

THE INDEPENDENT PHARMACIST'S GUIDE TO THE ON-SITE AUDIT AND SUMMARY OF THE HB 1358 AUDIT REFORM LAW

Amanda G. Fields, General Counsel for American Pharmacies (APRx) © American Pharmacies 2013

Introduction

Audits by insurance companies and third-party payors are a major threat to both the practice and business of pharmacy. Too often, the on-site audit is simply a mechanism to get in the door so they can recoup thousands of dollars, frequently from small independent pharmacies.

More often than not, on-site audit notifications request review of records and/or documents that are not within the scope of time or relevance permitted under Texas law. Unfortunately, many pharmacies that receive these notifications comply simply because they don't understand Texas law, and because they fear the consequences of non-compliance.

Once an insurance company or PBM has conducted an on-site audit, it typically notifies the pharmacy that it will recoup money by taking out payments from future money due. Many pharmacies give up a reimbursement just to continue the "privilege" of doing business with their tormentor.

It is imperative that you take steps to prevent audits, understand your rights under Texas law, voice opposition to unlawful audits and appeal any demands for recoupment. This guide provides useful tips on handling the on-site audit.



What Can I Do to Avoid an On-site Audit?

The best way to not experience the stress and inconvenience of an on-site audit is to avoid having one in the first place. Here are some simple things that you can do that may help prevent an audit:

► **Take advantage of services and representation from APRx CAPS.**

Comprehensive Audit Prevention Services—an APRx Preferred Vendor — provides comprehensive audit assistance to our members for only \$290 a year. You'll receive everything from on-call phone counseling, drafting correspondence for your stores, assisting in appeals to training and on-site assistance.



**Comprehensive
Audit
Prevention
Services, L.L.C.**

- **Carefully review your contract with an auditing entity before you sign it.** If possible, have an attorney or consultant review it for any unreasonable or prohibited auditing procedures. If every Texas pharmacy refuses to sign a contract containing unlawful auditing procedures, then insurance companies and third parties will be unable to continue to do business in Texas unless they comply.
- **Maintain sound filing practices.** You need to keep on file (preferably on-site at the pharmacy) all documents pertaining to your pharmacy's ongoing relationship with the insurance company or PBM. These include contracts, fee schedules, manuals, renewals and contracts amendments, supplemental documents to the contract and all documents that your pharmacy's representative signs and submits to the insurance company or third party. If a third party negotiates your contracts, then request copies of those documents to ensure that the terms pertaining to your pharmacy's legal relationship with the insurance company or PBM can be easily referenced and verified.
- **Once you sign the contract, consistently abide by the terms and conditions in the pharmacy service manual provided by the insurance company or PBM.** The pharmacy service manual, typically distributed annually outlines standard procedures and clinical and regulatory information. **Study the pharmacy service manual for any audit trouble spots you can avoid.**
- **If you do not already have copies of fee schedules for all the prescriptions the pharmacy fills, especially compounded prescriptions, request them immediately.** While it makes good business sense that a dispute over the price of a prescription should be resolved at the time of the affirmative adjudication, insurance companies and PBMs often don't see it that way. They frequently try to

audit prescriptions that were submitted via affirmative adjudication and resolved as a clean claim months and even years after the adjudication. Thus, the fee schedule is an immediate way for the pharmacy to know the fees to be paid.

Since none of these precautionary measures are a guarantee against the threat of audit recoupments, it is essential to know how to prepare for and handle an on-site audit.

How to Prepare for an On-site Audit

- ▶ **First, review the written on-site audit notification.** If you received other than a formal written notice of an entity to provide formal written notification. As you review the audit notification, determine whether the scope of the notification is lawful or can be limited. Texas law may help your position, as it imposes certain limits, such as how far back the audit can retrospectively cover. Does the scope of review comply with the prompt payment to providers and audit standards rules, as codified in Chapter 1369 of the Texas Insurance Code? If you are not sure, contact an attorney or consultant to assist you in this assessment. You might need legal expertise in opposing an unlawful on-site audit notification.

For example, the auditing entity is generally not permitted to review clean claims submitted more than one year prior to the audit date. If the on-site audit notification is in violation of Texas law, you can ask that it be re-sent or that it be cancelled altogether. ***The auditing entity may attempt to claim that you waived these rights via your contract or pharmacy service manual, but the Texas Insurance Code provides that prompt pay and audit standards cannot be waived by contract.*** You should then determine whether the date and time set for the on-site audit is convenient and feasible. If it is not, ask for it to be re-scheduled.

- ▶ **Do not allow the on-site audit to occur on a day when you are unavailable. This is not a task that should ever be delegated to staff.** If the audit is rescheduled, ask for written confirmation of the new date, including the scope of records to be reviewed. What will the auditing entity be reviewing, i.e., what hard copies and signature logs or other records must be available for review during the audit? Begin thinking about any potential problems with your records.

- ▶ **After you carefully review the written audit notification, create an internal file and/or box for the audit.** Your internal file/box should begin with the written on-site audit notification and include all subsequent notes, correspondence and documented telephone conferences or other communications. **If it pertains to the audit, put it in your file/box.** Keep all files in chronological order with the most recent information on top. It is important to stay organized and document your actions at each phase of the audit.



Audit Preparation Checklist

- Carefully review the written notification of the audit;**
- Agree to an audit date only for a day when YOU are fully available. If the proposed date is inconvenient, reschedule.**
- Create a file/file box in which to keep all audit-related correspondence, records, notes and documentation of all related telephone calls.**
- Contact pharmacy owner colleagues for support & useful information.**
- Meet with your staff to prepare them for the audit.**
- Organize and prepare your records before the audit date.**
- Conduct a self-audit to identify any possible problems or issues.**
- Prepare a designated physical area for the audit that is private and out of view of your employees and operations**
- Consider videotaping or recording the audit for your records (and your protection!)**

Also keep a copy of your contract with the auditing entity, including all supplements and amendments, as well as your pharmacy service manual. Carefully review these documents, paying special attention to any provisions related to on-site auditing authority, procedures and policies.

- ▶ **Contact the auditing entity.** If the scope of the on-site audit notification is lawful, confirm in writing your availability for the audit and request what policies and procedures from your contract and/or pharmacy service manual govern the audit. Request a statement of why your pharmacy was selected for the on-site audit. Try to determine whether the auditing entity claims that it is random, related to their review of your dispensing trend analysis or for some other reason. Also request a copy of the prescription numbers that are the subject of the audit. The auditing entity may not respond to your written request, but you should attempt this task, as it is important to laying the early groundwork for your strategic defense of the audit and any potential negative findings.
- ▶ **Contact your pharmacist/ owner colleagues and connections within your pharmacy organizations** to determine if they have recently experienced an on-site audit by the same auditing entity. Ask them about their written on-site audit notification, the details of what the on-site audit entailed, and the outcome of the on-site audit findings. You should use these conversations as a means to educate yourself in ways to avoid a negative outcome for your pharmacy. Take notes during these discussions and place them in your internal file and/or box.
- ▶ You should **hold a meeting with your staff** in order to prepare them for the on-site audit. You should let them know the date and time of the on-site audit, and inform them of your expectations that they act with the utmost professionalism during the on-site audit. In particular, ensure that the staff is instructed not to actively communicate or interact with the auditor, and that if the auditor asks them questions or for information, that they should immediately refer the auditor to you. You do not want your staff directly involved in communicating with and/or assisting the auditor.
- ▶ **Organize and prepare your records** before the audit. De-clutter your pharmacy and make sure it appears to be a well-run, efficient operation.
- ▶ **Prepare a separate room (an empty office or break room) for the auditor to use**, and limit the audit to this designated area. Ideally, the audit should occur in an empty room with a table, and the auditor should remain in this room with the door closed when you leave to you track down any needed documents. Don't let the auditor sit next to your drug shelves, records or computers, or observe your pharmacy's transactions.
- ▶ **Conduct your own internal audit** well in advance to identify potential problem areas before the real audit. The written on-site audit notification will define the scope of the audit, i.e., the hard copies and signature log range required for review. You should conduct a random sampling and review of items within this range, and ensure that you have the original prescription for any refills, the delivery records are in order, correct DAW codes and NDC numbers are maintained, and most importantly, proper signature logs are maintained (no missing signatures!).

Compounded prescriptions are typically reviewed more aggressively, so check those with a careful eye. If at all possible, print a listing of each prescription that could be included in the on-site audit and review it. Ensure you billed the usual and customary price if the auditing entity requires such.
- ▶ **Consider videotaping the on-site audit.** You are permitted to record the audit with audio and/or video. If you decide to do so, please ensure prior to the audit day that your equipment works properly and that comfortable using it. If you would like, have another responsible staff member record the audit, but do not allow the "recorder" to become actively involved in the audit process. You, as the pharmacist/pharmacy owner, should be the exclusive contact or "go-to person" for the auditor during the entirety of the on-site audit.



What to Do During the Audit

- ▶ **Be on time to meet the auditor. You should be waiting for the auditor to arrive in the room** designated for the audit, and should be the first person to greet the auditor. Introduce yourself as the contact for the audit and offer your auditor a beverage and/or snack. **If you have decided to videotape the audit, begin filming at this time.** State the date and time and purpose of the taping on the video. Should the auditor state that videotaping is against company policy, don't engage in a debate. Explain that the videotape is so that you can remember the details of the audit for recordkeeping purposes and to help you train your staff in preparation for future audits. If the auditor is still unwilling to agree to the taping, then simply take detailed notes instead.
- ▶ **Always be professional, polite and courteous to the auditor.** Ensure that you maintain a high level of professionalism throughout the on-site audit. Being angry, sarcastic, rude or uncooperative will only ensure a more difficult and comprehensive audit. That does not mean you cannot question or challenge the auditor, but do so in a polite, respectful manner.
- ▶ **Take an active role in the audit.** Before the actual audit starts, discuss the scope of the audit and your mutual expectations for how the time will be spent. If you have not already obtained them, ask the auditor for a list of the prescriptions to be audited (typically about 100). Ask why your pharmacy was selected for the audit: is the audit random, due to a review of your dispensing trends or another reason. Determine if the auditing entity uses any extrapolation methods, and, if so, exactly what they are. Make it clear to the auditor that you are the only person to be questioned during the audit. After you establish a "game plan" for the on-site audit, assure the auditor that you will provide any needed documents or records. Express your desire to be helpful, resolve any discrepancies and make the process as painless as possible.
- ▶ **Take very detailed notes in a notebook or on a legal pad throughout the entire on-site audit.** These notes should include information about every aspect of the on-site audit and should go in your internal file/box when the audit is complete.
- ▶ **Ask questions during the audit and record the answers.** State all your questions politely and clearly. Answer all the auditor's questions honestly, but do not volunteer additional information. Many questions can be answered with a simple "yes," "no," "I do not know" or "I do not remember."
- ▶ **Protect patient information pursuant to the Health Insurance Portability and Accountability Act (HIPAA).** Be sure that the auditing entity has signed a "business associate agreement" with the third-party payor as required by HIPAA so that the auditor will keep information confidential. Provide information requested during the audit, but **do not disclose any records or documents outside the scope of the written audit notification.** The audit remains limited to the parameters of the written audit notification.



Checklist: What to Do During the Audit

- Be on time to meet the auditor.**
- Be professional, polite and courteous at all times.**
- Actively participate: discuss the audit's scope & mutual goals.**
- Take detailed notes throughout.**
- Ask any questions that arise and carefully record the answers.**
- Protect patient data in accordance with HIPAA guidelines.**
- Give copies – not originals – of documents & records.**
- Don't leave the auditor alone with your records or allow the auditor to wander the store.**
- Hold an exit meeting before the auditor leaves to determine all discrepancies/problems identified in the audit. If possible, get the list in writing.**

- ▶ **Always provide copies – NOT ORIGINALS – of records and documents** so you will have them later to review or to appeal/rebut any negative findings. Make written notes of what you provide the auditor. If the auditor later requests the same records, you can prove that you already provided them.
- ▶ **Do not leave the auditor alone with your records.** Bring all needed documents and/or records to the auditor and do not allow the auditor to wander around or accompany you to track down documents. Do not allow the auditor to walk among your drug shelves, search through records or look at your computer or electronic information. Allow the auditor to view only those items that are the subject of the written audit notification and that relate to the prescriptions being audited.
- ▶ **Hold an exit meeting before the auditor leaves** to ensure that the auditor discloses any problems and/or discrepancies found during the audit. If possible, obtain a written list of all discrepancies and/or problems, and ask the auditor to sign and date it. Ask the auditor how each discrepancy or problem can be resolved with supporting documentation and/or evidence so that you can limit the amount of any chargebacks in the audit findings. Take detailed notes throughout this exit meeting.

What to Do After the Audit is Finished

- ▶ **Begin immediately to prepare your rebuttal to the discrepancies or problems.** (You should have obtained a report of discrepancies or problems from your auditor during the exit interview.) If you need to gather supporting documentation/evidence, start compiling this information as soon as the audit ends. At times, the auditing entity requires that you produce this supporting documentation and/or evidence within a specific period, i.e., seven days. If so, prepare a cover letter detailing this supporting documentation and/or evidence and including copies of the documentation and/or evidence as an attachment. Send your letter by certified mail, return receipt requested, or by another method with signature of receipt so that you can prove the document was received. If necessary, contact your attorney and/or consultant for rebuttal arguments. Place copies of any supporting letters and documentation in your audit file/box.
- ▶ **You should receive a written report detailing the on-site audit findings after you have provided your supporting documentation/evidence. If necessary, you should rebut and/or appeal these findings.** During the rebuttal/appeal process, be sure to document each step of the appeal with written correspondence to the auditing entity. Send all correspondence by certified mail, return receipt requested, or by another method with signature of receipt so that you can prove the document was received. **If the audit findings are highly negative and will present a financial hardship, contact an attorney or consultant for assistance in the rebuttal and/appeal process.**



Post-Audit Checklist

- Immediately after the audit, start preparing your rebuttal to any discrepancies/problems identified during the audit .**
- Send the rebuttal with your supporting documentation to the auditing entity before its specified deadline.**
- After you receive the official report detailing the audit findings, rebut or appeal the findings as needed.**
- Get help from an attorney or consultant if you need it.**
- Send all correspondence by certified mail, return receipt requested.**

HB 1358 AUDIT REFORM LAW

Introduction

American Pharmacies and the Texas Pharmacy Business Council drafted and passed a comprehensive audit reform bill, which took effect on Sept. 1, 2013. This bill establishes reasonable audit protocols and procedures for plans and PBMs to abide by, ensuring that pharmacies can effectively maintain patient care while accommodating reasonable audits that are truly intended to detect fraud and abuse. Here is what the law does that will help independent pharmacies:

Applicability

- ▶ **The law applies to audits of commercial claims – meaning insurance claims – conducted by health plans and PBMs. The law does not apply to audits of claims under Medicaid, Medicare, CHIP, TRICARE, workers' comp, or self-funded health ERISA plans.**
- ▶ APRx understands the hardship that pharmacies face with Medicaid audits conducted under the new managed care regime, but **audit reform for Medicaid claims must occur at the federal level.** APRx and TPBC fully support legislative measures to obtain federal reform for Medicaid audits.
- ▶ **This new audit law applies to commercial/private-pay/insurance claims only.** It applies only to contracts between your pharmacy and a plan or PBM that are newly signed or renewed, on or after Sept. 1. Contracts signed before Sept. 1 – and audits under those contracts – are governed by the limited audit protections in place before this law took effect.

On-Site Audits

- ▶ **A plan or PBM must provide your pharmacy with reasonable notice of the audit** and accommodate your schedule to the greatest extent possible.
- ▶ The notice of an on-site audit must be in writing and sent by a means that allows tracking of delivery to you not later than the 14th day before the date of the audit.
- ▶ **A plan or PBM must reasonably grant your request to reschedule an on-site audit** to a mutually agreeable date if you request the rescheduling no later than the 7th day after the date you receive the audit notice.
- ▶ **A plan or PBM may not conduct an on-site audit more than twice annually in connection with a particular payor.** Before this law, there was no limit on the number of on-site audits.
- ▶ Finally, the plan or PBM may not conduct an on-site audit during the first five calendar days of January and December.



Desk Audits

- ▶ A plan or PBM cannot require you to submit documents in response to a desk audit any earlier than the 20th day after the date they request the documents. Before this law, there was no specified minimum time. We hope this allows you and your staff the time you need to respond.

Contracting

- ▶ **Your pharmacy's contract with a plan/PBM must state detailed audit procedures.** The previous law had no such requirement, and the plan or PBM would bury audit procedures in your manual.
- ▶ A plan or PBM must notify your pharmacy in writing of a change in an audit procedure not later than the 60th day before the effective date of the change.
- ▶ **The provisions of this audit reform law cannot be waived, voided or nullified by contract.**

Scope of Audit

- ▶ **An audit of a claim must be completed on or before the one-year anniversary of the date the claim is adjudicated.**
- ▶ **The list of your claims subject to audit must be provided in the written notice to you** and must identify claims by prescription numbers or a date range for prescriptions, allowing for the last two digits of the prescription numbers to be omitted.

- ▶ If the plan or PBM applies random sampling procedures to select claims for audit, the sample size may not be greater than 300 claims. There was no previous limit in the law.
- ▶ **A plan or PBM audit that involves involving your clinical or professional judgment must be conducted in consultation with a licensed pharmacist.**
- ▶ **No representative of plan or PBM may enter your pharmacy area unless escorted by an individual authorized by your pharmacy.** *Don't ever allow an auditor in your pharmacy area – The auditor should always be in a separate office or break room.*
- ▶ A pharmacy that is being audited may: (1) validate a prescription, refill of a prescription or change in a prescription with a prescription that complies with federal and state laws, (2) validate the delivery of a prescription with a written record of any other health care provider.
- ▶ A health plan or PBM may no longer calculate the amount of a recoupment based on: (1) an absence of documentation the pharmacy is not required by federal or state law to maintain; or (2) an error that does not result in actual financial harm to the patient or plan/PBM.
- ▶ **A plan or PBM may not require extrapolation audits** as a condition of participation in a network, nor may they use extrapolation to complete an audit or in recoupment calculations.
- ▶ **A plan or PBM may not include a dispensing fee amount when calculating an overpayment unless:** (1) the fee was a duplicate charge; (2) the prescription for which the fee was charged was not dispensed, or was dispensed without prescriber authorization, to the wrong patient, or with the wrong instructions; or (3) the wrong drug was dispensed.
- ▶ **An unintentional clerical or recordkeeping error (1) is not evidence of fraud or intentional misrepresentation;** and (2) is prohibited from being the basis of a recoupment unless the error results in actual financial harm to a patient or enrollee, health plan or PBM.
- ▶ After an audit is initiated, your pharmacy may resubmit a claim if the deadline for submission of a claim has not expired.
- ▶ A plan or PBM may access an audit report of a pharmacy only if the report was prepared in connection with an audit conducted by that health plan or PBM.
- ▶ **No individual performing an audit may directly or indirectly receive compensation based on a percentage of the amount recovered as a result of the audit.** *No more commission based audits!*



Audit Reporting

- ▶ At the conclusion of an audit, a plan or PBM must: (1) provide the pharmacy a summary of the audit findings; and (2) allow the pharmacy to respond to questions and any alleged discrepancies, and comment on and clarify the findings.
- ▶ No later than 60 days after the date the audit is concluded, a plan or PBM must send the pharmacy – by a means that allows tracking of delivery – a preliminary audit report stating the results of the audit and a list identifying any documentation required to resolve any alleged discrepancies found during the audit.
- ▶ A pharmacy – by providing documentation or otherwise – may challenge a result or remedy for a discrepancy stated in the preliminary audit report not later than the 30th day after the date it receives the report.

- ▶ A plan or PBM must reasonably grant your pharmacy's request for an extension of the time allowed to provide documentation supporting a challenge.
- ▶ No later than the 120th day after the date your pharmacy receives a preliminary audit report, a plan or PBM must send – by a means that allows tracking of delivery – a final audit report that states: (1) the audit results after review of the documentation submitted by the pharmacist or pharmacy in response to the preliminary audit report; and (2) the audit results, including a description of all alleged discrepancies and explanations for and the amount of recoupments claimed after consideration of the pharmacist's or pharmacy's response to the preliminary audit report.

Enforcement

- ▶ If you need enforcement of HB 1358, and if you have complaints about a failure of a health plan or PBM to follow the law, please consider contacting the Texas Department of Insurance, which is the state agency with oversight of this law.
- ▶ **The TDI ombudsman, Melissa Hield, can be reached at Melissa.hield@tdi.state.tx.us**
- ▶ Also, please bookmark the pharmacists' resource page where you can file an electronic complaint. www.tdi.texas.gov/hprovider/pharmacy.html
- ▶ You may want to consider legal action if TDI is unable to help, if the audit violations are particularly egregious or if the chargeback amount is large enough.

Questions? Please contact Amanda Fields at afields@aprx.org

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