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How to Respond to DEA and PBM Investigations and Audits

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Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

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Pharmacist and Technician Learning Objectives

1. Discuss best practices for implementing a robust compliance program.
2. List strategies to pivot a DEA or PBM investigation or audit into a “win-win” scenario.
3. Discuss how to structure a settlement.

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Avoiding DEA Inspections

- The DEA is authorized to "inspect the establishment of a registrant" as part of its regulatory oversight authority. 21 U.S.C. § 822(f).
- In implementing this authority for distributors of Schedule II-V controlled substances, the DEA has determined that the registrants "shall be inspected as circumstances may require…" 21 C.F.R. § 1316.13.

So, the key to avoiding a DEA inspection, is to **eliminate circumstances that might trigger an inspection**.

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Avoiding DEA Inspections

Then what circumstances can generate DEA scrutiny?

- Reports of theft/diversion
- Unusual or worrying dispensing history
- Tips of non-compliance
- Random inspections to ensure compliance

With the exception of periodic random inspections, DEA investigations are almost always the result of some specific compliance concern.

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Avoiding PBM Audits

- Unfortunately, PBM audits cannot be avoided.
- While a pharmacy may be able to limit the frequency and scope of PBM audits, PBMs will periodically audit the pharmacy's claims.

Mindset in Responding to a PBM Audit

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Mindset in Responding to a PBM Audit

- The pharmacy's approach should be "Let's solve the problem" as opposed to being defensive and attempting to win an argument. This approach is necessitated by the following:

  There is an old saying:

  "*Possession is 9/10ths of the law.*" At the end of the day, the PBM possesses the pharmacy's money. Regardless of whether the PBM is right or wrong, if it refuses to pay the pharmacy for new claims or recoups money previously paid to the pharmacy, the pharmacy will financially suffer.

Mindset in Responding to a PBM Audit

- Possessing the pharmacy's money places the PBM in a superior negotiating possession.
- The PBM has more money than the pharmacy and, as such, is better able to afford to "lawyer up."
- The PBM can terminate the pharmacy contract without cause. Thus, if the pharmacy engages in an overly-aggressive approach with the PBM, there is a risk that the PBM will exercise its termination right.

Involving A Health Care Attorney

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Role of Health Care Counsel in a PBM Audit

Why is it Important?

- It is important that, at the outset, the pharmacy hire a health care attorney who has experience in responding to PBM audits. It will do the pharmacy no good and will probably cause harm if the pharmacy hires an attorney with no experience in dealing with PBMs.
- The health care attorney can:
  - assist the pharmacy in organizing an effective response to the audit and
  - work with the pharmacy to avoid costly mistakes

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Role of Health Care Counsel in a PBM Audit

Working together, the pharmacy and its health care attorney have three goals:

1. Work with the pharmacy to ensure that it submits an effective audit response.
2. Avoid the scenario in which the PBM concludes that the pharmacy has committed fraud and, therefore, the PBM turns its documents over to the U.S. Department of Justice and/or the state's Attorney General's Office.

Role of Health Care Counsel in a PBM Audit

3. Avoid an extrapolated audit. An extrapolation occurs when the PBM reviews what it believes is a statistically valid sample of patient files and determines that x% of the reviewed files are deficient. At that point, the PBM will “extrapolate” by applying that percentage to all of the pharmacy’s files pertaining to the product made the subject of the PBM audit. This can result in a relatively small dollar-for-dollar overpayment becoming a very large overpayment.

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Determining What the PBM is Focusing On

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Identifying What the PBM is Focused On

Understanding what the PBM is focused on will help the pharmacy strategically respond to the audit.

- Hopefully, the pharmacy can determine from the PBM letter what it is that the PBM is focusing on.
- If the pharmacy cannot determine what the PBM is focusing on, the pharmacy should contact the PBM with the goal of making this determination.
- The PBM may be forthcoming. But there will be occasions when the PBM simply says: “We don’t have to tell you that. You just need to send us the documents we have asked for.” In this instance, all the pharmacy can do is make an educated guess.

Identifying What the PBM is Focused On

- In the past, the PBM's primary focus was on whether the pharmacy
  - received a valid prescription,
  - dispensed the drug in accordance with the prescription, and
  - submitted the claim for exactly what was dispensed.
- This type of inquiry was in line with what most pharmacies believe an audit should be (i.e., whether the pharmacy's documents are correct).

Identifying What the PBM is focused On

However, recently PBM audits resemble investigations more than they resemble documentation audits.

- The audit may request the pharmacy's documentation to determine if the pharmacy received a valid prescription, dispensed the drug in accordance with the prescription, and billed for exactly what was dispensed.

Identifying What the PBM is Focused On

- But most audits will go beyond basic documentation questions and ask for documentation/information designed to allow the PBM to determine if the pharmacy
    - Is in compliance with the terms of the PBM contract and collateral documents (e.g., PBM policies and procedures) incorporated by reference in the PBM contract and
    - Is engaged in fraudulent activities.

Identifying What the PBM is Focused On

- Remember, while understanding the initial focus of the audit is valuable, the scope of an audit can expand and change as the audit takes place.
- The pharmacy should not neglect issues that it considers to be secondary or less important, as that could result in additional problems.
- The pharmacy should respond to the audit as well as it can, and not be afraid to ask for clarification or additional guidance.

Compliance with Contract

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Key Issues to Pay Attention to: Collateral Documents

The pharmacy's contract with the PBM contains several obligations that the pharmacy must meet. Such obligations are found in the contact itself. But in addition, the contract will likely contain a clause that says something like the following:

- "Pharmacy agrees to abide by the provisions of PBM's policies and procedures including PBM's coverage policies."
  - These "collateral documents" are as much a part of the contract as the wording contained in the contract itself.

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Key Issues to Pay Attention to: Mail Order

- Most in-network pharmacies are in the PBM's retail network, not in the PBM's mail-order network.
- The contract between a PBM and a retail pharmacy will likely contain one of the following provisions:
  - Pharmacy will not ship drugs via mail-order.
  - Not more than __% of pharmacy's dispensed drugs will be via mail-order.
  - Not more than __% of pharmacy's gross annual revenue will be derived from mail-order.

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Mail Order

To investigate this issue, the PBM may ask one or more of the following questions:

- Does your pharmacy fill prescription claims under multiple NCPDPs?
- Does your pharmacy hold a license in more than one state?
- Is your pharmacy a retail walk-in pharmacy that services the general public?
- Is your pharmacy a closed-door pharmacy?
- Is 25% or more of your pharmacy business mail order?

Mail Order

- Is your pharmacy licensed to fill prescriptions for Medicare Part D long term care providers in multiple states?
- Is your pharmacy open for walk-in service 24 hours a day?
- Does your pharmacy offer emergency prescription services after hours?
- Does your pharmacy have a drive-through?
- Does your pharmacy offer a delivery service?

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Mail Order

- Is your pharmacy less than or equal to ¼ mile walking distance from public transportation?
- Is your pharmacy accessible by public transportation that charges set fares, runs on fixed routes, and is available to the public?
- Does your pharmacy offer patient consultation?
- Indicate the percentage of Rx volume in each of the following settings: Open Door/Retail/Community __%; Closed Door/Clinic Facility __%; Mail Order __%; Nursing Home/LTC __%; Internet Pharmacy __%; Other __%

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Mail Order

- Does the owner/pharmacist-in-charge currently hold any non-resident state licenses? If so, please submit a copy.
- Does your pharmacy deliver prescriptions to out-of-state customers? If yes, identify states where your pharmacy serves customers and provide out-of-state pharmacy licenses.

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Key Issues to Pay Attention to: Compounding

- PBM contracts and the collateral documents typically include very specific limits and requirements for pharmacy compounding.
- In order to determine if the pharmacy is engaged in prohibited compounding, the questions posed by the PBM in the audit may include one or more of the following:
  - Does your pharmacy participate in complex compounding?
  - Is your pharmacy registered/affiliated with a compounding supplier?

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Compounding

- Does your pharmacy have a dedicated lab/area for compounding?
- Does your pharmacy have dedicated technicians for compounding only?
- Does your pharmacy have any of the following compound equipment: unguator, hot plate, homogenizer, ointment mill, tube sealer, capsule filling system?
- Does your pharmacy anticipate filling more than 10% of retail claims as non-sterile compounds?

Compounding

- What types of compounds does your pharmacy make or anticipate making: topical analgesics, hormone replacement therapy, sterile compounds, scar cream, other?
- Indicate the percentage income derived from: Medicaid __%; Medicare __%; Workers Comp __%; 340B __%; Compounds __%; Dispensing Physician __%
- Does your pharmacy provide sterile compounding medications? If yes, please provide the most current certification document (e.g., PCAB, air flow hood/HEPA filtration, etc.).

Compounding

- Does your pharmacy provide compound product samples to physicians?
- Does your pharmacy provide compounding services for or through any other entities (i.e., providing compounding services through other pharmacies or directly to physicians for dispensing)?
- Does your pharmacy compound investigational/non-FDA approved compounds?
- Does your pharmacy provide sterile compounding medications? If yes, please provide the most current certification document (e.g., PCAB, air flow hood/HEPA filtration, etc.).

Key Issues to Pay Attention to: Collection of Copayment

- As it pertains to federal health care program (“FHCP”) patients, federal law requires a pharmacy to make a reasonable attempt to collect copayments and to reduce/waive a copayment on a patient-by-patient basis only if the patient establishes an inability to pay all or a portion of the copayment.
- If a pharmacy routinely reduces or waives copayments for FHCP patients, the pharmacy will likely violate the federal anti-kickback statute (“AKS”) and the federal beneficiary inducement statute.
- Most states have similar laws that apply to commercial insurance patients.

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Collection of Copayment

- A number of PBM contracts have a provision that requires a pharmacy to make a reasonable attempt to collect copayments and to reduce/waive a copayment on a patient-by-patient basis only if the patient establishes an inability to pay all or a portion of the copayment.
- Also, PBMs may restrict the circumstances in which copayments may be waived, where coupons can be applied, or other similar copayment assistance programs can be used. Failure to comply with these requirements can result in recoupment or termination.

Key Issues to Pay Attention to: Marketing

- The AKS makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person or entity to refer an individual for the furnishing or arranging for the furnishing of any item or service reimbursable by an FHCP, or to induce such person to purchase or lease or recommend the purchase or lease of any item or service reimbursable by an FHCP.
- If a pharmacy pays commissions to 1099 independent contractor marketing reps in exchange for the generation of FHCP patients, then the pharmacy likely violates the AKS.

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Marketing

- On the other hand, if a W-2 employee marketing rep generates FHCP patients for the pharmacy, and if the pharmacy pays discretionary bonuses to the employee that are based, in part, on the generation of FHCP patients, then the risk of violating the AKS is low. This is because of the employee exception and safe harbor to the AKS.
- In order to determine if the pharmacy is engaged in prohibited marketing practices, in an audit the PBM may ask the following questions:
  - Does your pharmacy use individual marketing reps to market your pharmacy's products and services?

Marketing

- If the answer to the preceding question is “yes,” are the marketing reps W-2 employees or 1099 independent contractors?
- If your pharmacy uses individual 1099 independent contractor marketing reps, how are the reps compensated?
- Does your pharmacy contract with marketing companies? If so, list their names and explain how the marketing companies are compensated.

Key Issues to Pay Attention to: Affiliated Pharmacies

- There is a saying in Western lore: “That cowboy is trying to stay one step ahead of the posse.”
- Some pharmacies have taken that saying and have applied it to how they conduct business. For example:
  - John Smith owns ABC Pharmacy.
  - Smith is aware that a PBM will likely terminate ABC’s contract.
  - So, Smith will open up XYZ Pharmacy, XYZ will secure a contract with the same PBM, and ABC will transfer its patients to XYZ.

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Affiliated Pharmacies

With the goal of uncovering this type of scheme, in an audit, the PGM may ask the following questions:

- Is your pharmacy directly or indirectly affiliated with any other pharmacies?
- List the identity of any person who has a direct or indirect ownership interest in your pharmacy.
- Do any of the pharmacy owners have a direct or indirect ownership interest in any other pharmacy?
- Have any of the owners, members, principals, officers or directors of your pharmacy owned any other pharmacies? If yes, please attach a list of the pharmacies, their NCPDP numbers, and the names of the owners, entity members, principals, officers and directors.

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Affiliated Pharmacies

- Has your pharmacy ever changed names? If yes, please attach a list of the previous names, NCPDP numbers, if different, and the dates of the name changes.

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Key Issues to Pay Attention to: Disciplinary Actions

- With many audits, PBMs want to determine if the pharmacy has had problems with government regulatory agencies. If the PBM determines that such problems do exist, the PBM may not want the pharmacy in its network.
- With the goal of discovering disciplinary actions, in an audit the PBM may ask the following questions:
  - Have any of your pharmacists, pharmacy technicians, owners or employees been disciplined by the State Board of Pharmacy, a government entity, or any other regulatory authority (i.e., State or Federal DEA or State Medicaid Program) in the last 10 years?

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Disciplinary Actions

- Has your pharmacy (or another pharmacy affiliated with your pharmacy) been disciplined by a State Board of Pharmacy, government entity or any other regulatory authority (i.e., State or Federal DEA or State Medicaid Program)? If yes, please attach explanation of action taken, Board order or letter, and any other supporting documents from the State Board of Pharmacy, government entity, or other regulatory authority.
- Presently, or at any time in the last 10 years, has your pharmacy, its owners, principals, or any of your pharmacists been the subject of a civil lawsuit or criminal prosecution involving fraud, deception, or a similar offense involving moral turpitude?

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Review, Organize, and Rehabilitate

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Review the Files to be Submitted

- The pharmacy needs to carefully review each document to be submitted. In doing so, the pharmacy needs to determine if the document complies with PBM coverage guidelines. These guidelines can be found in the pharmacy's contract with the PBM and in collateral documents that are incorporated by reference in the contract.
- It is human nature for the pharmacy not to be objective as it reviews its patient files. As such, it is wise for the pharmacy to have a health care attorney or a consultant review the patient files.

Review the Files to be Submitted

If the pharmacy desires to hire a consultant to review patient files, but the pharmacy is concerned that the consultant will find serious problems with the files, and if the pharmacy is further concerned that the consultant's work and findings are not protected by the attorney-client privilege, then the pharmacy may want to take the following steps:

1. The pharmacy will hire an attorney to review the documents and assist the pharmacy in responding to the audit.

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Review the Files to be Submitted

2. The attorney will, in turn, hire the consultant. The consultant will work for the attorney, not for the pharmacy. Assuming that the attorney and pharmacy take the proper steps to protect the attorney-client privilege, the consultant's findings do not have to be disclosed unless the pharmacy decides to disclose such findings.

3. Normally, the pharmacy will not have a problem with the consultant's findings being disclosed to the PBM. However, in the event that the consultant finds evidence of fraud, the pharmacy may want to protect such evidence with the attorney-client privilege.

Organize the Files to be Submitted

- When the pharmacy submits the requested files to the PBM, the files need to be organized in such a way that they tell a **clear, concise story**.

- The pharmacy cannot assume that the PBM employee (who reviews the files) will be as sophisticated as the pharmacy employee who submitted the files. If the PBM employee cannot understand a file, he/she will likely fill in the blanks with his/her imagination. In order to avoid this, the files should be organized in such a way that they will be easy for the PBM employee to understand.

Submission of Documents

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Tell a Story

The story that the pharmacy wants the files to tell is that

- Each product delivered to a patient was in response to a valid prescription,
- The pharmacy dispensed the exact product that was prescribed, and
- The pharmacy billed only for the product that was dispensed.

These are the *basics.*

- If the basics are present, then if there is a deficiency with some aspect of the patient file, hopefully, the PBM will overlook the deficiency and approve the claim.

Rehabilitate the Files to be Submitted

- In reviewing the files requested by the PBM, the pharmacy may conclude that some of them may be deficient. These are the files that the pharmacy concludes may trigger a recoupment.
- If possible, the pharmacy should take steps to rehabilitate the deficient files. “Rehabilitation” entails securing contemporaneous documentation that fills in the gaps.

Rehabilitate the Files to be Submitted

- For example, the pharmacy may determine that a physician's prescription (that was issued a year ago) lacks important information. The pharmacy can approach the physician and ask him/her to sign a document that corrects the prescription. Such a document will need to be dated today (not the date of the original prescription) and should say that this current information "relates back" to the original prescription. Such a rehabilitation attempt may or may not work, but it is better than doing nothing.
- In rehabilitating documents, it is important that the pharmacy be honest and transparent (e.g., no back dating).

Copies and Explanatory Letter

- Maintain two sets of copies
  - When the pharmacy submits the requested documents to the PBM, the pharmacy needs to retain two sets of copies: one set for the pharmacy and one set for the pharmacy's attorney.

- Explanatory letter
  - In some (but not all) instances, it is wise for the pharmacy to include an explanatory letter with the documents. Such a letter will explain points that are not clear on the face of the documents.
  - An explanatory letter needs to be from the pharmacy, not from the pharmacy's attorney. As a rule, PBMs do not want to deal with attorneys... unless they have no choice.

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Follow up with the PBM

- After it submits its documents to the PBM, the pharmacy should follow up with the PBM to confirm that the PBM has timely received the documents.

- In its follow-up phone call or email exchange with the PBM, the pharmacy should:
  - represent to the PBM that the pharmacy can supplement the submitted documents as requested by the PBM and
  - explain to the PBM that the pharmacy will be available any time that the PBM has questions.

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Protecting Against DEA Inspections

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Compliance as the Best Prevention

- The most effective deterrent to a DEA audit or inspection is sound pharmacy practices and vigilance by the pharmacy over the control and dispensing of controlled substances in its possession.
- This requires the implementation and enforcement of controls on record keeping, ordering, dispensing, and physical security of the stock of controlled substances.
- These steps, in addition to regular self-inspections and inventories will, in most cases, entirely prevent issues from cropping up in the first place and will allow pharmacies to quickly identify and correct any problems that do arise.

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Compliance as the Best Prevention

Not only does a **strong compliance program stave off most issues** that would result in a DEA investigation, if issues do arise, the existence of a robust compliance program also **goes a long way to build credibility with the DEA investigators and to mitigate any adverse consequences.**

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Common Causes of DEA Audit/Inspections

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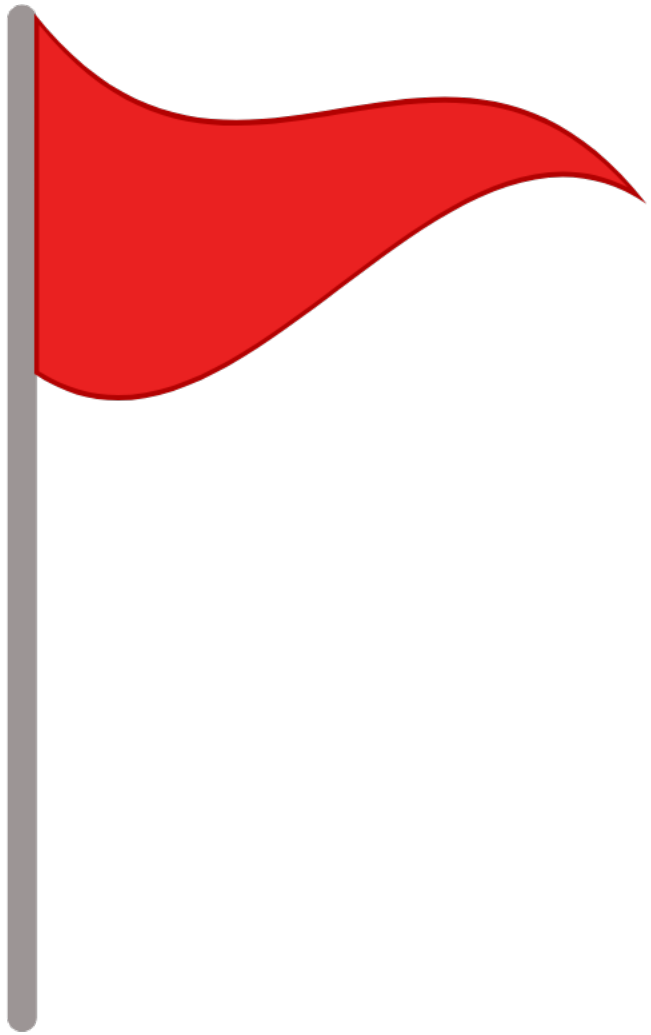
DEA Red Flags

- A DEA audit/inspection can be triggered by any number of issues, including the following:
  - Over dispensing commonly abused controlled substances;
  - Reports (including self-reports) of diversion; and
  - Notice of whistle blowing by the pharmacy's employees, business partners, or competitors.



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Key Areas of DEA Focus

- When an investigation occurs, it is useful to keep in mind that the DEA's area authority is ensuring that each pharmacy is safeguarding its portion of the controlled substances "closed system."

- This focus includes the following areas:
  - The validity of prescriptions;
  - The legitimacy of prescriptions;
  - Theft/diversion; and
  - Record keeping.

Valid Prescriptions

Whether a prescription is valid addresses the question of whether the prescription was written by an individual licensed to prescribe that drug. There are several **indicators to watch for:**

- Missing or incorrect DEA/license number
- Misspelled medication name
- Improper or suspicious signature
- Alterations or other improper erasures or markings
- Unusually high dose or drug combinations

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Valid Prescriptions

In addition to issues with the prescription, there are other factors the pharmacy should be watching for:

- A single person attempting to fill prescriptions for multiple third-parties;
- A patient's inability to explain the therapeutic purpose of the prescribed medication;
- Cash payments (especially for patients who have insurance); and
- Out-of-state or remote patients.

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Legitimate Prescriptions

- A key issue the DEA emphasizes is the pharmacy's corresponding responsibility to evaluate whether the prescription is valid.

- Many issues that relate to the validity of a prescription can also indicate a prescription is illegitimate. Issues that can flag an illegitimate prescription:
  - "Cookie-cutter" prescriptions;
  - A physician writing a prescription for a drug outside his or her normal practice area; and
  - A physician has a high volume of prescriptions for commonly abused or misused drugs.

Theft and Diversion

- Theft and diversion of drugs occur in many different forms. And as different means of diversion are identified, new and different ways of circumventing the pharmacy's controls are identified and developed.

- It is important to be vigilant when looking for potential weaknesses and to focus on all aspects of the pharmacy's operations.
  - How does the pharmacy obtain its controlled substances? Who has access to the ordering system? Who receives the drugs upon delivery?
  - How are the controlled substances stored? Are there locks, safes, security cameras, key logs, etc.? Who has access and under what circumstances?

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Theft and Diversion

- Does the pharmacy keep proper records of its controlled substance? How are those records organized and maintained?
- Are inventories conducted? How often and by whom? Are there periodic checks or random samplings of drugs?
- How are controlled substances dispensed? What controls does the pharmacy have in place to confirm the validity and legitimacy of prescriptions?

Record Keeping

- The DEA requires a pharmacy to maintain records of the controlled substances in its possession.
- In addition to monitoring and inspecting controlled substances in the possession of the pharmacy, the DEA also audits the pharmacy's records.
- Failure to properly maintain, store, and/or organize records can be on its own a violation of the Controlled Substances Act.

Walking Through a DEA Investigation

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A General Overview of the Investigation

While the facts will dictate the exact scope and extent of each DEA investigation, they typically follow a similar process.

- The DEA arrives at a pharmacy to conduct the audit/investigation. This likely consists of inspecting records, the pharmacy's stock of controlled substances, the premises, and possibly conducting interviews.
- After the audit, the DEA reviews the records and its findings in order to determine whether any discrepancies and/or violations exist.

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A General Overview of the Investigation

- If relatively few discrepancies exist, then the DEA might choose to resolve these through a Corrective Action Plan or a Letter of Admonition.
- For more significant discrepancies/violations, the matter may be referred to the Department of Justice ("DOJ"). While the DEA and DOJ generally coordinate the investigation at this point, this would be an additional action that would have to be resolved separately.

A General Overview of the Investigation

Civil Violations

- The DOJ portion of the investigation is typically resolved by settlement agreement/fine or through the final judgment of a lawsuit.
- The DEA portion is typically resolved through a Memorandum of Understanding/Agreement (MOU/MOA). For more egregious cases, the DEA may initiate an administrative action to revoke the pharmacy's DEA registration.

A General Overview of the Investigation

Criminal Violations

- If the DOJ pursues a criminal action, those matters are generally resolved through a plea agreement or by conviction/acquittal at a criminal trial.
  - While criminal actions against companies are not unheard of, criminal actions are typically against individuals. In the case of pharmacies, these would be against owners and pharmacists.
- If the pharmacy or relevant individuals are convicted of a criminal violation, then the DEA will often move to revoke the pharmacy's DEA registration.

Practical Guidance for Walking Through a DEA Investigation

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Preparing for an Inspection

- **Have health care counsel on hand.** The pharmacy does not want the first time it considers who to retain as health care counsel to be when the DEA has arrived unannounced for an inspection. Not only can health care counsel assist in preparing and implementing a compliance program, but having health care counsel the pharmacy can call at the start of an investigation will significantly aid the pharmacy in the investigation.
- **Know what key areas the DEA will likely be focused on and be knowledgeable about where key records**—such as licenses and DEA registration—and information are stored.

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The Initial Inspection

The pharmacy's goals during the inspection are to **learn what it can about the reasons for the inspection, convey an attitude of cooperation and compliance, and to avoid any mistakes that cannot be undone.**

- Be courteous and do not refuse access to records.
- Gather as much information as the pharmacy can about the reasons for the inspection. The pharmacy can ask questions but should not be pushy or demanding.
- Take careful notes of what the DEA asks about and focuses on.
- Do not agree to an interview without first conferring with counsel.

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Immediate Next Steps

- Debrief with regulatory counsel and consider engaging counsel with specific experience handling DEA inspections. This should be done as soon as possible after the inspection.
- Begin working to prepare any additional/supplemental information to address any deficiencies that were identified during the course of the investigation. For example, if the DEA noted that records were missing during the investigation, the pharmacy should see that it can locate those records and provide them.

Immediate Next Steps

- Consider conducting an internal investigation, with counsel. This should include the areas inspected by the DEA, the pharmacy's main classes of controlled substances, and a thorough debrief of any employees who interacted with the DEA.
- The pharmacy should work with counsel to begin preparing its response.
- The pharmacy should evaluate its obligations to report the investigation. Many payor agreements require notification in the event of an investigation. Other governmental agencies can also require notice of investigations.

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Take Corrective Actions

The pharmacy should work with its counsel to assess whether any changes need to be implemented. What those might be will depend on the specific issues identified in the investigation but might include the following:

- Staffing changes;
- Increases in security measures; and
- Review and revision of pharmacy procedures and controls.

Further Work with the DEA

Interview

- During the initial inspection, agreeing to be interviewed is rarely advisable. But as the investigation progresses, the decision becomes more difficult.
  - In many cases, an interview can be very helpful in working through issues with the DEA and helping to clarify issues.
  - But if there are concerns about potential criminal liability, it might be best to decline an interview.
  - This is a decision that the pharmacy will need to carefully consider with counsel. But in any event, the pharmacy should only give an interview once it has been prepared.

Further work with the DEA

- Additional inspections
  - The DEA might determine that additional inspections are warranted. Treat these as seriously as any other inspection by the DEA.
- Supplemental requests for information
  - As the DEA reviews the results of its inspection and the pharmacy's response it will often request additional information or records.
  - The pharmacy should work with its counsel to address these questions and requests.

Resolving an Investigation by Agreement

- While the DEA can issue an Order to Show Cause and proceed with an administrative hearing, most investigation involving serious violations are resolved through a MOU/MOA.
- While most of the terms of these are standard and are not subject to negotiation, there are some steps the pharmacy can take to obtain the best outcome.
  - Read and understand the terms of the MOU/MOA. The pharmacy should raise any questions it has with its counsel.
  - Read the allegations in the statement of facts to ensure they fairly represent the facts, and request correction, if necessary.

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Resolving an Investigation by Agreement

- Negotiate for a non-admission of guilt in the MOU/MOA.
  - It is common practice for other government agencies to issue reciprocal discipline based on DEA actions. Including a statement that the pharmacy is not admitting the truth or validity of the allegations as a term in the agreement can help the pharmacy in those later actions.
- During the term of any MOU/MOA, the pharmacy should be diligent about keeping its regulatory counsel and the DEA notified of any issues or questions that the pharmacy encounters.

Wrapping It All Up

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Key Takeaways

- Prevention is, as usual, the best cure. The best way to handle an audit or investigation is to never have any. And when the pharmacy does have one, to nip it in the bud as early as possible.
- The pharmacy only gets one first bite at the apple. Do not waste it. The pharmacy's first response will be its most impactful response. Take the time to make it count.
- Know your audience. The party on the other side has substantial power over the pharmacy's ability to operate as a pharmacy—including possible criminal consequences—and has substantial discretion. The pharmacy must keep this in mind.

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Key Takeaways

- Recognize when to involve the pharmacy's health care attorney. Legal counsel is costly, but involving knowledgeable counsel early in the process can prevent higher legal expenses down the line and help to mitigate and even avoid negative outcomes.
- Cooperation is advised. This does not mean that the pharmacy admits all wrongdoing and does not push back. But the pharmacy should present itself as an asset and as being aligned with the goals of the DEA and PBM.

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