



EDUCATIONAL RESOURCES

# Preparing for & Responding to PBM Audits

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# Introduction

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# Basis of PBM Audits

- All claims submitted to a PBM are subject to audit
- PBM Audit programs serve a dual purpose:
  - Contractual compliance with Provider Manuals and Agreements: PBM Audit Programs are designed to ensure claims are “submitted and dispensed in accordance with [PBM] guidelines, and that [pharmacies] comply with those guidelines.”
  - Compliance with applicable law and regulations, and detection of potential Fraud, Waste, and Abuse (“FWA”)

# Goals of a Successful Audit Response

- Reversing recoupment
- Preventing escalation of Audit Results
  - Maintenance of Provider Agreement(s), preventing termination or suspension
  - Referrals to federal and/or state investigators for FWA
  - Notice to the PBMs of the audit/investigation report



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# Preparing for a PBM Audit or Investigation

## Compliance as the Best Prevention and Defense

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# Avoiding PBM Audits & Investigations

- PBM Provider Manuals address the certain circumstances under which the PBM may conduct a regular audit or investigation (including limitations on number per year) without cause. Additional audits or investigations may be permitted “for cause”
- Then what circumstances can generate PBM scrutiny?
  - Member complaints
  - High volume of high value prescriptions
  - Claims for medications of limited clinical efficacy
  - Inappropriate billing of compounded drugs
  - Overbilling
  - And more ...

# Understanding the Audit Scope

- PBMs have various audit types, which may review different aspects of the pharmacy's compliance with the PBM Provider Manual. Audit types can include:
  - Regular audits
  - Desktop audits
  - Investigative audits
  - Marketing audits
  - Payor-specific audits
  - And so on ....

# Documentation is Key

- Regardless of audit type, proper and thorough recordkeeping is a pharmacy's best defense against an unfavorable audit result
  - Good organization– tight deadlines to respond means a robust response requires ease of access
  - Document and keep copies
    - Licenses, credentialing documents, patient/prescriber interactions, prescriptions, payments, etc.
  - Well drafted Policies and Procedures promoting compliance with Provider Manuals
    - Economic Assistance Policy/ Copayment Waiver Policy
    - FWA policies



# Compliance as the Best Prevention

- Not only does a **strong compliance program addressed in a pharmacy's Policies and Procedures stave off most issues** that would result in a PBM alleging claim discrepancies or FWA, if issues do arise, the existence of a robust compliance program also **goes a long way to build credibility with the PBM auditor/investigator and to mitigate any adverse consequences.**



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# Initiation of a PBM Audit or Investigation

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# Production of Information & Documentation

- Generally, a PBM will send an information request prior to conducting an audit or investigation.
  - Note the source from which information will be accepted
    - Generally, if purchase invoices are requested, summaries from wholesaler/distributor (and other sources) must be submitted to the PBM directly by the wholesaler/distributor. Internal copies of invoices will not be accepted
- Alternatively, the PBM may send notice of an upcoming, in-person audit.
  - Check state-specific PBM law for required notice, and restrictions on in-person audits/investigations

# Production of Information & Documentation

- When in doubt, err on the side of over-production than under-production
- If the pharmacy requires any clarification from the PBM for requested documents, make such requests in writing.
- Prompt response is key, but extensions of deadline to respond may be granted by the auditor/investigator, at their discretion
- Be patient and remain prepared for supplemental requests and clarifications
  - Maintaining a prompt and professional rapport with the auditor/investigation may help to prevent escalation



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# Responding to a Preliminary/Initial Audit Report

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# Immediate Next Steps

- Make note of deadlines stated in audit/investigation letter. No late responses will be accepted by the PBM. Additionally, make note of required submission method(s)
- Debrief with regulatory counsel and consider engaging counsel with specific experience handling PBM audits/investigations. This should be done as soon as possible after the receiving notice of an audit or investigation is FWA is alleged.

# Immediate Next Steps

- Begin working to prepare any additional/supplemental information to address any deficiencies that were identified during the course of the audit/investigation.
  - For example, if the PBM noted that records were missing, the pharmacy should see that it can locate those records and provide them.
- Verify acceptable dispute documentation and begin collecting external documents first
  - Some discrepancies require PBM-forms or certain information to be included on documents from pharmacy (i.e. Authorized Practitioner Statements)
  - If audit/investigation will require prescriber or patient action, contact those individuals as soon as possible after receiving audit.

# Compiling a Response

- A robust response should include (at least) the following elements:
  - Copies of the audit documents from the PBM
    - Including all communications between the PBM and pharmacy related to the audit, and a copy of the audit letter/report. If there is a reference number, it must be included.
  - Explanatory cover letter referencing dispute documentation and basis for reversing claim discrepancies
    - Include a summary of events so far (dates of communication)
    - Reference most helpful supporting documents
    - Narrative explanations
    - Cite specific claim/prescription numbers with which the pharmacy disagrees
  - Dispute documentation
    - Label and organize as to not “hide the ball”
    - If information is hard to find, PBM will not make the extra effort





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# Trending Enforcement

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# PBMs on a Warpath

- We have noticed an uptick of enforcement against certain types of claim discrepancies, including:
  - Prescriptions lacking necessary elements
    - Illegible prescriptions/ prescription elements
    - “use of directed” or similarly vague may be interpreted as lacking directions for use
    - Scrutinize each written prescription prior to filling
  - Lack of proper credentialing with PBM
    - Ensure operations are within scope of licensure and credentialing (retail pharmacy vs. mail order credentialing; state pharmacy licenses)
      - Discrepancies sometimes noted for out-of-state fills for traveling patients

# PBMs on a Warpath

- We have noticed an uptick of enforcement against certain types of claim discrepancies, including (cont'd):
  - Clinical appropriateness/Medically-Accepted indication
    - Know your ultimate payor and payor-specific requirements. Generally, prescriber authorization and order is not enough
    - For example, Medicare Part D claims must have a “medically-accepted indication” and PBM will require compendia citations/references for the drug.
  - Copayment Issues
    - Non-compliant copayment waivers or reductions
    - Pharmacy should retain receipts and reconciliation data for manufacturer rebates, copayments, and patient’s secondary insurance, where applicable.

# Wrapping It All Up



# Key Takeaways

- **Prevention is, as usual, the best cure.** The best way to handle a PBM audit or investigation is to emphasize compliance on the front-end. When the pharmacy does have a PBM audit or investigation, 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 and has substantial discretion. The pharmacy must keep this in mind. Demonstrable, objective facts and documentation are generally more effective than impassioned or argumentative responses.

# 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 PBM and its ultimate payors.
  - Demonstrate professionalism, openness, and compliance in all communications



Questions?



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# Thank you

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