



# Billing for Compounded Meds: Best Practices

Trenton Thiede, PharmD MBA

President  
*PAAS National*

1

## Outline

- PAAS Background
- General audit issues that apply to compounds
- PBM compound considerations

2



# PAAS National

- Unlimited Expert Audit Assistance
  - 5 RPh & 6 CPhT (and support staff)
  - Detailed audit preparation
  - Post-audit and appeals guidance
  - Proactive Tips and Prevention
    - Third-Party Newsline – Newsletter
    - Valuable resources
- FWA/HIPAA Compliance
- Cultural Competency Training
- USP <800> Compliance

ASSISTING WITH



# 10,000

AUDITS A YEAR

SAVING OUR MEMBERS

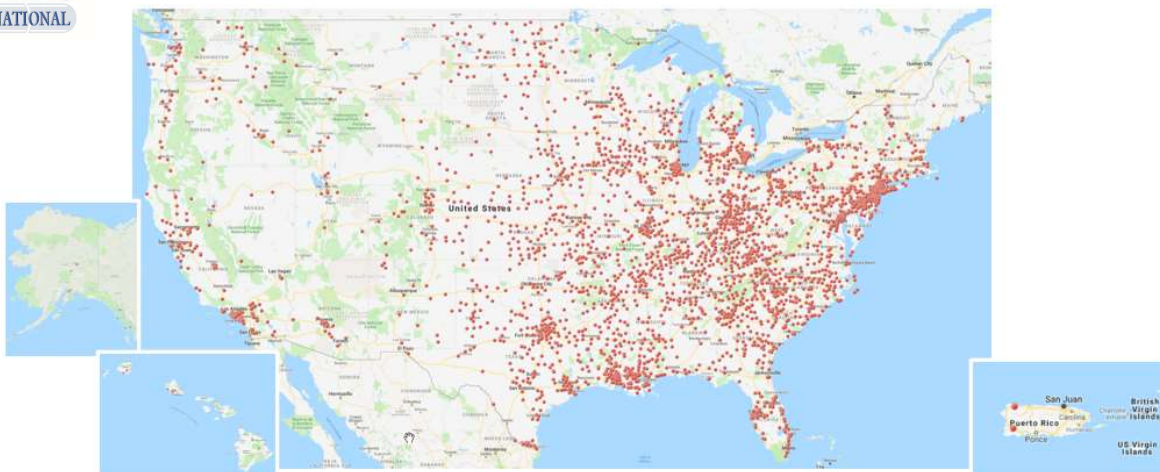
# \$983 million



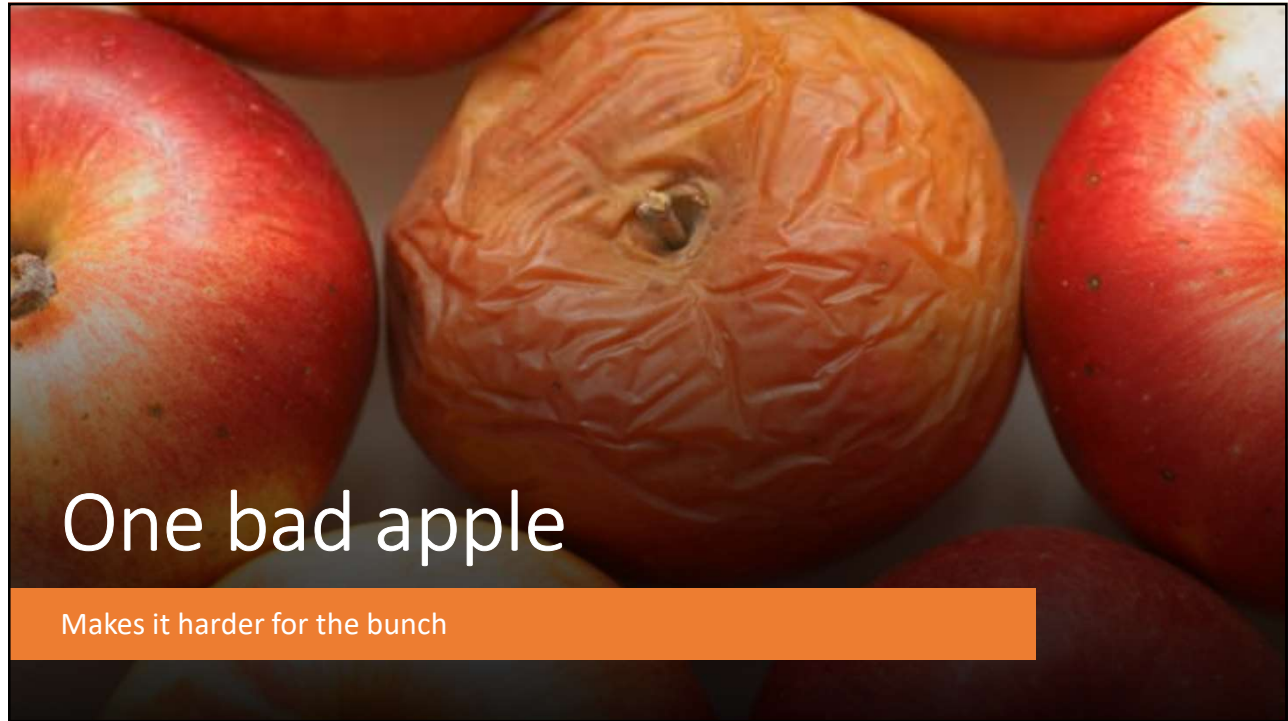
3



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4



5

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## Three Men Sentenced for \$54M Fraudulent Prescriptions Scheme

Tuesday, November 14, 2023

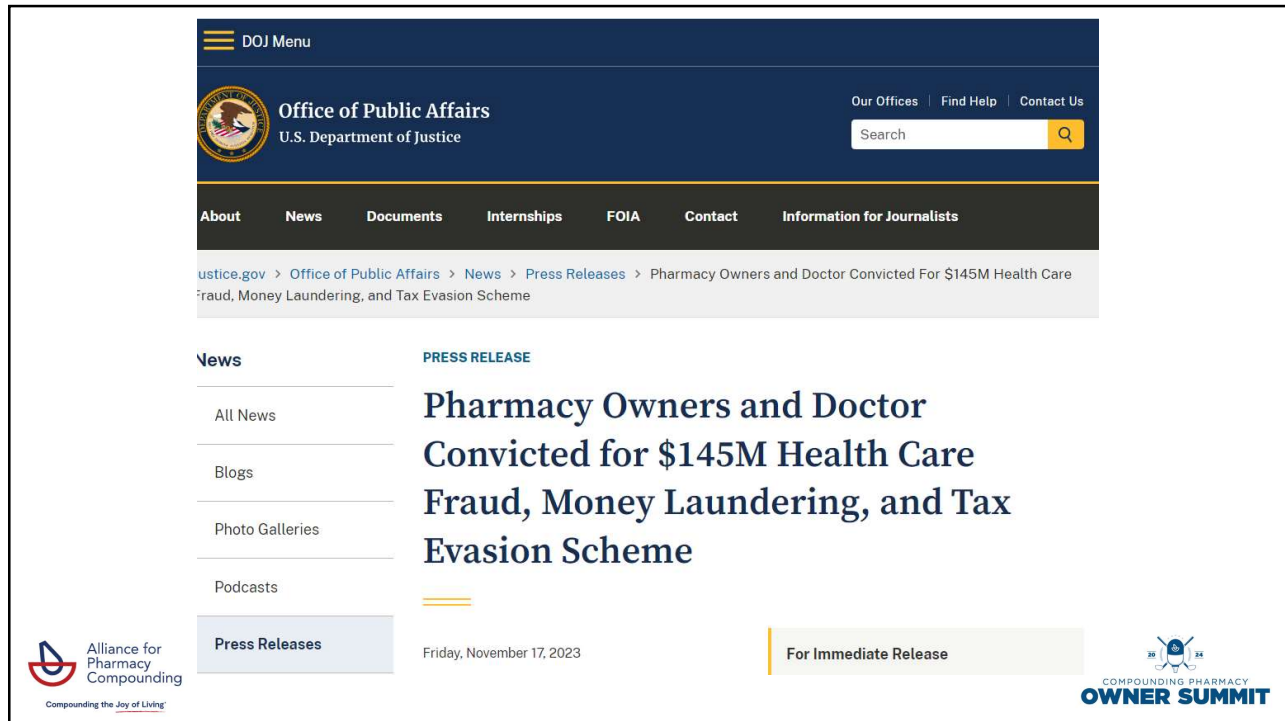
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6



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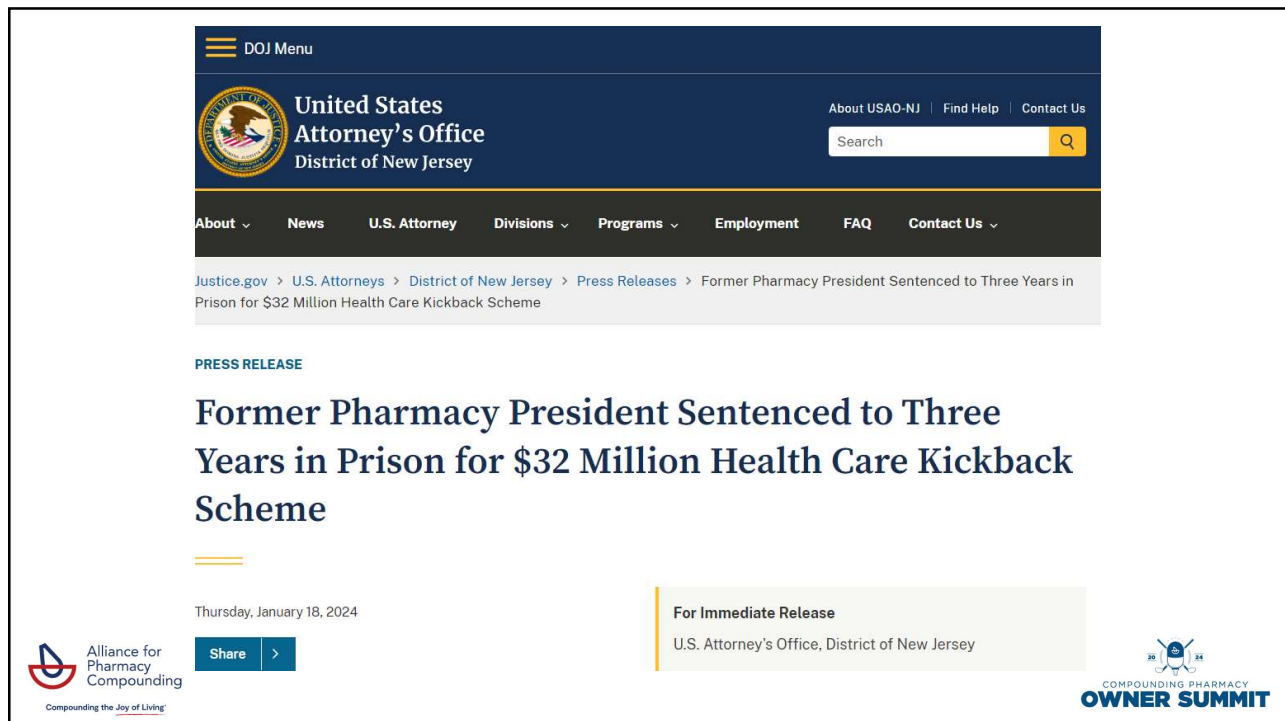
## Pharmacy Owners and Doctor Convicted for \$145M Health Care Fraud, Money Laundering, and Tax Evasion Scheme

Friday, November 17, 2023

For Immediate Release

7



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**PRESS RELEASE**

## Former Pharmacy President Sentenced to Three Years in Prison for \$32 Million Health Care Kickback Scheme

Thursday, January 18, 2024

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8

# General Audit Issues

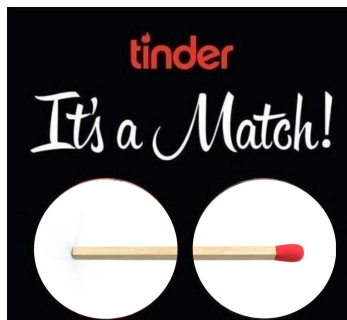
That Apply to Compound Prescriptions



9

## Matching NDCs

- Prescription must match compound log and claim billed
  - Pharmacies often forget to update pharmacy management system compound to current generic NDCs being dispensed
  - Cannot bill tablets/capsules but using bulk powders



10

## PBM Provider Manual Pre-printed Forms

- ESI: Providers utilizing prescription forms with multiple medications and substitution language must document consultation with the prescriber on appropriate medication prior to dispensing unless previously covered under a collaborative practice agreement.
- CRK: Provider must not use pre-printed prescriptions that result in the dispensing of Covered Items that are not the most cost-effective even if they are different salts, bases, release characteristics, or additional drugs in combination.
- Elixir: A pre-printed substitution drug is not valid without a new prescription or a properly documented verbal authorization from prescriber.



11

## Telemedicine



- Questions to consider when reviewing prescriptions:
  - Is the prescription valid?
  - Can you confirm patient/provider relationship?
  - Medical claim filed?
  - Is the prescriber licensed in the state the patient resides?
  - Prescriber's scope of practice?
  - What's the pharmacy's relationship with the telemedicine provider?
  - Are prescriptions being mailed?



12

## Proof of Delivery

Elements:

1. Rx #
2. Date of Service and refill indicator
3. Signature of Patient/Representative



- “Mail”, “Drive Thru” or “Delivery” will NOT be sufficient
- Preparing a short-dated compound (e.g., 30-day BUD), but not dispensing for several days can also lead to issues

13

## Proof of Delivery - Mailing

- Mailing requires tracking # tied to prescription number and signature of receipt or tracking confirmation
  - Print and retain tracking information
- OptumRx and Humana prohibit mailing
- Be careful when mailing out of state, may require licensure



14

## Proof of 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
  - 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



15

## Part D Definition of a Covered Drug

### Medicare Part D

- Definition of a Part D Covered Drug: A Part D covered drug is **available only by prescription, approved by the FDA, used and sold in the United States, and used for a medically accepted indication** (as defined in section 1927(k)(6) of the Act).
- Section 1927(k)(6) states a medical accepted indication is “any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations include or approved for inclusion in any compendia described in subsection (g)(1)(B)(i)”
  - Section 1927(g)(1)(B)(i) lists the three compendia including:
    - American Hospital Formulary Service Drug Information (AHFS)
    - United States Pharmacopeia-Drug Information (or its successor, which is Micromedex)
    - DRUGDEX Information System (also Micromedex)

16



## Part D Definition of a Covered Drug

- 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.
- OptumRx – medically accepted indications not only refers to the indication, but also the route of administration of the compound



17

## PBM Compound Considerations



18

## Express Scripts

*“Compound claims are highly susceptible to audit or investigation”*

19

## When is it not a compound

- Reconstitution is not considered a compound
- Medications that are not manipulated
  - IVIG
- Single NDC pre-made compound
- Compound Kits



20

## Compound Worksheet

- Compound log or recipe worksheet
  - Should include math and/or master formulation record
  - Final quantities
  - Name and dates of compounding personnel
  - BUD/Temp/Labeling requirements



21

## Caremark Compliance Reviews

- Provider must not separate cash and third-party prescription business or own, operate or affiliate with a non-participating Provider to manipulate Eligible Person prescription claims processing or pricing.



22

## Caremark Complex Compound Provider

- Non-complex compounds
  - Mixture of chemicals that do not involve bulk chemicals (APIs), aliquots or dissolutions of tablets or capsules.
  - Route of administration remains in accordance with FDA approved labeling/indications
  - Do not require specialized equipment (unguator, ointment mill, etc)
  - Do not require specialized training, gowning or special environmental conditions



23

## Caremark Complex Compound Provider

- [CompoundApplicationTeam@CVSHealth.com](mailto:CompoundApplicationTeam@CVSHealth.com)
  - Be currently preparing non-sterile complex compounds
  - Provide a list of top ten non-sterile compounds
  - Offer a variety of dosage forms
  - Be in good standing with Caremark
  - Avoid relationships with any pharmacy staff not currently in good standing with Caremark
  - Caremark compound application



24

# Caremark Complex Compound Provider

Re: CVS Caremark® Provider Agreement – Notice of Compound Contract Violation

Dear Pharmacy Owner:

Pursuant to the "Addendum to Caremark Provider Agreement, Compounding: Limited Scope of Pharmacy Services" dated **10/27/2023** ("Addendum"), you agreed to not submit complex compound claims. The Addendum states:

*A non-complex compound is a mixture of chemicals that do not involve bulk chemicals (API), aliquots, or dissolutions of tablets and/or capsules. Non-complex compounds are those where the route of administration remains in accordance/unchanged with FDA-approved labeling/indications for each ingredient contained within the compound. Non-complex compounds would not require specialized equipment (mortar and pestle, ointment mill, etc), training, or gowning and non-complex compounds would not require special environmental conditions to protect pharmacy staff and public.*

We have not received any written request from you to amend the terms of our agreement to allow you to submit complex compounds.

Based on our review of your prescription claims submission history, your pharmacy is submitting complex compounds claims (see table below) in breach of your Provider Agreement with CVS Caremark.

**REQUIRED ACTIONS:**

1. You must immediately cease and desist submitting claims for complex compounds and provide written acknowledgment and agreement to comply with Item #1; and
2. Reverse all of the complex compound claims in the table (Exhibit A) below by no later than



25

# Caremark Multi-Ingredient Compound Processing

- Enter each active and inactive item used in the preparation
  - Include consumable items (e.g., capsules)
- Calculated cost
  - cannot include waste
  - should be no greater than combined AWP cost of all ingredients plus nominal professional allowance based on Level of Effort (LOE)
- Provider must not manipulate claims pricing or the compound indicator for inappropriate financial gain or cause claim to inappropriately pay.
- Provider must bill Caremark a single claim for the final compounded product using multi-ingredient functionality (including all active and inactive items...) and must not bill separate claims to Caremark for individual items..
  - In an effort to protect the integrity of the final product and control the compounding environment for the safety of the Eligible Person, Provider must compound and dispense the final compounded product...



26

## Express Scripts Submission of Compound Claims

- At least one NDC must be a legend drug ingredient covered by the member's prescription drug program
- Additional supplies used to create the compound (e.g., syringes or capsules) may be included when calculating the price of a compound as long as the items have an active NDC in the PBM's drug file source
  - This includes supplies used to dispense the final product (e.g., syringes)
- Gloves, smocks or booties are considered part of the cost of doing business



27

## Express Scripts Submission of Compound Claims

- Network Providers may not circumvent Sponsor's benefit design
  - Resubmit rejected compound prescription ingredients as individual, non-compounded items
  - Omit non-covered ingredients
  - Submit partial fills less than a 30-day supply to avoid coverage limits
- Violations are deemed a material breach and can result in immediate termination



28

## Express Scripts Records Requirements

- NDC
- Metric quantity of each medication
- Certificates of Analysis
- Compound recipe sheet/log with quantity calculations
  - In accordance with USP 795

## Express Scripts Audit Discrepancies

Discrepancy Glossary		
Description	Definition	Code
Billed Wrong Drug	Submitted drug and/or compound log does not match prescription. If Prescriber changes medication or strength, it must be written on the prescription indicating the date of the change and Prescriber authorization, or a new hard copy prescription must be issued. Supporting documentation must be viewable at time of audit.	XDB
Compound Documentation Required	Claim was submitted for a compound without appropriate documentation (e.g., compounding log, Certificate of Analysis (COA), compound calculations, or other applicable documentation requested by PBM).	CDR
Cut Quantity	Compound ingredient was excluded in the claim submitted by Network Provider.	CQ
Billed Wrong NDC	Claim submitted using NDC for a package size incongruent with the prescribed dosage, inconsistent with the dispensed NDC or for an NDC that does not match the compound log.	BWN
Overbilled Compound	Compound claim submitted with inaccurate information resulting in an incorrect reimbursement (e.g. compound prescription ingredients submitted in excess of the quantity written on the prescription and compound log, inaccurate Level of Effort submission.)	OC

## OptumRx Compound Credentialing Program

- Credentialing requirement that 'validates' any Network Pharmacy Provider
- [optimized.credentialing@optum.com](mailto:optimized.credentialing@optum.com)



31

## OptumRx Submission of Compounds

- Network Pharmacy Provider shall not attempt to circumvent the PA process by either
  - (i) altering the days' supply and maintaining the same quantity or
  - (ii) reducing the quantity and the day supply to receive a paid Claim (i.e. such practices are deemed as fee-splitting and is not permitted).
  - For the latter, reducing the quantity of the Prescription and the day supply is permitted if such change does not cause the Member to incur an increased copayment amount over the life of the Prescription.
- Network Pharmacy Provider shall not submit a Compounded Drug Claim that is an equivalent alternative to a commercially available Drug Product.
- For each ingredient in which Network Pharmacy Provider uses tablets or capsules in a compounded medication, (weight/weight compounds in which the weight of the tablet displaces the weight of the final product not applicable to other compounds such as weight/volume), Pharmacy must document the total weight of the tablets or capsules prior to adding them to the compound.



32



## OptumRx Price Rolling

- Network Pharmacy Provider shall not engage in practices deemed as price rolling. Price rolling is defined as the practice of submitting Claims such that the Network Pharmacy Provider obtains the highest reimbursement possible by circumventing the standard Prior Authorization (PA) process. For example, the Network Pharmacy Provider submits a Compounded Drug Claim and receives a rejection; the Network Pharmacy Provider shall proceed with obtaining a PA. The acts of resubmitting a Claim multiple times with the same quantity and different Usual and Customary (U&C) until a paid Claim is received, or upon multiple submissions the quantity is changed to receive a paid Claim, shall be deemed as price rolling.



33

## OptumRx Level of Effort

	Code Compounded Drug Description	Examples of Compounded Drugs
11	Compounded Drug do NOT contain an Active Pharmaceutical Bulk Powder Ingredient or Excipient	Magic Mouthwash, combinations of manufactured dermatological creams/ointments
12	Compounded Drug CONTAINING at least 1 Active Pharmaceutical Bulk Powder Ingredient	Simple suspensions, dermatological preparations
13	Compounded Drug requiring pH adjustment for stability, use of liposomal bases, troches, rapid dissolve tablets, suppositories, capsules (any route of administration)	Lansoprazole suspensions, omeprazole suspensions, pain creams in liposomal bases, troches, rapid dissolve tablets, suppositories, capsules (oral, nasal, etc.)
14	Compounded Drug CONTAINING Hazardous/Controlled	Compounded Drug hormone (any dosage form), topical pain creams containing controlled substances, chemotherapy
15	Sterile Compounded Drug - must be compounded in a <797> compliant environment and are dispensed as sterile finished preparation	Any sterile Compounded Drug



34

## Contact Information

**Trenton Thiede, PharmD MBA**  
**Trent@paasnational.com**  
**608-873-1342**

