manufacturer’s omeprazole which was reimbursable at a significantly higher rate than most omeprazole. In reality, the dispensed medication was generic omeprazole purchased at big-box warehouse retail stores.”

The screenshot shows the official website of the Office of Public Affairs, U.S. Department of Justice. The page features a dark blue header with the department's seal and logo, navigation links for 'Our Offices', 'Find Help', and 'Contact Us', and a search bar. Below the header is a dark navigation bar with links for 'About', 'News', 'Documents', 'Internships', 'FOIA', 'Contact', and 'Information for Journalists'. The main content area has a breadcrumb trail: 'Justice.gov > Office of Public Affairs > News > Press Releases > Pharmacy Owner and Operations Manager Convicted of \$2.3M Ohio Medicaid Fraud'. On the left, a 'News' sidebar lists categories: 'All News', 'Blogs', 'Photo Galleries', 'Podcasts', and 'Press Releases' (which is highlighted). The main headline reads 'Pharmacy Owner and Operations Manager Convicted of \$2.3M Ohio Medicaid Fraud' under the 'PRESS RELEASE' category. The date is 'Wednesday, February 28, 2024'. A 'Share' button is visible. A yellow box on the right contains the text 'For Immediate Release' and 'Office of Public Affairs'.



Invoice Audit Problems

- Invoices must be submitted directly from wholesalers
 - More wholesalers = more problems
- Invoice audits don't account for inventory on hand
 - Medication with low turnover, dead inventory
 - Purchasing in bulk
- PBMs expect the Date of Service to be the date on which the Covered Item is prepared and readied for dispensing
 - Pharmacies should exercise caution when billing claims in advance of having medication available
 - NCPDP definition of 401-D1 Date of Service: Identifies date the prescription was filled or professional service rendered...

Invoice Audit Solutions

- Always be on copy of wholesaler documentation to PBM
 - Confirm correct dates are sent
- Include all wholesaler accounts (e.g., 340B)
- Limit wholesalers to simplify process
- Notify Caremark of any bulk purchases
- Ensure you're buying from appropriate sources!!!

Acquiring Drugs from Appropriate Sources

- Considerations should include:
 - NABP Accredited Drug Distributors
 - Licensure as a wholesaler
 - Registered with FDA
 - Authorized distributor of the manufacturer
 - Certain pharmacy to pharmacy transfers

Acquiring Drugs from Appropriate Sources

NABP Accredited Drug Distributors

National Association of Boards of Pharmacy (NABP). Accredited Drug Distributors. [Accessed September 18, 2024].
<https://nabp.pharmacy/programs/accreditations/drug-distributor/accredited-drug-distributors/>

The screenshot shows the NABP website's 'Accredited Drug Distributors' page. At the top, there is a search bar and an 'e-Profile Login' link. The NABP logo and name are prominently displayed. Below the logo, there are navigation links for 'Programs', 'Members', 'Initiatives', 'Meetings', 'News & Resources', and 'About'. A breadcrumb trail indicates the current location: 'Home > Programs > Accreditations > Drug Distributor Accreditation > Accredited Drug Distributors'. The main heading is 'Accredited Drug Distributors'. Below this, there is a section titled 'Find an Accredited Drug Distributor' which contains a search form with fields for 'Facility Name' and 'State' (set to '(All)'), and 'Search' and 'Reset' buttons. Below the search form, it states 'Current list of 746 NABP-Accredited Drug Distributors'. A note mentions 'Accreditation is valid for three years' and 'Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.' At the bottom, there is a pagination control showing '1 2 3... 73 74 75' and a 'Next >>' link.

Acquiring Drugs from Appropriate Sources

Licensure as a wholesaler
(in your state)

Check Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

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Drug Supply Chain Integrity

[FDA Leads Effort to Create a Supply Chain Security Toolkit for Medical Products](#)

[Drug Supply Chain Security Act \(DSCSA\)](#)

Valid License is Required Under the Law

Prescription drugs should only be purchased from wholesale drug distributors with a valid license in the U.S. and who are authorized by law. Unlicensed and unauthorized trading partners put patients at risk of taking unsafe, possibly illegitimate drugs that may be counterfeit, stolen or diverted.

Third-party logistics providers also must be authorized if a manufacturer, wholesale distributor or dispenser uses a third-party logistics provider to coordinate warehousing or other logistics services.

Check whether a wholesale drug distributor or third party-logistics provider is an authorized trading partner

1. Check the applicable state licensure website listed below to determine if the wholesale drug distributor or third-party logistics provider has a valid license in the state where they are conducting business and
2. Check [FDA's annual reporting database](#) to determine if a wholesale drug distributor or third-party logistics provider submitted an annual report to FDA.

Content current as of:
06/12/2024

Regulated Product(s)
Drugs

U.S. Food and Drug Administration (FDA). Verify Wholesale Drug Distributor Licenses. [Accessed September 18, 2024].
<https://www.fda.gov/drugs/drug-supply-chain-integrity/verify-wholesale-drug-distributor-licenses>

Acquiring Drugs from Appropriate Sources

Diabetic Testing Supplies

- OTC distributors are typically not licensed as wholesalers
 - Not required for OTC products
 - Falls outside DSCSA
 - OptumRx requires pharmacies to purchase diabetic supplies from wholesalers, not distributors
 - Must be licensed as a wholesaler

Acquiring Drugs from Appropriate Sources

Diabetic Testing Supplies

- Authorized Distributor of the Manufacturer
- Manufacturer produces list of approved distributors
- Required by Caremark and Express Scripts

Authorized Distributor of Record (ADR) List

Distributor	City	State	Retail (Pharmaceutical Benefit)	(Medical Benefit)
AmerisourceBergen	Chesterbrook	Pennsylvania	Yes	No
CardinalHealth (including Parmed Pharmaceuticals)	Dublin	Ohio	Yes	No
McKesson (excluding Masters Drug Company, Masters Pharmaceuticals, & River City Rx)	San Francisco	California	Yes	No
Dakota Drug	Minot	North Dakota	Yes	No
Gemco	Hudson	Ohio	Yes	Yes
H D Smith	Springfield	Illinois	Yes	No
Independence Medical	Twinsburg	Ohio	Yes	Yes
Kinray	Whitestone	New York	Yes	No
Louisiana Wholesale Drug Co	Sunset	Louisiana	Yes	No
Morris & Dickson	Shreveport	Louisiana	Yes	No
Mutual Drug Company	Durham	North Carolina	Yes	No
Smith Drug Company	Spartansburg	South Carolina	Yes	No
Value Drug	Altoona	Pennsylvania	Yes	No
Roche Diabetes Care Inc.	Indianapolis	Indiana	Yes	Yes
DDP Medical Supply	St. Petersburg	Florida	Yes	No
Capital Wholesale Drug	Columbus	Ohio	Yes	No
Dixon Shane Inc. dba R&S Northeast, LLC	Fountain Run	Kentucky	Yes	No
Medline Industries	Mundelein	Illinois	Yes	Yes
Pharmacy Buying Association, Inc. dba PBA Health	Kansas City	Missouri	Yes	No
McKesson Medical-Surgical	Richmond	Virginia	Yes	Yes

The ADRs listed herein represent those trading partners of Roche Diabetes Care, Inc. that have signed and executed distributor agreements.

[Click here for an overview of the distributor agreements](#)

Roche Accu-Check. Authorized Distributor of Record (ADR) List. [Accessed September 18, 2024]
https://rxvp.accu-chek.com/welcome/adr_list

Acquiring Drugs from Appropriate Sources

Authorized distributor of the manufacturer

- Does not automatically include subsidiaries
- NABP ADD ≠ Authorized Distributor



Diabetic Supplies

People with diabetes require various pharmaceutical products to maintain a healthy lifestyle. We stock over a hundred diabetic supplies like syringes, meters, lances, test strips, socks, creams, and more.

is not an authorized distributor of record for diabetic supply products.

Masters Pharmaceutical. Products. [Accessed
September 18, 2024]
<https://mastersrx.com/pharmaceutical-products/>

Acquiring Drugs from Appropriate Sources

Pharmacy to Pharmacy (P2P) transfers:

- Caremark Provider Manual:

For those Covered Items received from other pharmacies, where permitted by and consistent with Law, Provider must obtain and maintain the entire Transaction Statement, Transaction History, and Transaction Information from the selling entities. Failure to acquire and maintain records will result in the Covered Items received from other pharmacies being ineligible to be dispensed to Eligible Persons.

Drug Substitution Issues

- How PBMs use analytics to identify suspect claims
- Biologic definitions and substitutions
- Other common substitution errors

Drug Substitution Issues

- PBMs utilize rejected claim information to help determine the validity of future claims
- A prescription billed for Basaglar[®] (rejected) and then billed for Semglee[®] within a short time period (e.g., < 5 minutes) will likely be flagged by PBMs for audit
 - PBM assumes Basaglar[®] was prescribed
 - Semglee[®] substitution was in a short interval that would indicate it was unlikely to have been verified with the prescriber
 - High likelihood of claim being flagged for recoupment

Biologics – Purple Book

- Located in the FDA Purple Book
 - Approved under Biologic License Application (BLA)
 - There are no “generics” or “AB ratings”

The screenshot shows the FDA Purple Book website interface. At the top left is the FDA U.S. Food & Drug Administration logo. To the right is a 'Purple Book Glossary' link and a search bar. The main heading is 'Purple Book Database of Licensed Biological Products'. Below this is a navigation menu with links: 'Purple Book Homepage', 'About Purple Book', 'User Guide', 'FAQs', 'Patent List', and 'Download Purple Book Data'. The main content area contains three paragraphs of text describing the database's scope and search instructions. At the bottom, there is a search input field with the placeholder text 'Enter at least 3 letters' and a magnifying glass icon. Below the search field are links for 'Advanced Search' and 'Database last updated: February 13, 2024'. The NCPA logo is visible in the bottom right corner.

FDA U.S. FOOD & DRUG ADMINISTRATION

[Purple Book Glossary](#)

Purple Book Database of Licensed Biological Products

[Purple Book Homepage](#)

[About Purple Book](#)

[User Guide](#)

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[Patent List](#)

[Download Purple Book Data](#)

The Purple Book database contains information on all FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products.

The Purple Book also contains information about all FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research (CBER).

Enter a product's proprietary (brand) name or the nonproprietary (proper) name to find biological products. As you type, a list of potential results will begin to appear below the search box based on what you are typing. Click on a product from the auto-populated results list below to view the results page. The results page for your selected product will include all biological products that share a core name (i.e., biosimilar, interchangeable, reference, and related biological products).

[Advanced Search](#) Database last updated: February 13, 2024

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Biologics - Terminology

Type	BLA License Type	Like an Orange Book...	Example
Reference Product	351(a)	Brand drug	Humira®
Biosimilar	351(k) biosimilar	B-rated generic (must obtain prescriber approval to substitute)	Yusimry™
Interchangeable Biosimilar	351(k) interchangeable	A-rated generic	Cyltezo®
Unbranded Biologic	Approved under another BLA	Authorized generic NOT found in Purple Book	Adalimumab-adbm

Equivalent Biologics

- Insulin glargine-yfgn unbranded can be substituted for Semglee®



<https://dailymed.nlm.nih.gov/dailymed/>

Equivalent Biologics

Unbranded biologics can be identified by matching the BLA # of the reference product and the unbranded biologic.

The screenshot shows the DailyMed website interface. At the top, there is a navigation bar with the NIH logo and the text "U.S. NATIONAL LIBRARY OF MEDICINE". To the right of this bar are links for "REPORT ADVERSE EVENTS" and "RECALLS". Below the navigation bar is the DailyMed logo and a search bar with the placeholder text "Enter drug, NDC code, drug class, or Set ID". The search bar is surrounded by tabs for "ALL DRUGS", "HUMAN DRUGS", "ANIMAL DRUGS", and "MORE WAYS TO SEARCH". Below the search bar is a horizontal menu with links for "HOME", "+ NEWS", "FDA RESOURCES", "+ NLM SPL RESOURCES", "+ APPLICATION DEVELOPMENT SUPPORT", and "HELP".

Two search results are displayed side-by-side. The left result is for "SEMGLEE" (insulin glargine-yfgn injection, solution). The right result is for "INSULIN GLARGINE" (insulin glargine-yfgn injection, solution). Both results show a "MARKETING INFORMATION" table with the following data:

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761201	11/15/2021	

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761201	11/16/2021	

The URL <https://dailymed.nlm.nih.gov/dailymed/> is visible at the bottom of the screenshot.

Insulin Glargine Substitution

Okay to substitute WITHOUT prescriber approval (based on state law)

Prescription written as:	Okay to substitute WITHOUT prescriber approval (based on state law)				
	Lantus® BLA 021081 <i>Reference Product</i>	Insulin glargine (Winthrop) BLA 021081 <i>Unbranded biologic</i>	Semglee® BLA 761201 <i>Interchangeable Biosimilar</i>	Insulin glargine-yfgn (Mylan) BLA 761201 <i>Unbranded biologic</i>	Basaglar® BLA 205692 <i>Reference Product</i>
Lantus®	Yes	Yes	Yes	Yes	No
Semglee®	Yes	Yes	Yes	Yes	No
Basaglar®	No	No	No	No	Yes
Insulin glargine	Yes; however, consider patient history and Plan formulary				

Insulin Glargine – Purple Book

Biosimilar(s) ⓘ

No biosimilar data at this time.

Interchangeable(s) ⓘ

<p>Proprietary Name <i>Rezvoglar</i></p> <p>Proper Name <i>insulin glargine-aglr</i></p> <p></p> <p>■ PRODUCT LABEL</p>	<p>Proprietary Name <i>Semglee</i></p> <p>Proper Name <i>insulin glargine-yfjn</i></p> <p> </p> <p>■ PRODUCT LABEL</p>
--	--










Reference Product(s) ⓘ

<p>Proprietary Name <i>Basaglar</i></p> <p>Proper Name <i>insulin glargine</i></p> <p></p> <p>■ PRODUCT LABEL</p>	<p>Proprietary Name <i>Lantus</i></p> <p>Proper Name <i>insulin glargine</i></p> <p>  </p> <p>■ PRODUCT LABEL</p>	<p>Proprietary Name <i>Semglee</i></p> <p>Proper Name <i>insulin glargine</i></p> <p> </p> <p>■ PRODUCT LABEL</p>	<p>Proprietary Name <i>Toujeo</i></p> <p>Proper Name <i>insulin glargine</i></p> <p></p> <p>■ PRODUCT LABEL</p>
--	--	---	--







Matching color cards indicate a biological product is biosimilar to or interchangeable with a reference product

Adalimumab – Purple Book

Biosimilar(s) ⓘ

<p>Proprietary Name Amjevita</p> <p>Proper Name adalimumab-atto</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Cyltezo</p> <p>Proper Name adalimumab-adbm</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Hadlima</p> <p>Proper Name adalimumab-bwwd</p>  <p>■ PRODUCT LABEL</p>
<p>Proprietary Name Hulio</p> <p>Proper Name adalimumab-fxjp</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Hyrimoz</p> <p>Proper Name adalimumab-adaz</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Idacio</p> <p>Proper Name adalimumab-aacf</p>  <p>■ PRODUCT LABEL</p>
<p>Proprietary Name Simlandi</p> <p>Proper Name adalimumab-ryvk</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Yufyma</p> <p>Proper Name adalimumab-aaty</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Yusimry</p> <p>Proper Name adalimumab-aqvh</p>  <p>■ PRODUCT LABEL</p>

Interchangeable(s) ⓘ

<p>Proprietary Name Abrilada</p> <p>Proper Name adalimumab-afzb</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Amjevita</p> <p>Proper Name adalimumab-atto</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Cyltezo</p> <p>Proper Name adalimumab-adbm</p>  <p>■ PRODUCT LABEL</p>
<p>Proprietary Name Hadlima</p> <p>Proper Name adalimumab-bwwd</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Hyrimoz</p> <p>Proper Name adalimumab-adaz</p>  <p>■ PRODUCT LABEL</p>	<p>Proprietary Name Simlandi</p> <p>Proper Name adalimumab-ryvk</p>  <p>■ PRODUCT LABEL</p>

Targeted Drug Substitutions

- Albuterol HFA
- Epinephrine
- Methylphenidate
- Isotretinoin
- Novolog/Humalog
- Lantus/Basaglar
- Changes in dosage form

Workflow Prevention Strategies



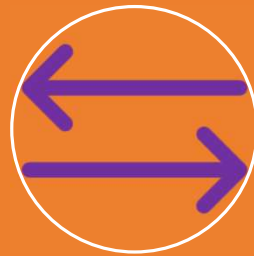
Prescription Drop-Off



Verify apparent alterations



Clarify “use as directed” for insulin or topicals with prescriber



Implement Rx scanning if possible



Suggested *Clinical Note* Format:

1. Who you spoke with
2. When you spoke
3. What was discussed
4. Who made the note

Data Entry

Quantity

1. Verify correct NCPDP billing unit (EA, GM, ML)
2. Quantity unit of measure is present/appropriate for eRx
3. Some products must be dispensed in original container

Day's Supply

1. **Must be calculable based on quantity and SIG**
2. Call PBM help desk for override if smallest unbreakable packages

DAW Codes

1. Only submit if supported by documentation

Filling



Match 11-digit
NDC on stock
bottle against
billing label



Confirm quantity
prepared matches
billing label



If time allows spot
check DAW, Day
Supply, Origin
Code

Verification



Match 11-digit NDC on stock bottle against billing label using barcode technology if possible



Double **check** days' supply estimate as per documented calculations

Pay close attention to insulin, topicals, eye drops, inhalers



Verify additional Data Entry elements such as DAW, SIG and Origin Code

Add elements to "backtag"

Cashier



Conduct
Return to
Stock on a
regular basis



Obtain
patient
signature for
Proof of
Delivery



For mail,
make sure Rx
is “tied to”
carrier
tracking ID #



Collect
copays at
dispensing,
maintain
proof



In-house
charge
accounts
must have
good
accounting
practices

Other Support Staff/Manager



Create reports to audit high risk claims (e.g., DAW 1, days' supply for targeted products)



Review adherence to Return to Stock procedures



Ensure Proof of Delivery and Copay Collection are available and retrievable, in accordance with PBM requirements



Incorporate audit training and prevention strategies for all staff

Questions?





Contact Information

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