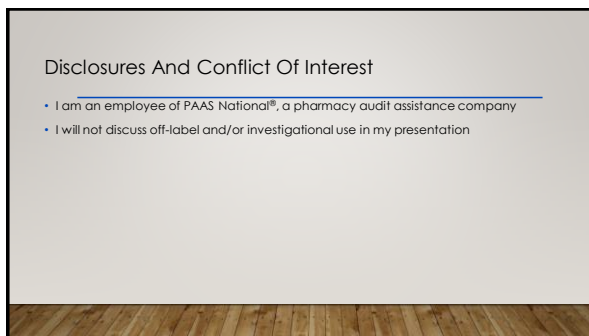
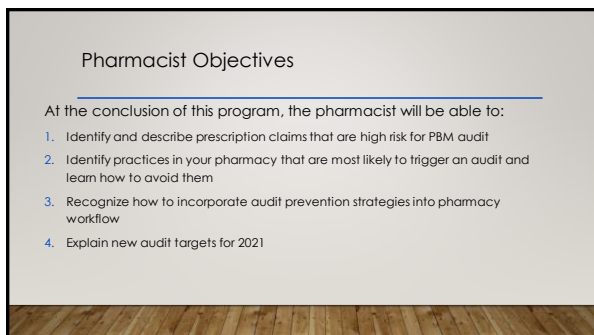


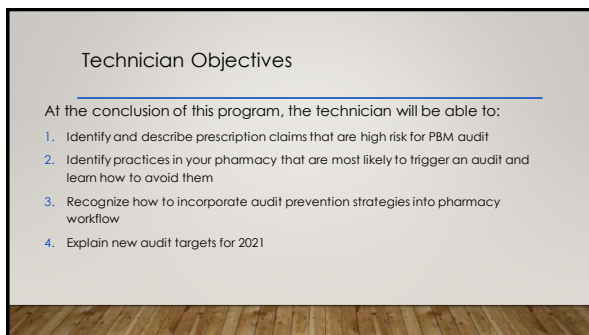
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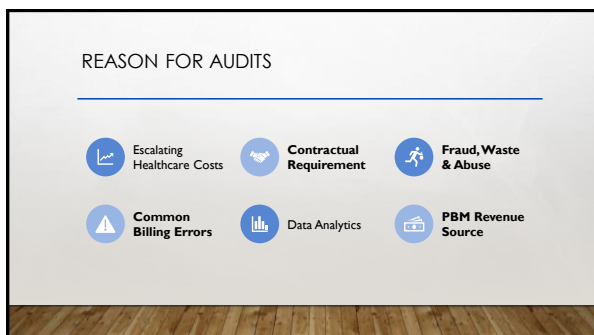
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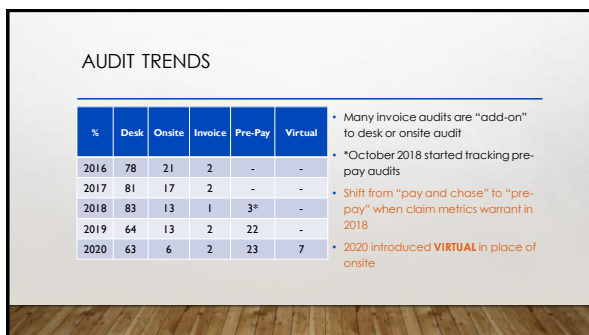
3



4



5



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AUDIT PENALTIES

- FINANCIAL RECOVERY
- CORRECTIVE ACTION PLAN
- NETWORK TERMINATION
- REPUTATION
- LICENSE
- OIG EXCLUSION
- FINES
- PRISON

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AUDIT PENALTIES

FOR IMMEDIATE RELEASE
Wednesday, March 24, 2021

Ocean Springs Man Sentenced to Federal Prison for Complicity in Carmel Health Care Fraud

Irishburg, Miss., — Damir “Roya” Levi, 51 and Jeffrey Wayne Rubin, 44, of Ocean Springs, were sentenced today by U.S. District Judge Faith Stowell for their role in a multi-million dollar scheme to defraud TSCA, the health care benefit program serving U.S. military, veterans, and their family members, as well as private health care benefit programs, announced Acting U.S. Attorney Darren J. Lukanow and Special Agent in Charge Michele Surjan of the Federal Bureau of Investigation in Mississippi.

Both Levi and Rubin were sentenced to serve 18 months in federal prison, followed by three years of supervised release, and pay \$14,525,000 in restitution to Medicare, Tricare and Veterans Affairs. Additionally, the government received a forfeiture of \$754,114.40.

<https://www.justice.gov/usao-ndms/press-pharmacy-owner-pharmacist-sentenced-federal-prison-conspiring-commis-health-care-fraud>

FOR IMMEDIATE RELEASE
Wednesday, April 21, 2021

Quorum Pharmacy Owner Pleads Guilty to Health Care Fraud

Defendant Used Proceeds of Schemes to Purchase Luxury Items, Including Yacht and Jewelry

BROOKLYN, NY — Earlier today, in federal court in Brooklyn, Aksh Mohanmood pleaded guilty before United States District Judge Eric N. Vladaver to most fraud, health care fraud, and conspiracy to commit health care fraud, among other things, in connection with several health care fraud schemes, including obtaining more than \$4.5 million from Medicare Part D Plans and Medicare drug plans. With settlement, the defendant faces up to 40 years’ imprisonment. As part of the plea agreement, Mohanmood has agreed to forfeit \$21 million, and pay over \$4.5 million in restitution.

<https://www.justice.gov/usao-ny/press-pharmacy-owner-pharmacist-sentenced-federal-prison-conspiring-commis-health-care-fraud>

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SURVEY QUESTION #1

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COVID-19 AUDIT ISSUES

- Most PBMs issued concessions in **early March 2020** to relax billing & documentation requirements with end dates tied to HHS Public Health Emergency Declaration (90-day increments)
 - Patient signatures
 - Mail/Delivery
 - Early refill overrides
 - Audit postponements
- Pharmacies must have some proof of delivery in place of patient signature
 - “Impacted by COVID-19” notation by pharmacy staff
 - Date/time of delivery
 - Link to carrier tracking ID #

<https://www.hhs.gov/emergency-preparedness-and-response/health/audit-issues/>

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COVID-19 TELEMEDICINE

- IS THE PRESCRIPTION VALID?
- VALID PATIENT-PRESCRIBER RELATIONSHIP?
- WHY IS PATIENT BEING TREATED BY THIS PRESCRIBER?
- IS THE PRESCRIBER LICENSED IN THE STATE THE PATIENT RESIDES?
- PRESCRIBER'S SCOPE OF PRACTICE?
- IS THIS A REGULAR PATIENT OF YOUR PHARMACY?

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COVID-19 VACCINE

Billing

- Quantity
- Day Supply
- SCC02 vs SCC06

Documentation

- Suggest “placeholder Rx” for your files
- Vaccine Administration Record (VAR)
- EUA Fact Sheet

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PBM "VIRTUAL" ONSITE AUDITS

- Began July 2020 in place of in-person audits at your pharmacy
- Hybrid of traditional desk and onsite
- Document submission via fax, email, mail, or web portal
 - Up to 125 prescriptions and 100+ signature logs
 - Copies of licensure, liability insurance
- Phone interview to ask compliance questions (10-15 minutes)
- Photos of pharmacy including consult area, sink, refrigerator, compound lab

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BIG PICTURE

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SURVEY QUESTION #2

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COMMON AUDIT DISCREPANCIES

 Prescription Missing or Invalid Rx Altered Rx	 Data Entry Unauthorized Refill Overbilled Quantity Refill too Soon Unsupported DAW Code	 Dispensing Missing or Invalid Signature Log Dispensed > 10 days Copy Collection
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AUDIT ALGORITHMS

Sophisticated Claims volume Δ Geographical You vs. Network Outliers	Presumed Billing Errors Quantity Day Supply DAW Code Origin Code	Historical Documentation Errors Illegible Overwrites Authorized Changes Transfer Rx "Special" drugs	Fraud Patterns Pill Mills Gray Market Compounds Telemedicine
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DMEPOS STANDARD WRITTEN ORDER (SWO)

- NEW as of January 1, 2020
- Replaces the previous different order types:
 - Detailed Written Order (DWO)
 - Five Element Order for ACA Items (SEO)
 - Seven Element Order for PWD (TEO)
- CMS Final Rule 1713 November 8, 2019
- When to have in your possession
 - Before billing = ALWAYS
 - Before delivery = SOME items require (WOPD)

Elements include:

- Beneficiary name OR Medicare Beneficiary Identifier (MBI)
- The order date*
- A description of the items ordered
- The quantity to be dispensed, if applicable
- Treating practitioner's name OR NPI
- Treating practitioner's signature*

*Signature and date stamps are not allowed

NEW: Notably absent (i) instructions for use and (ii) refills
 NEW: Pharmacies may clarify and add Clinical Notes

https://www.gomedicare.com/education/what-is-sw_o_for-1713.htm

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DMEPOS TARGETED PROBE & EDUCATE (TPE)

Targeted

- Suppliers with high claim denial rates
- Product categories with high error rates

Probe

- Review of 20-40 claims in 3 "rounds"
- Opportunity to exit loop if successful

Educate

- 1-on-1 education offered by DME MAC to facilitate improvement
- 45 days between rounds to implement corrective measures

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Targeted-Probe-and-Educate-TPE>

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WORKFLOW PREVENTION STRATEGIES

RX DROP OFF DATA ENTRY FILLING VERIFICATION CASHIER

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RX DROP OFF

- Verify apparent alterations
- Clarify "use as directed" for insulin or topicals with prescriber (or patient)
- Implement Rx scanning if possible

Clinical Note Best Practice:

- Who** you spoke with
- When** you spoke with them
- What** you spoke about
- Who** is writing the note

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DATA ENTRY

Quantity

- Verify correct NCPDP billing unit (EA, GM, ML)
- Quantity "1" = smallest package size
- Must dispense in original container as per labeling or U.S. NLM DailyMed

Day Supply

- Always estimate as per quantity and instructions for use
- Call PBM Helpdesk for override if unbreakable package
- Document calculations

DAW Codes

- Only submit if supported by documentation
- Don't force to get paid claim

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

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FILLING

- Match NDC on stock bottle against billing label (including package size) using barcode technology if possible
- Confirm quantity prepared matches billing label
- Spot check: DAW code, Day Supply and Origin Code

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VERIFICATION

Match Match NDC on stock bottle against billing label (including package size) using barcode technology if possible

Check Double check Day Supply estimate as per documented calculations
• Pay close attention to insulin, topicals, inhalers and eye drops

Verify Verify Data Entry elements such as Day Supply, DAW and Origin Code
• Suggest adding to "backtag" if doing paper verification

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CASHIER (DISPENSING)

- Conduct Return to Stock at least twice a week and use Pharmacy Technology to help you
 - Document any unique exceptions where Rx was dispensed > 10 days
 - If patient promises to come "next week", then reverse/rebill/label to give more time to maintain compliance
 - Turn on "hard stop" at Point-of-Sale register to prevent Rx from being sold after 10 days
- Obtain patient signature and date, implement electronic capture if possible
 - COVID-19 waivers have been in place since March 2020 – patient signatures NOT required as of **June 11, 2021**
- If mailing, make sure that Rx # is "tied to" carrier tracking ID #
- Collect Copy at dispensing, implement Point-of-Sale (POS) itemized system
- In-house charge accounts must have good accounting practices

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"TOP 10" AUDIT DISCREPANCIES

- Day Supply – Insulin
- Day Supply – Topicals
- Day Supply – Inhalers
- Day Supply – Eye Drops
- DAW
- Controlled Substance Rx
- Electronic Rx
- Transfer RX
- Compound Rx
- Proof of Dispensing & Copay Collection

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SURVEY QUESTION #3

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1. DAY SUPPLY – INSULIN

- Do NOT break boxes of insulin pens as of November 15, 2019
 - FDA intervened June 2019
 - "Dispense in this sealed carton" language on outside of package
 - Industry "flip flop" from Walgreens-DOJ decision January 2019
- Must submit accurate day supply if possible
- Call helpdesk to request override
- Consider Beyond Use Dating (per pen)

Sample Rx #1	
John Doe	06-01-2021
Insulin aspart U-100 Pen 15 mL	
UAD per sliding scale	
5 refills	
Dr. Smith	
06-01-2021 per Cece, RN max daily dose = 60 units	
EEH	
Calculation: 1500 units/60 units/daily = 25 days	

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FDA GUIDANCE – INSULIN PEN PACKAGING & DISPENSING OCTOBER 13, 2020

- There is an increased risk of dispensing errors and patients using the wrong product if individual insulin pens are stored or dispensed outside of their carton. Insulin pens dispensed individually outside of their cartons may have contributed to medication errors including wrong-drug and wrong-dose errors resulting in hyper- or hypoglycemia, missed doses, complaints of possible tampering, and dispensing without the instructions for use.
- Insulin pens are approved to be dispensed in their original sealed cartons. Although FDA approved the first single-pen carton size for an insulin product on June 11, 2020, insulin pens are generally marketed in cartons containing two to five pens. Insulin pens are not labeled for dispensing as individual units.
- FDA understands that there are situations where health care professionals may choose to dispense individual pens (outside of the carton), not in accordance with FDA-approved labeling, based on their professional judgment. In these situations, health care professionals should consider the known risks of dispensing individual pens and incorporate additional safety measures (e.g., adding tamper-indicator tape, providing a copy of the instructions for use to the patient, labeling individual pens for individual patient use) to mitigate those risks.

<https://www.fda.gov/drug/safety-and-availability/fda-advises-health-care-professionals-and-patients-about-insulin-pen-packaging-and-dispensing>

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2. DAY SUPPLY – TOPICALS

- Must submit accurate day supply if possible
- Mathematical instructions for use
 - Grams per application (if one area only)
 - Max Daily Dose or expected day supply
 - List of affected areas + Fingertip Unit (FTU) Method


Sample Rx #2	
John Doe	06-01-2021
Calcipotriene 0.005% cream 240 GM	
AAA BID	
5 refills	
Dr. Smith	
06-01-2021 per Cece, RN affected area = both arms EEH	

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FINGERTIP UNIT METHOD

Fingertip Unit (FTU) Method

- 1 FTU ≈ 0.5 gram (adult!)
- 1 FTU covers one hand (front/back)



Body Surface	# of FTUs
Hand (both sides)	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

Long CC, Finley AS: The Fingertip unit—a new practical measure. Clin Exp Dermatol. 1991;16(5):444-447. doi:10.1111/j.1365-2230.1991.tb01232.x

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EXAMPLE CALCULATION

Calcipotriene 0.005% cream
Quantity 240 GM, sig AAA BID (both arms)

- 1 arm = 3 FTU (per chart)
- 3 FTU x 2 = 6 FTU/application
- 6 FTU twice daily = 12 FTU/day
- 12 FTU/day x 0.5 gm/FTU = 6 gm/day
- 240 gm/6 gm/day = 40 ds

If plan limit = 30 ds, then reduce to 120 gm as 20 ds

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3. DAY SUPPLY – INHALERS

- Must submit accurate day supply if possible
- Do not refill early
- Strategies
 - Call PBM helpdesk for day supply override
 - Add note to sig field after patient instructions for use
 - Train staff to watch for refill intervals
- Do not "force" to get paid claim
 - Documentation must support use
 - On prescription itself
 - In pharmacy computer system

Sample Rx #3

John Doe 06-01-2021

Fluticasone propionate 110 mcg HFA Inhaler 12 GM

1 puff BID

5 refills

Dr. Smith

Calculation: 120/2 puffs daily = 60 days

Example sig on Patient dispensing label = "Inhale 1 puff two times daily (60 days)"

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4. DAY SUPPLY – EYE DROPS

- Must submit accurate day supply if possible
- In General
 - 20 drops/mL for solution
 - 15 drop/mL for suspension
- PBMs have their own "estimates"
 - Caremark® 15
 - Express Scripts® 16
 - Optum® 15-20
- Document any patient factors that may impact ability to dose accurately (e.g., Parkinson)

Sample Rx #4

John Doe 06-01-2021

Brimonidine tartrate 0.1% solution 15 mL

One drop OU TID

5 refills

Dr. Smith

Calculation: (Assume patient has Caremark®) 15 mL x 15 drop/mL = 225 drops/6 = 37 or 38 days

*If plan limit = 30 days, then MUST reduce to 10 mL as 25 days

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5. DAW

- NCPDP Field 408-D8
- Values 0-9
- Default should be 0 (zero)
- Do not "force" to get paid claim
- Documentation must support use
 - On prescription itself
 - In pharmacy computer system

Code	Description
0	No Product Selection Indicated
1	Substitution Not Allowed by Prescriber
2	Substitution Allowed – Patient Requested Product Dispensed
8	Substitution Allowed – Generic Drug Not Available in Marketplace
9	Substitution Allowed By Prescriber but Plan Requests Brand

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6. CONTROLLED SUBSTANCE RX

Federal Law

3 elements as per 21 CFR 1306.05(a)

- Patient Address
- MD Address
- DEA number

State Law(s)

- NM – All CS Rx valid x 6 months
- Part D Opioid Restrictions

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

<https://www.dea.gov/press-releases/2016/01/13/2016-01-13-0020.html>

Sample Rx #5

John Doe, Jr. (DOB 1/1/1973) 06-01-2021

123 Main Street, St. Louis, MO

Buprenorphine/naloxone 8/2 mg film #20 (twenty)

1 film sublingual BID

0 refills

Dr. Smith

555 Second Street, St. Louis, MO

AB1234567 X81234567

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7. ELECTRONIC RX

Quantity

- "1" = smallest package size
- Unit of Measure "unspecified"

DAW

- DAW field vs. Sig field vs. free text field
- Erroneous – generic drug or brand with no generic approved

Day Supply


- Does DS field conflict with quantity/sig calculation?

Invalid eRxs

- Failover to Fax (not a valid eRx)
- Email

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8. TRANSFER RX




- 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
- State Specific:
 - NM Rule 14.19.4.23(D)
- Suggest using a dedicated transfer Rx pad with all required elements
- Data Entry – original date vs. transfer date


<http://164.66.110.134/parts/ide/16/16.0/19.0206.html>

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9. COMPOUND RX




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



Level of Effort codes 11-15
Be careful with defaults
Each PBM has a different definition

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10(A) PROOF OF DISPENSING

Retail/PBM

- Elements
 1. Rx #
 2. Date dispensed
 3. Signature of Patient/Representative*
- **Exceptions during COVID as previously noted**
- Outside of COVID pandemic, placeholders such as "mail" or "drive-thru" are NOT sufficient

DMEPOS

Elements (in-person)

1. Beneficiary's name
2. Delivery address
3. Description of item
4. Quantity delivered
5. Date delivered
6. Beneficiary (or designee) signature

- Retail/PBM signature log is NOT SUFFICIENT!
- Date delivered must match billing date (cannot hold in will-call bins)

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10(B) COPAY COLLECTION PEARLS

- **Contracts require collection WITH PROOF (limited exceptions)**
- Copayments are used to sensitize patients to the cost of their medications
- Documentation
 - Copies of checks (front & back)
 - Credit card receipts (with last 4 digits) or merchant account reporting
 - Bank slips showing cash deposited
 - Screenshots of secondary payers (insurance or coupons)
- House Charge Accounts
 - Written Policies & Procedures
 - Timely invoicing
 - Documented efforts to collect (phone calls, monthly statements)
- Hardship Waivers
 - Written Policies & Procedures
 - Objective evidence to qualify (tax returns)
 - Must NOT be advertised
- Manufacturer Coupons
 - Medicaid/Medicare/TRICARE prohibited
 - Capmax/Provider Manual limits
 - Non-FDA approved
 - Dietary Supplements
 - Medical Devices

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SPEAKER CONTACT INFORMATION

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