



The poster for the NCPA 2019 Annual Convention in San Diego features a large, colorful, multi-colored 'San Diego' text. A blue banner across the middle reads 'Changing the Pharmacy Payment Model'. The NCPA logo is in the top right, with the text 'NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION'. Below the logo, the dates 'OCTOBER 26 - 29' and the website 'ncpanet.org/convention' are listed. Several circular inset photos show attendees: a woman clapping, a man speaking, and groups of people interacting. A small image of the San Diego skyline is also present.

San Diego

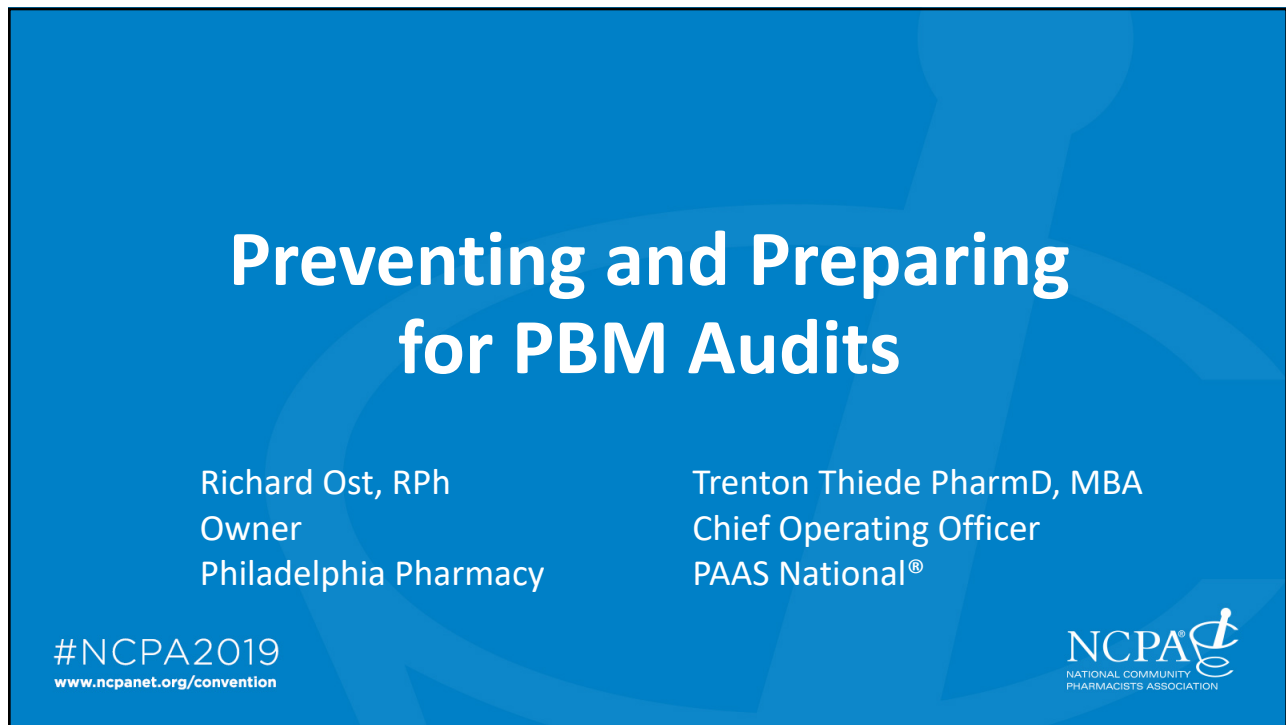
Changing the Pharmacy Payment Model

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CONVENTION

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OCTOBER 26 - 29
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The slide has a blue background with a faint silhouette of a person. The title 'Preventing and Preparing for PBM Audits' is in large white text. Below the title, two speakers are listed: Richard Ost, RPh, Owner of Philadelphia Pharmacy, and Trenton Thiede PharmD, MBA, Chief Operating Officer of PAAS National. The hashtag #NCPA2019 and the website www.ncpanet.org/convention are in the bottom left. The NCPA logo is in the bottom right.

Preventing and Preparing for PBM Audits

Richard Ost, RPh
Owner
Philadelphia Pharmacy

Trenton Thiede PharmD, MBA
Chief Operating Officer
PAAS National®

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Disclosure and Conflict of Interest



Trent is the COO of PAAS National®, a pharmacy audit assistance service. The conflict of interest has been resolved by peer review.



Richard is the Owner of Philadelphia Pharmacy



We will not discuss off-label and/or investigational use in my presentation

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Pharmacist and Pharmacy Technician Learning Objectives



Identify practices in your pharmacy that are most likely to trigger an audit



Discuss how pharmacy employees can incorporate audit prevention strategies into pharmacy workflow



Identify and describe the current industry audit trends



Explain and evaluate Medicare Part D audit challenges



Identify how to create a proactive post-bill audit program

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THIS SESSION WILL BE UTILIZING AUDIENCE POLLING SOFTWARE


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Why so many audits?


 Escalating Healthcare costs


 Opioid Epidemic

 **Contractual Requirement**

 **Fraud, Waste & Abuse**

 Common Billing Errors

 Data Analytics/Outliers

 **PBM Revenue Source = \$\$\$**

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Audit Penalties



Financial Recovery



Network Termination



Reputation



License



OIG Exclusion



Fines



Prison

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FOR IMMEDIATE RELEASE

Friday, June 14, 2019

United States Files False Claims Act Complaint Against Two Compounding Pharmacies and Their Owner For Submitting Inflated Claims and Improperly Waiving Patient Copayments

FOR IMMEDIATE RELEASE

Wednesday, August 21, 2019

Two Los Angeles Pharmacy Owners Found Guilty in Multimillion-Dollar Health Care Fraud and Money Laundering Scheme



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Audit Trends from 2014-2018

- 5-year trend is a 60.3% increase in audits overall
- 2018 started tracking '72-hour prescription validation' requests
 - Extrapolated to 10.7% of annual total

*Many invoice audits are in addition to desk/onsite audit

	Desk %	Onsite %	Invoice* %
2014	72	27	1
2015	73	26	1
2016	78	20	2
2017	82	16	2
2018	86	12	1

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Big Picture

Prescription	Do you have a prescription? Is prescription legal/valid per state and federal laws?
Data Entry & Filling	Did you fill and bill accurately (including calculable directions?)
Dispensing	Do you have proof of dispensing? Do you have proof of copay collection?
Other	Did you purchase enough inventory from an appropriate source?

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Common Audit Discrepancies

Prescription

- Missing/Invalid Rx
- Altered Rx



Data Entry

- Overbilled Quantity
- Refill Too Soon
- Incorrect DAW Code



Dispensing

- Missing/Invalid Signature Log
- Dispensed > 14 Days
- Copay Collection



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Audit Algorithms ≠ Random



Historical
Billing/Documentation Errors

1. Days' Supply
2. DAW



Historical Fraud Targets

1. Controlled Substances – “Pill Mills”
2. Compounds



Telemedicine & Delivery –
Zip code analysis

1. Patient
2. Prescriber
3. Pharmacy

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Telemedicine Questions to Consider



Is the prescription valid?



Valid patient/provider
relationship?



Is the prescriber licensed in
the state the patient
resides in?



Prescriber's scope of
practice?



Why are the prescriptions
coming to your pharmacy?



Are you mailing the
prescription?



And many more...

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“Top Eleven” Audit Discrepancies

Day Supply – Insulin
Day Supply – Topicals
Day Supply – Inhalers
Day Supply – Eye drops
DAW
Controlled Substance Prescriptions
E-Prescriptions
Transfer Prescriptions
Compound Prescriptions
Proof of Dispensing/Copay Collection
Non-FDA approved products or FDA approved devices

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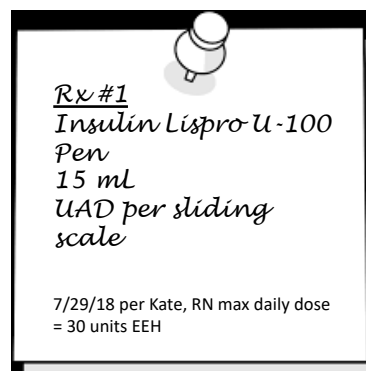
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1. Days Supply - Insulin

1 box of pens (15 mL)

- **Obtain Max Daily Dose and add a *Clinical Note***
- ***Submit accurate DS***
- **Must break boxes if plan limits exceeded!!**



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1. Days Supply - Insulin DOJ Settlement with WAGs

- January 22, 2019 - \$209.2 million settlement
 - Regarding billing and dispensing of insulin pens (WAGs had Rx system set up to prevent breaking boxes)
 - Forced pharmacies to alter Days' Supply to plan limits
 - Then put patients on auto-refill program leading to early refills
 - DOJ cited examples of patients selling insulin on Craigslist
 - For Single Patient Use Only
 - FDA safety announcement from 2015: guidance regarding HCP utilizing the same pen on multiple patients and just swapping the pen needles
 - Remember to provide Patient Information Handouts
- Seeing PBMs enforce (Humana, EnvisionRx, ESI, OptumRx, and Prime)!

D1 Note: The quantity billed exceeds the quantity authorized by the prescriber or plan.
Comments: As a result of recent DOJ decision, Humana will require pharmacies to break boxes of insulin depending on the directions and quantity prescribed. Submitted 30 for 90 days' supply (= 100 days' supply) Plan maximum 90 days' supply.

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Sources: DOJ <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-2692-million-recovery-walgreens-two-civil-healthcare>
 FDA <https://www.fda.gov/Drugs/DrugSafety/ucm435271.htm>

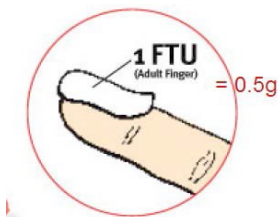
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2. Days Supply - Topicals

Finger Tip Unit (FTU) Method

- 1 FTU \approx 0.5 gram (adult)
- 1 FTU covers one hand (front/back)



Body Surface	# of FTUs
Hand	1
Foot	1
Arm + Hand	4 (3+1)
Leg + Foot	8 (7+1)
Buttocks	4
Trunk (front or back)	8 each
Face & Neck	2.5

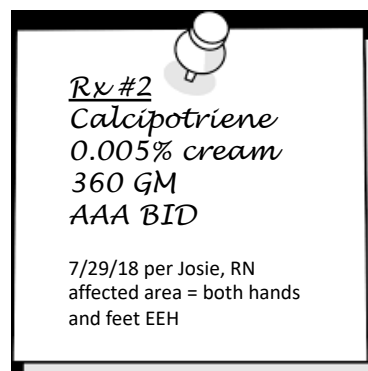
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2. Days Supply - Topicals

- **Submit accurate DS if possible**
- **Mathematical instructions for use**
 - Grams per application (if one area only)
 - Max Daily Dose per MD or expected day supply
 - List of affected areas + Finger Tip Unit (FTU) Method



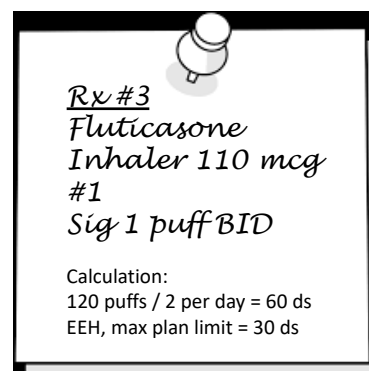
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3. Days Supply - Inhalers

- **Submit accurate DS if possible**
- **Do not refill early**
- **Strategies**
 - Call for DS override
 - Add note to sig field (e.g. 60 ds)
 - Train staff to watch for refill intervals
- If patient requests early assess circumstances and document



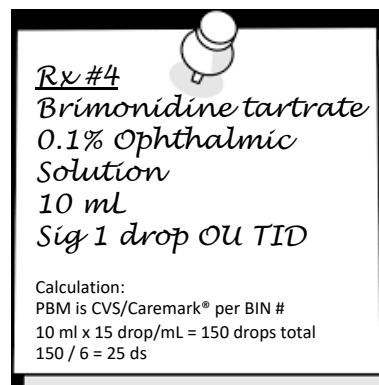
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4. Days Supply – Eye Drops

- **Submit accurate DS if possible**
- In General
 - 20 drop/mL for solution
 - 15 drop/mL for suspension
- PBMs have their own “estimates”
 - CVS/Caremark® 15
 - Express Scripts® 16
 - OptumRx® 15
- Document any patient factors that may impact ability to dose accurately (e.g. Parkinson)



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5. DAW

- Values 0-9
- 0 = Default for brand and generic
- 1 = Brand per **Prescriber**
- 2 = Brand per **Patient**
- Generally avoid 3-8
- 9 = Brand per **Plan**
- **DOCUMENTATION must support**

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6. Controlled Substances

Federal Law

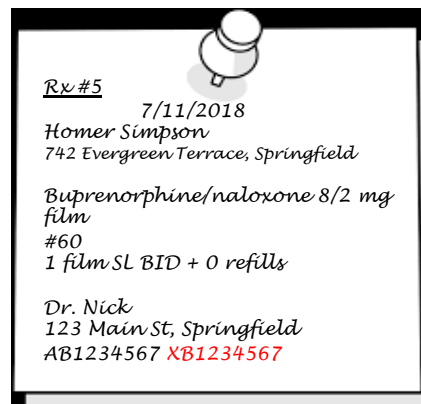
3 elements as per 21 CFR 1306.05(a)

- Patient Address
- MD Address
- DEA number

State Law(s)

- Where applicable
- Part D Opioid Restrictions

**Buprenorphine/naloxone – DATA 2000 Waiver ID
aka “X DEA number” in addition, not in replace of**



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7. Electronic Prescriptions

- Quantity “1” = smallest package size
- DAW – default? (false positives – furosemide, Lyrica®)
 - Sig field vs. free text
- Days’ Supply
 - Be cautious about DS field when conflict with quantity/Sig calculation
- Invalid eRx
 - Failover to Fax (not a valid eRx)
 - eClinicalWorks
 - Downloading prescriptions (HITECH Act vs. NCPDP SCRIPT Standard)

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8. Transfer Prescriptions

- General Requirements
 1. "Copy" or "Transfer"
 2. Transferring pharmacy info – RPh, pharmacy, address, phone, DEA #
 3. Rx info
 4. Rx history – Rx #, first/last fill, original/remaining refills
 5. Your info – date of transfer, RPh
- **Suggest using a dedicated transfer Rx pad with all required elements**
- **Data Entry – original date vs. transfer date**

TRANSFER PRESCRIPTION	
NAME _____	TRANSFER DATE _____
ADDRESS _____	
ORIGINAL RX # _____	R_x
DATE OF ISSUE _____	
DATE FIRST FILLED _____	
ORIGINAL REFILLS _____	
REFILLS REMAINING _____	
DATE LAST REFILL _____	
PHARMACY _____	
ADDRESS _____	
DEA # _____	
PHARMACIST OF RECORD:	
TRANSFERRING _____	
RECEIVING _____	
MAY SUBSTITUTE _____ DISPENSE AS WRITTEN _____	
ADDRESS _____	
DEA NO. _____	
Recorder Item #6107	Total Pharmacy Supply, Inc. 1-800-676-2622

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9. Compounds



**Rx must match
 compound log AND
 Claim**

NDCs
 Quantities



**Ingredient strengths
 assumed to be "final"
 unless specified**

E.g. *in lidocaine 5% ointment*



**Base QS amount –
 make sure software
 does not overbill**



LOE codes 11-15

Be careful with defaults

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10. Proof of Dispensing & Copay Collection

Proof of Dispensing

Elements

1. Rx #
2. Date of Service
3. Signature of Patient/Representative
- **“Mail”, “Drive Thru” or “Delivery” will NOT be sufficient**

Copay Collection

- **Contracts require collection WITH PROOF (limited exceptions)**
- In-house charge accounts
- Manufacturer Coupons
 - Medicaid/Medicare
 - Caremark: non-FDA approved

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10. Copay Collection

- Copayments are used to sensitize patients to the cost of their medications
 - Documented proof of collection
 - Front/Back copies of canceled checks, bank deposits, and even Credit Card Merchant Account Reporting, including evidence of settlement and payment through bank records
 - How could you prove copay collection on a transaction from last year on a specific prescription?
 - House Charge Accounts (Red Flag)
 - Documented Policy and Procedures
 - Timely invoice and documented attempts at collection
 - How are payments applied
 - Bad Debt/Hardships
 - Documented Policy and Procedures
 - Tax return documentation, etc

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11. Non - FDA approved products or FDA approved devices

- Medicare Part D definition of a covered drug:
 - A Part D covered drug is **available only by prescription, approved by the FDA** (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Act), used and sold in the United States, and **used for a medically accepted indication** (as defined in section 1927(k)(6) of the Act). A covered Part D drug **includes prescription drugs, biological products, insulin** as described in specified paragraphs of section 1927(k) of the Act, vaccines licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration. The definition also includes **medical supplies directly associated with delivering insulin to the body**, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes, can satisfy the definition of a Part D drug.
 - **No dietary supplements or FDA approved devices**
 - **No off-label use**

Source: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf>

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11. Non - FDA approved products or FDA approved devices


- Medicare Part D definition of a covered drug:
 - Compounded prescription drug products can contain: (1) all Part D drug product components; (2) some Part D drug product components; or (3) no Part D drug product components. As defined in §423.120(d), only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not contain any ingredients covered under Part B as prescribed and dispensed or administered, may be covered under Part D. **Only costs associated with those components that satisfy the definition of a Part D drug are allowable costs under Part D** because the compounded products as a whole do not satisfy the definition of a Part D drug. For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary. **Bulk powders (i.e., Active Pharmaceutical Ingredients for compounding) do not satisfy the definition of a Part D drug and are not covered by Part D.** For any non-Part D ingredient of the Part D compound, the Part D sponsor's contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.

Source: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf>

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Practical Keys to Preventing Audit Recoupments



Staff Training and Follow up



Integrate Workflow Checks



Documentation- Tell the story



Documentation

Format: WWW

Who authorized the changes (time & date)

What changes are being made

What are you changing

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Staff Training and Follow up



You cannot do it all yourself



Lead Technician- Trainer



Problem Technician- Problem solver



Post Audit Technician

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Workflow Processes = Prevention Strategies



1. RX DROP OFF



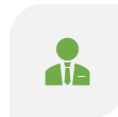
2. DATA ENTRY



3. FILLING
QA



4. PHARMACIST
VERIFICATION



5. CASHIER

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Rx Drop Off



Verify all controlled prescriptions
Look for apparent alterations



Confirm that the Patient's Name is the same on all
prescriptions



Confirm Patient's Address, Date of Birth, Insurance
Information, and Allergies



Separate patients and establish pick up priority using
colored bins-One bin per patient

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Data Entry

Quantity	<ol style="list-style-type: none"> 1. Verify correct NCPDP billing unit (EA, GM, ML) <ul style="list-style-type: none"> • Be cautious with syringes and “kits” 2. Quantity “1” = smallest package size unless confirmed otherwise 3. Some products must be dispensed in original container – see NLM DailyMed for product labeling-Document quantity discrepancies
Days' Supply	<ol style="list-style-type: none"> 1. <u>Estimate as per quantity and SIG, must submit accurately, call PBM helpdesk for override if smallest unbreakable package</u> 2. Document calculations on prescription- Staff Training and Tools 3- Spot Check DAW
Hard Copy	<ol style="list-style-type: none"> 1. Each RX should have a Hard Copy 2. Print Electronic RX's

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Data Entry-Continued

Changes, Clarifications, and Documentation	<p>All documentation should tell a story.</p> <p>Who authorized the changes (time & date)</p> <p>What changes are being made</p> <p>What are you changing</p>	WWW
Prescribers Information	<p>Verify NPI and License numbers</p> <p>DEA and “X” number where applicable</p>	
Hard Copy Scan	<ol style="list-style-type: none"> 1. Scan Hard Copy RX at data entry <u>only</u> after any changes have been documented. 	

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Data Entry sample E-scripts documentation

Drug: INSULIN DETEMIR (U-100) 100 UNIT/ML (3 ML) QTY: 15 Milliliter
 QTY: FIFTEEN
 SUBCUTANEOUS PEN
 NDC: 00169-6438-10
 Refills: 5
 Sig: INJECT 10 UNITS INTO THE SKIN NIGHTLY.
Handwritten: 100 units 9ml 3x3pens LEVEMIR 90 day phm limit R3X 12/1/19 2/19

Drug: OZEMPIC 1 MG/DOSE (2 MG/1.5 ML) SUBCUTANEOUS PEN QTY: 45 Milliliter
 QTY: FORTY FIVE
 INJECTOR
 NDC: 00169-4136-02
 Refills: 6
 Sig: INJECT 1 MG INTO THE SKIN EVERY 7 DAYS.
Handwritten: 100 units clarification qty=6pens @ 3 REFILLS 9-11-19 932

Drug: LEVEMIR FLEXTOUCH 100 UNIT/ML SUBCUTANEOUS SOLUTION QTY: 1 Package
 QTY: ONE
 PEN-INJECTOR
 NDC: 00169-6438-10
 Refills: 5
 Sig: 20-30 UNIT UNIT TWO TIMES DAILY
Handwritten: 100 units 15ml 5x3ml 12/20/19 clarification R3X 5/2/19 25day supply

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Data Entry-Insulin Calculator

3 ML Insulin Pens	BILL QTY	ML/ Package	Units/ MCG Package	Number of Pens dispensed (RX)	Total Units dispensed	Total Units/ Day (RX)	Day Supply
Admelog	3	3ml 1 pens	300 (A)	(B)	(C) AxB=C	(D)	(E) C/D=E
Apidra							
Basaglar							
Humalog 70/30							
Humalog 75/25							
Humalog 100							
Humulin N or R							
Lantus Solo							
Levemir							
Tresiba 100u							
Novolog (ALL)							
Other Pens			(A)				
Toujeo	6	4.5 ml	1350 Units				
Toujeo MAX	6	6ml	1800 units				
Tresiba 200u	9	9	1800 Units				
Victoza 18mg	6	6	36mg				
Victoza 18mg	9	9	54mg				
Bydureon	4	2mg/pen /one pen per week					
Trulicity 0.75mg	4	0.75mg/0.5ML/pen /one pen per week					
Trulicity 1.5 mg	4	1.5mg/0.5ML/pen /one pen per week					
Byetta 5 mcg	2	Each package has 60 doses 5mcg each (1.2ML)					
Byetta 10mcg	3	Each package has 60 doses 10mcg each (2.4ML)					
Ozempic Starter	2	2mg/pen- one (1) 1.5 ML pen per package					
Ozempic	4	2mg/pen- two (2) 1.5 ML pens per package (4mg/total/package)					

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Filling-Quality Assurance Station

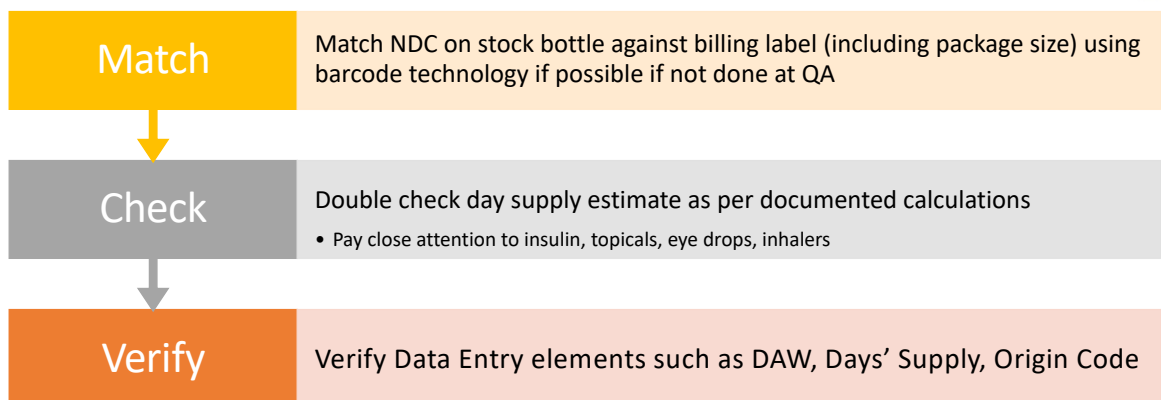
- Match NDC on stock bottle against billing label (including package size) using barcode technology
- Confirm Patients Name and Quantity- Hardcopy Prescription matches the Billing Label
- Spot Check DAW, Day Supply and Origin Code
- Scan Hardcopy RX- Scanning at the QA station scans the final RX with all documentation written

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RPh Verification



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Cashier (Dispensing)

Verify patients name and address- Obtain signature (electronic if possible)

If mailing, make sure that Rx # is "tied to" carrier tracking ID #

Collect Copay at dispensing, implement itemized POS system

In-house charge accounts must have proper accounting practices

Conduct Return to Stock at least twice a week

- Document any unique exceptions where Rx was dispensed > 10 days
- If patient promises to come "next week", then reverse/ rebill/ relabel to give more time to maintain compliance

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Post Fill Audit



Audit all RX's over \$150



Create a report using your Pharmacy Management System



Implement into daily work of a specific employee

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Post Fill Audit Report

DOS	Rx#	DW	Pat Last Name	Pat First Name	Dtr Last Name	NPI	Dtr DEA	Drug Name	NDC	DAW	Qty	Days
8/7/2019	9759708	4/3/2019	DUCK	GEORGE	CURLY	1124544999	MC5214851	TRULICITY 1.5/0.5 INJ	00002-1434-80	0	4	26
8/20/2019	9759707	4/3/2019	DUCK	SUSAN	CURLY	1124545000	MC5214852	LANTUS SOLOSTAR(M140D/P)	00088-2219-05	0	15	26
8/7/2019	9751512	10/9/2018	GOOFY	GEORGE	CURLY	1124545002	MC5214854	SYMBICORT AER 160-4.5 120 P	00186-0370-20	0	11	30
8/26/2019	9778925	7/3/2019	MOUSE	SUSAN	CURLY	1124545001	MC5214853	FLOVENT HFA AER 110MCG 12	00173-0719-20	0	12	30
8/27/2019	9778926	7/4/2019	MOUSE	SUSAN	CURLY	1124545002	MC5214854	ADVAIR DISKUS 250/50	00173-0696-00	0	60	30
8/4/2019	9786700	7/16/2019	DOG	BIG	LARRY	1152414712	AL1235472	HUMULIN 70/30 VIAL	00002-8715-01	0	10	10
8/4/2019	9786701	7/16/2019	DOG	BIG	LARRY	1152414713	AL1235473	DIOVAN 160MG	00078-0359-34	0	30	30
8/22/2019	9791463	8/22/2019	DOE	JOHN	MOE	1142142122	FM5419315	HUMALOG MIX 75/25 (M28D/A	00002-7511-01	0	10	40
8/7/2019	9779130	6/24/2019	DOE	SUSAN	MOE	1142142123	FM5419316	HUMALOG KWIK 100U INJ (M1	00002-8799-59	0	15	38
8/19/2019	9782958	7/9/2019	MOUSE	DAVID	MOE	1142142121	FM5419314	JANUVIA TAB 100MG	00006-0277-31	0	90	30
8/23/2019	9765501	5/4/2019	PABLO	LUCIANO	MOE	1142142123	FM5419316	VASCEPR 1GM	52937-0001-20	0	120	30
8/24/2019	9765502	5/5/2019	PABLO	LUCIANO	MOE	1142142124	FM5419317	JANUVIA TAB 100MG	00006-0277-31	0	30	30
8/3/2019	9786536	7/15/2019	DUCK	SUSAN	SHEMP	1185598339	FC8521475	SYMBICORT AER 80-4.5 120 PU	00186-0372-20	0	11	30
8/26/2019	9778924	7/3/2019	MOUSE	DAVID	SHEMP	1185598341	FC8521477	BIKTARVY TAB	61958-2501-01	0	30	30
8/28/2019	9768280	5/22/2019	PAN	JOHN	SHEMP	1185598340	FS8521476	TRIUMEQ TAB	49702-0231-13	0	3	30

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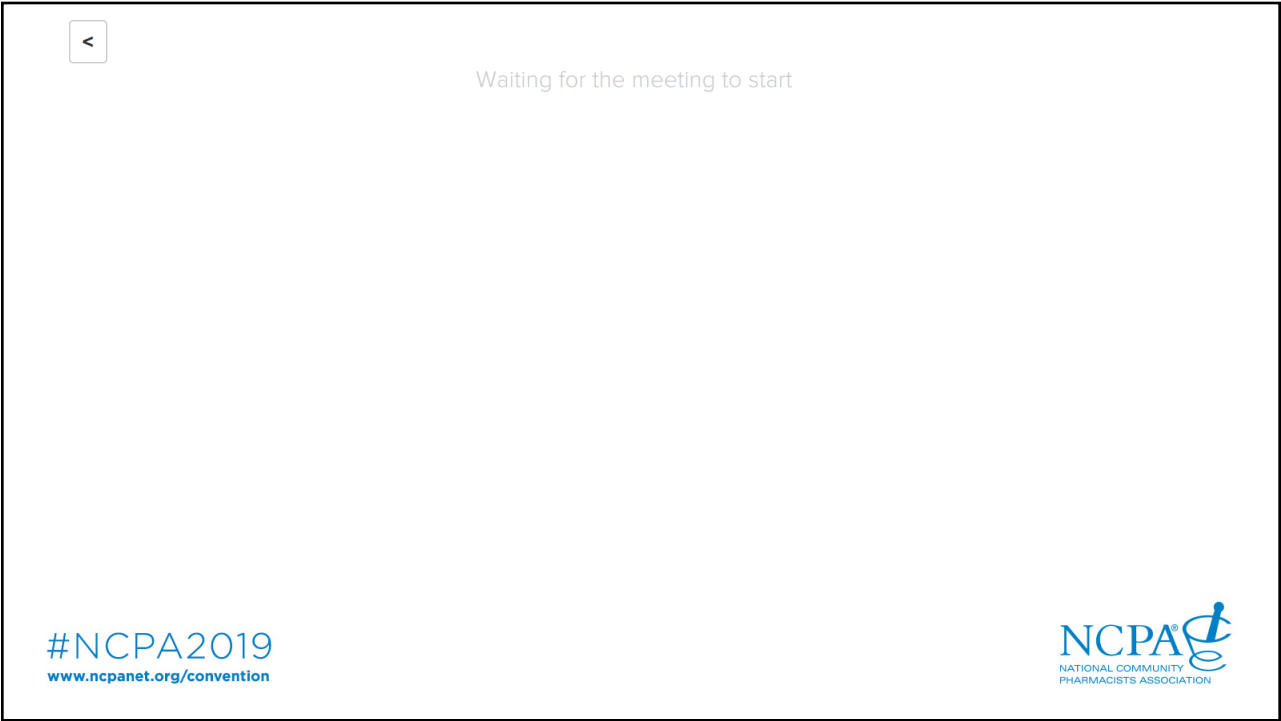


Please go to **MEET.PS/PBMAUDIT** to answer poll questions!

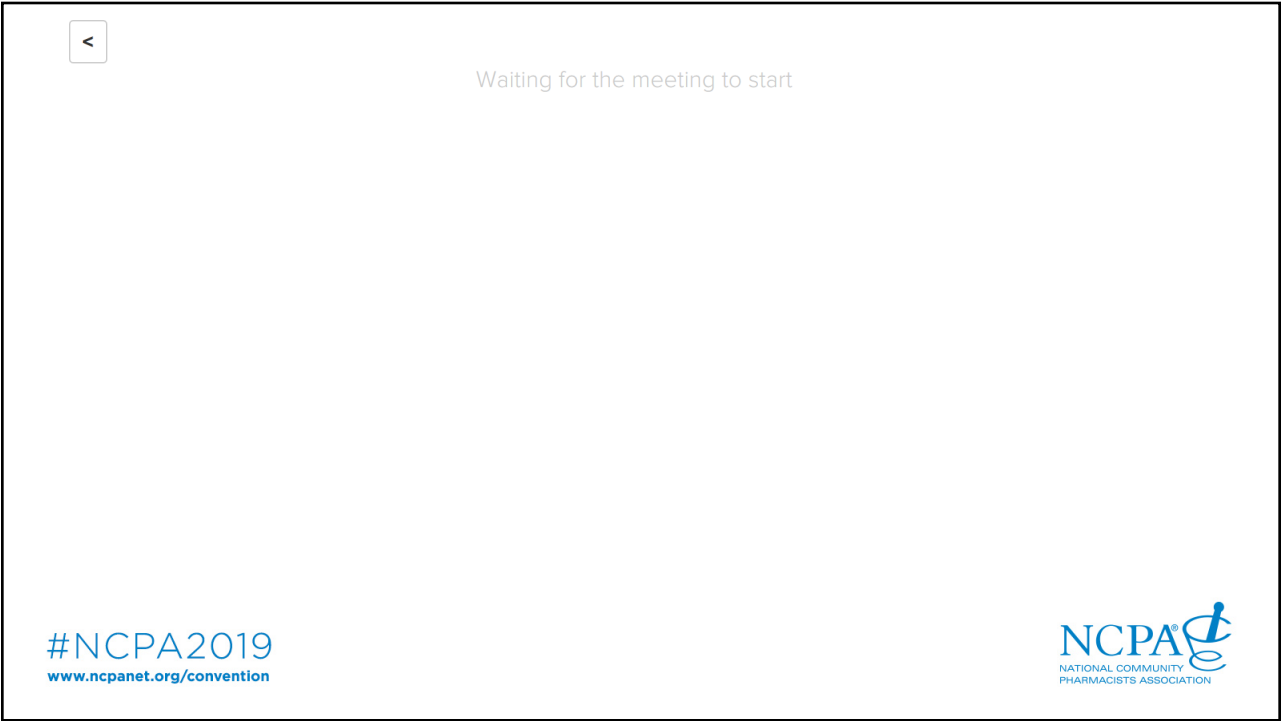
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Key Takeaways

1. Identify Audit Flags
2. Methods to educate pharmacy staff on audit prevention
3. Procedures to reduce audit risk

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Questions?



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