

THE PHARMACIST'S GUIDE TO THE ON-SITE AUDIT PROCESS

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Introduction

As the Texas pharmacy industry knows, audits by insurance companies and third party payors are out of control. Insurance companies and pharmacy benefit managers (“PBMs”), in particular, are threatening to hurriedly eliminate both the practice and the business of pharmacy. Their weapons of choice are audits, and the on-site audit is simply a mechanism to get in the door in order to 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 time or relevance scope of permissibility under Texas law. Unfortunately, many of the pharmacies that receive these notifications simply comply because of a lack of understanding about Texas law, as well as a fear of the perceived consequences for noncompliance.

Once the insurance company or PBM has conducted an on-site audit, they characteristically send correspondence notifying the pharmacy that they will be recouping money by taking out payments from future money due. Many of the pharmacies are giving up their reimbursement in order to continue the “dubious privilege” of doing business with their current tormentor.

It is imperative that pharmacies take steps to prevent audits, be conscious of their rights under Texas law, voice their opposition to unlawful on site audits and appeal any demands for recoupment. This guide will briefly shed light on how to handle the on-site audit.

How can I prevent an on-site audit from occurring?

The first step is to attempt to avoid an unlawful audit before it even occurs. There are some simple things that you can do to try and avoid on-site audits.

You should review the proposed contract with the auditing entity prior to signature. If possible, have an attorney or consultant review it to determine whether it contains any unreasonable or prohibited auditing procedures. If every Texas pharmacy refuses to sign a contract containing unlawful auditing procedures, then the insurance companies and third parties will be unable to continue to do business in Texas unless they comply.

It is critical to ensure that you maintain sound filing practices. You need to have on file (and preferably on-site at the pharmacy) all documents pertaining to the pharmacy's

ongoing relationship with the insurance company or PBM. Those include contracts, fee schedules, manuals, renewals and amendments to contracts, supplemental documents to the contract and all documents that the pharmacy's representative signs and submits to the insurance company or third party. If there is a third party who negotiates the pharmacy's contracts, then immediately request all copies of these documents. This is significant so that the terms pertaining to the pharmacy's legal relationship with the insurance company or PBM are easily referenced and verifiable.

Once a pharmacy has signed the contract, it should consistently abide by the pharmacy service manual provided by the insurance company or PBM. A pharmacy service manual is a manual distributed to the pharmacy (typically on an annual basis) that outlines standard procedures and clinical and regulatory information. Study the pharmacy service manual for auditing pitfalls that the pharmacy can avoid, if possible.

If you do not already have copies of fee schedules for all the prescriptions the pharmacy fills, especially compounded prescriptions, then 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, the insurance companies and PBMs do not often see it that way. They frequently endeavor to audit prescriptions that were already 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 should I prepare for the on-site audit?

First, it is important to **review the written on-site audit notification**. If you received notice of an on-site audit via means other than a formal written notification, immediately request that the auditing entity to provide you with a written on-site audit notification. As you are reviewing the on-site audit notification, determine whether the scope of the on-site audit notification is lawful or can be limited. Texas law may help your position, as it imposes limits on the auditor's ability to audit, such as how far back the auditing entity can conduct a retrospective review. Does the scope of review comply with the prompt payment to providers' and audit standards rules, as codified in Chapters 843 and 1301 of the Texas Insurance Code? If you are not sure, contact an attorney or consultant to assist you in this assessment. You might need their expertise and counseling in opposing an unlawful on-site audit notification. For example, the auditing entity is generally not permitted to review clean claims submitted more than 180 days prior to the on-site audit date. If the on-site audit notification is in violation of Texas law, you should ask for it to be re-noticed to comply with Texas law or 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 these 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 that you are unavailable. The on-site audit is not a task that can be delegated to staff. If the on-site audit is re-scheduled, ask for confirmation of the new on-site audit date (including the scope of records to be reviewed) to be sent to you in writing. What will the auditing entity be reviewing, i.e., what hard copies and signature logs or other records are required to be available for review during the on-site audit? Begin thinking of potential problems with your records, if any.

Once you have carefully reviewed the written on-site audit notification, you should **begin to create an internal file and/or box related to this on-site audit**. Your internal file and/or box should begin with the written on-site audit notification, and include all subsequent notes, correspondence and documented telephone conferences or other communication. If it pertains to the on-site audit, put it in your file and/or box. Ensure that the file is kept in chronological order, with your most recent information on top. It is important to stay organized and document your actions at each phase of the on-site audit. Also in the file and/or box, you should include a copy of your contract with the auditing entity, including all supplements and amendments thereto, as well as your pharmacy service manual with the entity. At this time, you should review these documents, paying special attention to any provisions related to on-site auditing authority and/or on-site auditing procedures and policies.

At this time, you should **contact the auditing entity**. If the scope of the on-site audit notification is lawful, you should send written correspondence confirming your availability for the on-site audit and requesting what policies and procedures from your contract and/or pharmacy service manual govern how (the logistics, policies and procedures) the on-site audit will occur. Also in this correspondence, request a statement of why your pharmacy was selected for the on-site audit. You should attempt 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. Additionally, request a copy of the prescription numbers subject of the on-site audit. Be aware that the auditing entity may be unresponsive to this written correspondence, but you should make an effort to complete this task, as it is important to develop your strategic defense of the on-site audit (and any potential negative findings) early.

You should contact and **communicate with your pharmacist/pharmacy owner colleagues and connections within your pharmacy organizations** to determine whether 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.

You should **organize and prepare your records** before the on-site audit. Do the same for the rest of your pharmacy. De-clutter your pharmacy. Ensure your pharmacy looks the part of a well-run, efficient and professional operation. You should ensure that there is a separate room (such as an empty office or break room) for the on-site audit to occur. You want to limit the on-site audit to an isolated area, such that you are bringing documents and/or records to the auditor, not such that the auditor is snooping around your pharmacy or following you while you track down these documents. In an ideal situation, the on-site audit should occur in an empty room with a table, with you bringing any documents and/or records to the auditor and the door closed while the auditor waits for you. You do not want the auditor sitting next to your drug shelves, records or computers, observing your pharmacy's transactions occur.

You should **conduct a self on-site audit** well in advance of the actual on-site audit. Use this time to uncover problem areas before the auditor does. The written on-site audit notification will define the scope of the on-site 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 on-site audit with audio and/or video. If you decide to do so, please ensure prior to the on-site audit day that your equipment is properly functioning and that you are familiar with how to use the equipment prior to the on-site audit. If you would like, have another responsible staff member videotape the on-site audit, but do not allow the "recorder" to become actively involved in the process of the on-site audit. 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. Again, you do not want your staff directly involved in communicating with

and/or assisting the auditor. Should the auditor state that his company prohibits videotaping, then it is not recommended that you engage in a debate with the auditor about this. Explain to the auditor that the videotape is so that you can remember the details of the on-site audit for your pharmacy's record keeping purposes, and further, for educational purposes so that you can train your staff and appropriately prepare for the next on-site audit. If the auditor is still unwilling to agree to the taping, then simply take detailed notes during the audit.

What should I do during the on-site audit?

Do not be late to meet the auditor. You should be waiting for the auditor to arrive in the room designated for the on-site audit, and you should be the first person to greet the auditor and introduce yourself as his contact for the on-site audit. Offer your auditor a beverage and/or snack. If you have decided to videotape the on-site audit, **begin filming** at this time. State the date and time and purpose of the taping on the video. Explain to the auditor that the videotape is so that you can remember the details of the on-site audit for your pharmacy's record keeping purposes, and further, for educational purposes so that you can train your staff and appropriately prepare for the next on-site audit. Again, if the auditor is still unwilling to agree to the taping, then simply take detailed notes during the on-site audit.

Do not be hostile with the auditor. **Always be professional.** You should always be polite and courteous. Never, never, never get angry, yell or make inappropriate or sarcastic comments to the auditor. Ensure that you maintain a high level of professionalism throughout the on-site audit. It is not smart to be rude or difficult, and you can expect a more difficult and comprehensive on-site audit if you are. That does not mean you cannot question or challenge the auditor, but do so in an appropriate and respectful manner.

Do not take a passive role in your on-site audit. Prior to the on-site audit occurring, you should discuss the scope of the on-site audit and your mutual expectations for how the time will be spent. If possible, and if you have not already obtained them, obtain from the auditor a list of the prescriptions to be audited (typically about 100). Question the auditor as to why your pharmacy was selected for the audit. Determine whether the auditing entity claims that it is random, due to a review of your dispensing trend analysis or another reason. Ask whether the auditing entity utilizes any extrapolation methods. If the answer is yes, ask which methods of extrapolation the auditing entity utilizes. Ensure that the auditor understands that you are the person he should direct his questions to during the on-site audit. After you have a "game plan" for the on-site audit, let the auditor know that you will be obtaining all documents that he needs to complete the on-site audit, and that you are sincere about wanting to help him, resolve any discrepancies, and make the process as painless as possible.

Do not come empty-handed to the on-site audit. You should take very detailed notes in a notebook or on a legal pad throughout the entirety of the on-site audit. These notes should include information about every aspect of the on-site audit and will go in your internal file and/or box when the on-site audit is complete.

You should **ask questions** that you have during the on-site audit and note the answers. These questions should not be aggressive in tone. Do not refuse to answer the auditor's questions during the on-site audit. Answer the auditor honestly, but do not volunteer additional, irrelevant or superfluous information. You will be surprised how many questions can be answered with "yes" or "no" or "I do not know" or "I do not remember." Often, nothing more is necessary.

Remember to **protect patient information** pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"). For instance, ensure 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 the auditor with the information requested during your initial meeting with the auditor, but **do not disclose to the auditor records and documents outside the scope of the written on-site audit notification.** You should ensure that the on-site audit remains limited to the parameters of the written on-site audit notification.

Do not give original records and documents to the auditors. You should ensure that you provide the auditor with copies of relevant records and documents, so that after the on-site audit is over, you can study what was audited and prepare for appealing or rebutting any negative findings. Additionally, if the auditor comes back for the same records at some point because the auditor lost the records and documents, you will be able to prove that you already produced the records or documents at issue. Again, take notes in regard to what copies were provided to the auditor. Do not leave the auditor alone with your records. You should stay by the auditor's side during the entirety of the on-site audit. Do not allow the auditor to conduct a fishing expedition—walking amongst your drug shelves, searching through records, looking at your computer or electronic information. Only allow the auditor to view those items that were subject of the written on-site audit notification and in relation to the prescriptions being audited.

Do not allow the auditor to leave without an exit meeting. During this meeting, ensure that the auditor discloses to you any discrepancies and/or problems he found during the on-site audit. If possible, obtain a written list of all discrepancies and/or problems, and ask the auditor to sign and date it. Request information from the auditor on how each and every discrepancy or problem can be resolved with supporting documentation and/or evidence so that you can limit the amount of the chargebacks contained in the audit findings. Take detailed notes throughout this exit meeting.

What should I do after the on-site audit?

You should have obtained a report of the discrepancies or problems from your auditor during the exit interview before the auditor left. Immediately **begin to prepare your rebuttal** to the discrepancies or problems. This may require that you gather supporting documentation and/or evidence. Begin compiling this information as soon as the on-site audit has ended. At times, the auditing entity requires that you produce this supporting documentation and/or evidence within a specific time frame, i.e., seven (7) days. If this is the case, prepare a cover letter detailing this supporting documentation and/or evidence, as well as copies of the documentation and/or evidence as an enclosure to the letter. Ensure that you send your correspondence via certified mail, return receipt requested, or via another method with confirmation of signature or receipt so that you can prove that the auditing entity received the document. If necessary, contact your attorney and/or consultant for rebuttal arguments. Remember that copies of any supporting letters and documentation should go in your file/box related to the on-site audit.

You should **receive a written report** detailing the on-site audit findings after you have provided your supporting documentation and/or evidence. If necessary, you should **rebut and/or appeal these findings**. During the rebuttal and/or appeal process, ensure that you document each step of the appeal with written correspondence to the auditing entity. Ensure that you send your correspondence via certified mail, return receipt requested, or via another method with confirmation of signature or receipt so that you can prove that the auditing entity received the document. If the findings are exceptionally negative and will present a financial hardship, contact an attorney and/or consultant for assistance in the rebuttal and/or appeal process.

Questions? Please contact Ms. Fields at amandacfields@gmail.com