PHARMACISTS DON'T LOOK GOOD IN ORANGE:

HOW TO AVOID BECOMING A TARGET OF DOJ, DEA, & STATE REGULATORS

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KPhA works with the Kentucky Pharmacy Education and Research Foundation, Inc. to certify its courses. KPERF is accredited by ACPE as a provider of continuing pharmacy education.

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DISCLOSURES

Faculty

Matthew Agnew, faculty for this activity, has no relevant financial relationship(s) with ineligible companies to disclose.

How We Will Talk About Enforcement

Complaints and indictments are allegations. Settlements are not automatically admissions. Board orders and convictions mean something different. The status of the source matters.

Planners

None of the planners for this activity have any relevant financial relationships with ineligible companies to disclose.

PHARMACIST OBJECTIVES:

- Identify at least five current federal and state enforcement risk areas (including controlled substance dispensing, documentation, and compliance failures) and explain how they arise in daily practice.
- Recognize and document at least three specific red flags that commonly trigger DEA, DOJ, or Board investigations.
- Implement at least two operational or documentation changes to reduce regulatory risk within their pharmacy setting.
- Determine when legal counsel should be engaged by applying a three-step framework to real-world enforcement scenarios.

TECHNICIAN OBJECTIVES:

- Identify at least three common compliance and documentation errors that contribute to enforcement actions.
- Recognize at least three red flag scenarios related to controlled substances or prescription processing and appropriately escalate concerns.
- Demonstrate proper documentation practices in at least two high-risk workflows (e.g., controlled substances, refill processing).
- Apply a clear reporting protocol for compliance concerns to pharmacists or supervisors in accordance with workplace policy.

Objectives and flight plan

Identify
Federal and State of Kansas enforcement pathways

Explain
What Neumann changes and what it does not

Analyze
Facts and records that increase or reduce risk

Apply
An escalation protocol when contact occurs

15 min — Federal enforcement

15 min — DEA and Neumann

30 min — Kansas risk & response

It is 8:03 Monday morning.

Four problems arrive at once. Which one worries you most?

- A payer wants pickup and prescriber records
- The Kansas Board is at the front counter
- Your wholesaler asks about an ordering spike
- A DEA investigator asks for the pharmacist-in-charge

Active Learning
Vote now.

Turn to a neighbor: Why did you pick that one?

We will vote again before Q&A.

Orange starts gray

1 Anomaly
Outlier, complaint, missing record, discrepancy

2 Question
Audit, inspection, wholesaler, DEA, Board

3 Response
Records, interviews, explanations, corrections

4 Exposure
Civil, licensing, exclusion, DEA, criminal

The response often multiplies or reduces the risk.

A missing record is usually not the same problem as a recreated, backdated, deleted, or overconfident record.

PART I

Federal enforcement

Data sees what you miss.

The claim, record, product, and response must all tell the same story.

The government has a dashboard. Do you?

455
Defendants charged in the 2026 National Health Care Fraud Takedown

$6.5B+
Alleged false claims in that coordinated action

1,403
CMS billing-privilege revocations announced with the takedown

928
DEA administrative cases since Oct. 1, 2025

The point for an independent pharmacy

You may see one patient, one fill, one reversal, or one spreadsheet. The government may see claim volume, prescriber concentration, cash patterns, acquisition gaps, ordering spikes, and outlier behavior across markets.

The audit response can become the crime

Missing record

Compliance problem

- Preserve originals
- Find reliable source records
- Document what you know and do not know
- Centralize the response

Fabricated record

Integrity problem

- Do not backdate
- Do not delete or overwrite
- Do not certify what you cannot prove
- Do not let staff improvise

Case lesson:

A pharmacy owner and technician were sentenced in 2026 after false audit documents and pickup records were submitted to benefit programs.

Purchased. Dispensed. Billed. Collected.

The claim must match the real transaction.

Acquisition
Can acquisition records support the volume billed?

Dispensing
Can you prove the medication actually left the pharmacy?

Claim
Did the product, quantity, and price match the claim?

Payment
Were patient obligations handled under a lawful policy?

Federal cases keep returning to the same evidentiary chain: acquisition > dispensing > claim > payment.

The GLP-1 shortage ended. The enforcement tail did not.

What changed
Shortage-based discretion for semaglutide and tirzepatide copies has ended under FDA policy.

What remains possible
Patient-specific 503A compounding may still exist when the statutory conditions are actually met.

What is dangerous
Marketing as same-as, generic, FDA-approved, or clinically proven equivalent can draw FDA attention.

Owner question:

Who approved the words on your website, prescriber scripts, labels, social posts, and vendor landing pages for GLP-1s?

PART II

DEA & Controlled Substances

Red flags are evidence. So is your response.

DEA does not see one prescription. It sees a pattern.

Drug mix
Opioids, benzos, stimulants, combinations

Payment
Cash, inflated price, unusual discounting

Geography
Distance traveled, prescriber clusters

Volume
Outlier orders, high-strength products

History
Warnings, prior inspections, repeated conduct

Question for the room: If the DEA walked into your pharmacy tomorrow and asked for one report from your computer system, which report would make you the most nervous?

Neumann: uncomfortable facts, important law

The facts included
Opioid/benzodiazepine combinations
Cash payment patterns
Distance and prescriber concerns
Related prescriber / self-filling issues
Limited documentation of some conversations

DEA action
DEA revoked the pharmacy registration after finding red-flag and usual-course violations.

Fifth Circuit
Vacated and remanded. The legal theory mattered.

The case is powerful precisely because the facts were not comfortable.

What Neumann actually held

Section 1306.04(a)
A pharmacist violates the regulation only if the pharmacist fills an invalid prescription knowingly.

DEA theory rejected
The court rejected substituting an objective knows-or-has-reason-to-know formulation for the regulation.

Willful blindness
Possible, but it requires subjective belief of a high probability plus deliberate avoidance.

Binding in the Fifth Circuit. Persuasive elsewhere. Not a Kansas or Tenth Circuit holding.

What Neumann did not hold

- It did not repeal corresponding responsibility.
- It did not make unresolved red flags safe.
- It did not make a generic prescriber call a shield.
- It did not bind Kansas or the Tenth Circuit.
- It did not prevent DEA from proving actual knowledge or willful blindness.

Case study: fill, pause, refuse, or call?

Scenario

Patient presents opioid and benzodiazepine prescriptions from a clinic 90 miles away. The patient pays cash for controlled substances but uses insurance for maintenance drugs. The prescriber sends several similar patients. The office says only: "The doctor knows the patient and says it is medically necessary."

Table task

1. What facts require verification?
2. What would you ask the prescriber?
3. What would a useful note contain?
4. Which fact would change your decision?

Debrief: A call is not the same as a resolution.

Your note is a time machine

Signal	Steps	Sources	Specific facts	Decision
What triggered concern?	What did you do?	Who or what did you consult?	What resolved or intensified the concern?	What did you decide and why?

"Verified with MD" is not a time machine.

Someone is at the counter. First identify the paper.

Consent / notice
Do not sign or consent without knowing scope.

Administrative warrant
Do not obstruct. Identify scope and inventory process.

Criminal search warrant
Do not obstruct. Notify designated leaders and counsel.

Subpoena / records request
Preserve, calendar, review, produce carefully.

Board inspection
Cooperate within lawful authority; document requests.

Do not obstruct lawful process. Do not expand it through panic.

The first 30 minutes: calm, contain, preserve

1. Request credentials and the authorizing document.
2. Notify PIC, owner, and designated counsel.
3. Do not delay or obstruct lawful authority.
4. Preserve records. Do not delete, revise, or backdate.
5. Assign an escort and a contemporaneous log.

Staff script: "Let me get the pharmacist-in-charge and the person designated to receive legal or regulatory documents."

Federal heat map: the cases change; the story repeats

Healthcare fraud, kickbacks, false records, and FDA marketing cases turn pharmacy operations into evidence.

BILLED, NOT DISPENSED	**$13M fraud conspiracy**	Four pharmacist-owners were sentenced after trial evidence showed pharmacies billed Medicare, Medicaid, and private insurance for drugs not dispensed.	SENTENCED DOJ 2025
AUDIT FILE "FIXED"	**False pickup records**	A pharmacy owner and technician received prison sentences after fabricated prescriber authorizations and pickup records were submitted in response to an audit.	SENTENCED DOJ 2026
PRESCRIPTIONS BOUGHT	**$110M kickback case**	A pharmacist admitted paying marketers tied to prescribers and clinics to steer expensive compounded-drug prescriptions to his pharmacy.	GUILTY PLEA DOJ 2025
COMPOUNDING MARKETS	**GLP-1 claims targeted**	FDA warned 30 telehealth companies over allegedly false or misleading claims about compounded GLP-1 products, including "same as" or "generic" messaging.	WARNINGS FDA 2026

Recurring federal theme: repeated profit + mismatched records + an explanation that does not survive the data.

The clearest cases are the ones the data can tell without you

Not a formal DOJ ranking; this is a practical reading of repeated public pharmacy cases and 2025/2026 enforcement priorities.

	MOST REPEATED CRIMINAL / CIVIL NARRATIVES	WHY THEY MOVE
1	**False claims: billed but not purchased, dispensed, received, or medically needed**	WHY IT IS EASY TO BUILD: Claims, wholesaler purchases, inventory, pickup records, reversals, and payment records can be electronically compared.
2	**Kickbacks and steering: prescriptions purchased through marketers, clinics, or prescribers**	WHY IT IS EASY TO BUILD: Bank records, contracts, texts, referral volume, and claim mix can show motive and the value of the relationship.
3	**False records: audit packets, authorizations, pickup logs, and retroactive documentation**	WHY IT IS EASY TO BUILD: The original record, metadata, emails, and witness testimony often reveal when the file was "completed" after the fact.
4	**FDA / FDCA risk: compounded products marketed as equivalent, approved, generic, or source-verified**	WHY IT IS EASY TO BUILD: Website screenshots, ads, call scripts, social media, labels, and vendor material are easy to preserve and quote.

Active learning prompt: Which packet would you least want copied into an indictment: claims, inventory, pickup, texts, or marketing?

The prosecution shortcut: "The pharmacy said X. The records say Y."

The controlled-substance cases are pattern cases

DEA and DOJ do not only ask what happened once. They ask what the pharmacy kept doing after the warning signs appeared.

CIVIL CSA + FCA	**Walgreens settlement**	Up to $350M to resolve allegations that millions of invalid opioid and controlled-substance prescriptions were filled and billed to federal programs.	ALLEGED / SETTLED DOJ 2025
OXYCODONE PATTERN	**335,351 oxycodone 30 mg pills**	Florida pharmacist convicted after evidence of cash-only dispensing, roughly 10x pricing, and customers with no medical need.	CONVICTED DOJ 2026
GHOST PHARMACY	**2.26M+ opioid pills**	Houston owner/PIC sentenced to 19 years after pharmacy operated as a bulk opioid source without real prescriptions or patients.	SENTENCED DOJ 2025
INSIDER DIVERSION	**Fake patients + hidden inventory**	Recent pharmacist cases include fake patient profiles, self-diversion, missing inventory, and controlled substances acquired by deception.	SENTENCED DOJ 2025/26

DEA danger signs become powerful when they repeat: volume, cash, distance, prescriber clusters, missing records, and prior warnings.

Most visible target: the pharmacy that stops acting like a gatekeeper

The theory usually becomes simple: the pharmacy knew, avoided knowing, or kept dispensing after the pattern was obvious.

MOST REPEATED CSA TARGETS	WHY DEA / DOJ CAN EXPLAIN THEM
1 **Dispensing outside legitimate medical purpose / usual course**	WHY IT IS EASY TO BUILD Pattern evidence: drug combinations, early fills, prescriber concentration, distance traveled, dose, cash, and repeated overrides.
2 **Diversion by pharmacist, technician, owner, or employee**	WHY IT IS EASY TO BUILD Inventory, ordering, access logs, cameras, fake patient profiles, collection-bin records, and internal witness accounts.
3 **Record manipulation or failure to report controlled-substance activity**	WHY IT IS EASY TO BUILD PMP/K-TRACS submissions, ARCOS data, invoices, inventories, loss reports, and "readily retrievable" records can be cross-checked.
4 **Online / telemedicine dispensing without valid prescriptions**	WHY IT IS EASY TO BUILD DEA can tell a public-safety story: a closed distribution system was bypassed and drugs moved without a legitimate prescription.

Think-pair-share: What pattern report would you least want to see for the first time as a government exhibit?

Controlled-substance cases are usually not about one red flag. They are about unresolved red flags that became a business model.

PART III

Kansas Enforcement

It becomes real when it is public, reportable, or on the clock.

A Kansas complaint can become a searchable career event

Who can start it?

Anyone. Patients, employers, law enforcement, media, other regulators, and health professionals may be sources.

What is collected?

Medical records, personnel records, agency records, other-state discipline, interviews, and statements.

When public?

Complaints and investigations are not public, but effective formal discipline is posted and reported to NABP.

Operational lesson: Treat every Board letter as a deadline, a record-preservation event, and a potential public-record event.

Inspection findings are easier to find

What changed

Kansas posts pharmacy inspection reports online. Reports are updated weekly and certified by the Board as primary-source verification.

What it is not

A "needs improvement" or "non-compliant" finding does not itself constitute disciplinary action.

What to do

Correct promptly. Preserve proof. Confirm the public record and internal corrective action tell the same story.

Public does not always mean discipline. But it does mean visible.

The small checkbox can become a large exhibit

Application history

Board compares answers to KBI/FBI reports. Contradictions may be treated as an attempt to obtain a license by fraudulent means.

CE proof

Pharmacists need 30 hours and technicians need 20 hours each renewal period. Proof may be required in audit.

Record retention

CE records used for renewal must be kept up to five years.

Do not let renewals become memory tests.

Move first and register later? Kansas says no.

Sleeptopia example

A facility moved to a new address before obtaining updated registration. The Board concluded it operated from the new address without a valid registration and imposed a $1,000 fine.

Owner lesson

Leases, moves, acquisitions, nonresident shipments, wholesalers, and facility changes need regulatory change control before operations begin.

The application being in process is not the same as authorization to operate.

One employee can create four exposures

Employee

Criminal, licensing, employment

PIC / owner

Supervision, security, reporting

Facility

Inventory, records, permit discipline

DEA / Board

One-day and one-business-day clocks

Kansas examples

Recent District of Kansas indictments alleged diversion by a pharmacy technician and by a pharmacist. Indictments are allegations, not proof.

The Kansas clock is measured in days

1 day

Kansas notice of suspected diversion, theft, or loss of any controlled substance

1 business day

DEA notice of theft or significant loss; Form 106 due within 45 days

5 / 30 days

Outgoing PIC notice; owner must secure incoming PIC within 30 days

2 days

PIC controlled substances and drugs-of-concern inventory windows

15 days

Summary Order hearing request must be received by the Board

Fix it internally, investigate it, or call now?

GREEN: Correct and trend

Isolated error
Complete records
No reporting deadline
No serious patient harm

YELLOW: Preserve and investigate

Repeated discrepancy
Unclear facts
Payer, wholesaler, or Board inquiry
Possible pattern

RED: Call now

Warrant or subpoena
DEA or DOJ contact
Suspected diversion
Altered records
License, registration, exclusion, or criminal risk

Build the file you would want to defend

Controlled substances
Inventories, red flags, K-TRACS, losses

Claims integrity
Purchase, dispense, pickup, reversal, price

People and governance
PIC, tech scope, training, CE, attestations

Products and compounding
Source, patient-specific basis, labels, marketing

Response and improvement
Incident, CQI, audit, corrective-action proof

A policy is useful. Evidence that it was followed is better.

Local enforcement is operational before it is dramatic

Kansas examples often start with a form, a report, an inspection, a registration, or an inventory question.

INSPECTION RECORDS **Dandurand Drugstore**	Board order described missing CQI / incident records, later-produced CQI forms, falsified/backdated documents, and a $3,000 administrative fine.	FINAL ORDER KS 25-221
CE ATTESTATION **Melanie Ables**	Renewal attestation said required CE was complete; audit showed 10.25 of 20 hours. Board ordered a fine and 19.5 penalty hours.	SUMMARY ORDER KS 26-009
INSIDER DIVERSION **Technician / pharmacist indictments**	Kansas federal cases in 2026 alleged unauthorized acquisition of Adderall, Ritalin, Vyvanse, and oxycodone by pharmacy personnel.	ALLEGED DOJ-KS 2026
PUBLIC VISIBILITY **Inspection reports online**	Since July 2026, Kansas pharmacy inspection reports are posted online and updated weekly; "needs improvement" is not discipline but is visible.	PUBLIC DATA KSBOP 2026

Kansas risk is local, searchable, and practical: if the record should exist, assume someone may ask for it.

The easiest Board case to build is often the one with a missing or false record

Not a formal ranking; this is a practical compliance read of Kansas Board pages, public inspection reports, and recent orders.

VISIBLE KANSAS ENFORCEMENT THEMES	WHY OWNERS / PICs SHOULD CARE
1 **Registration and change-control failures: location, facility, ownership, PIC, wholesale / nonresident activity**	WHY IT IS EASY TO BUILD The Board can compare business activity, shipping, location, license status, and public registration records.
2 **Inspection readiness: CQI, incident reports, readily retrievable records, inventories, and K-TRACS submissions**	WHY IT IS EASY TO BUILD The question is not "do we usually comply?" It is "can we produce the required record when asked?"
3 **Individual accountability: CE, renewal answers, criminal history, diversion, impairment, and technician supervision**	WHY IT IS EASY TO BUILD Applications and renewals are sworn/attested operational evidence; audits expose shortcuts quickly.
4 **Loss/diversion reporting and controlled-substance discrepancies**	WHY IT IS EASY TO BUILD Kansas Board and DEA clocks can start before management has finished debating what happened.

Monday test: Can you name the person responsible for each deadline and the backup if that person is gone?

Kansas defense posture: preserve the record, verify the facts, correct the process, and escalate before the response becomes the violation.

Monday morning, before lunch

- Run a 90-day controlled-substance outlier report.
- Reconcile ten high-risk products from purchase through payment.
- Test three red-flag notes against the five-field framework.
- Confirm reporting, PIC, CE, incident, and inspection deadlines.
- Review compounded-product sourcing and marketing language.
- Run the front-counter government-arrival drill.
- Pick one weakness, assign an owner, and preserve proof of correction.

Closing idea: The goal is not perfect hindsight.

It is a system that notices, pauses, preserves, verifies, documents, reports, and learns.

POST-TEST 1

1. During an audit response, which action most increases enforcement risk?

A. Preserving original records

B. Transparently reconstructing from reliable sources

C. Backdating a prescriber authorization

D. Identifying who owns the response

POST-TEST 1 - ANSWER

1. During an audit response, which action most increases enforcement risk?

A. Preserving original records

B. Transparently reconstructing from reliable sources

C. **Backdating a prescriber authorization**

D. Identifying who owns the response

POST-TEST 2

2. Which is the best description of Neumann?

A. Red flags no longer matter

B. A prescriber call always cures the concern

C. DEA must apply the text of its regulations, including invalidity and knowledge under Section 1306.04(a)

D. The decision binds Kansas courts

POST-TEST 2 - ANSWER

2. Which is the best description of Neumann?

- **A.** Red flags no longer matter
- **B.** A prescriber call always cures the concern
- **C.** **DEA must apply the text of its regulations, including invalidity and knowledge under Section 1306.04(a)**
- **D.** The decision binds Kansas courts

POST-TEST 3

3. A Kansas pharmacy suspects diversion, theft, or loss of a controlled substance. What is the safest first clock to identify?

- **A.** One day to notify the Kansas Board; one business day to DEA for theft or significant loss
- **B.** Thirty days after completing the investigation
- **C.** At the next license renewal
- **D.** Only after criminal charges are filed

POST-TEST 3 - ANSWER

3. A Kansas pharmacy suspects diversion, theft, or loss of a controlled substance. What is the safest first clock to identify?

- **A.** **One day to notify the Kansas Board; one business day to DEA for theft or significant loss**
- **B.** Thirty days after completing the investigation
- **C.** At the next license renewal
- **D.** Only after criminal charges are filed

POST-TEST 4

4. When an investigator, inspector, or agent arrives, what is the best first-response posture?

- **A.** Refuse all cooperation
- **B.** Answer everything from memory so it goes faster
- **C.** Identify the authority, notify the designated leaders, preserve records, and do not obstruct lawful process
- **D.** Fix incomplete records before anyone sees them

POST-TEST 4 - ANSWER

4. When an investigator, inspector, or agent arrives, what is the best first-response posture?

A. Refuse all cooperation

B. Answer everything from memory so it goes faster

C. Identify the authority, notify the designated leaders, preserve records, and do not obstruct lawful process

D. Fix incomplete records before anyone sees them

References

- Neumann Pharmacy v. DEA, No. 25-60068 (5th Cir. Feb. 13, 2026)
- 21 C.F.R. 1306.04(a); 21 C.F.R. 1306.06; 21 U.S.C. 880; 21 C.F.R. 1301.76(b)
- DOJ, 2026 National Health Care Fraud Takedown, June 23, 2026
- DOJ, Pharmacy Owner and Technician Sentenced, July 14, 2026
- DOJ, Florida Pharmacist Convicted, July 22, 2026
- FDA, GLP-1 compounding policy updates and telehealth warning letters
- Kansas Board of Pharmacy FAQs
- Kansas Board Individual Disciplinary Actions
- Kansas Board Facility Disciplinary Actions
- Kansas Board Inspection Reports
- K.A.R. 68-20-15b; K.A.R. 68-1-9
- Kansas Board, Sleeptopia Inc., Case No. 26-012

Full source links are included in speaker notes for the related slides.

THANK YOU!

Questions?

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