


Compliance Blog - R.J. Hedges & Associates

6 Tips for Passing a Pharmacy Inspection

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Inspections, audits, on-site surveys, or any visits from a regulatory power are probably not on anyone's "Top 10 list of fun things to do at the Pharmacy this week" list. Ensuring your pharmacy is prepared for an inspection is an ongoing task; and you'll never really be "finished" with preparation because there are things you need to accomplish on both a daily and monthly basis. If your fretting about an upcoming inspection, audit, or you have a 6th sense that something is looming in your future, here are a few things to ponder, consider, and possibly take action to ensure you will be a few steps closer to passing an inspection.

The Nitty Gritty

Inventory control, drug security, and record keeping are daily items that are vital to ensuring your pharmacy passes an inspection. There are best practices that should be done daily, weekly, monthly, and annually such as trainings, internal audits, and inventory, etc., but you must also pay attention to more trivial matters too. Things like fire extinguisher inspection dates, dusty shelves, and even staff appearance can play part a in inspections, depending on the entity performing the inspection.

While some of these smaller matters might seem inconsequential, some very real risks come with inspections. For example, DEA form 222's require that each line item have date received, quantity received, and be initialed. Failing to do so could result in a \$14,000 fine for each missed line item. Other items may be ones you hope never happen, but you should have a good plan or process in place to help mitigate. If you experience a breach that results in the loss of Protected Health Information (PHI), failure to follow procedure could result in fines of \$1 million. In the end, the best way to ensure your pharmacy does not experience fines (or worse), is to do everything you can to maintain a tight ship  n it comes to compliance preparation.



Tips for Dealing with Inspectors

Audits, inspections, and surveys never seem to happen on a slow day. You might have 40 scripts on the counter waiting to be filled when an inspector walks in unannounced. Unfortunately for you, inspectors are following a schedule and don't care what day or time they come in; so those scripts will have to wait.

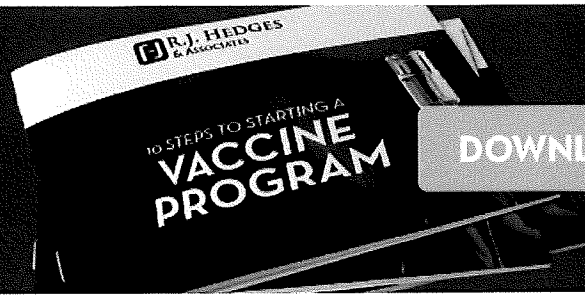
It can be frustrating and even a little frightening to deal with an inspection on top of an already busy schedule, but it is important not to be combative or argumentative with whoever enters your pharmacy. Don't throw them out or ask them to leave! They are following a schedule and need to accomplish a task, by denying entry you basically fail whatever audit or inspection was about to happen; and heaven only knows what the end result will look like. So, as difficult as it might be, bite your tongue, be as polite and pleasant as possible. Treating the inspector with respect can help minimize any penalties; rudeness may incite them to spend more time or dig even deeper during their visit.

This inspector or auditor has a lot of power; they can pull your license, your contracts, and they can fine you. Help the inspector or auditor capture all the information they need promptly. If they indicate you are deficient in some way, you should have the opportunity to correct it or provide items to clear the deficiency.



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Tips for Properly Handling Inspections

Whether you receive a visit from the DEA, OCR, a PBM, or State Board, one thing is for certain: No two inspections are the same. It would take several blogs to go over all the likely scenarios you could encounter, but for now, here are six things to get you started:

1. Breaches Are Not a Death Sentence; but don't underestimate

The HIPAA breach notification rule revolves around the loss of Protected Health Information (PHI). Breaches can be scary in the beginning because they may result in a fine, but they don't have to be. There are two types of breaches: reportable and non-reportable.

- ✔ Non-reportable breaches make up the vast majority of all breaches and often come in the form of a patient receiving the wrong medication. In this scenario, a patient might leave with the wrong medication and return to let the pharmacy know of the mistake. If the prescription went out, came back, was not tampered with, and the individual promises not to disclose the patient info, the situation is non-reportable. Just complete the proper paperwork and keep it on file for 6 years.
- ✔ Reportable breaches are rare, but still possible. One common scenario is a robbery (typically at night) where they take all the drugs from the "will call bin", which all have patient information on them. Another situation may involve a delivery vehicle(s). If keys are left in the vehicle while a delivery is being made, theft has been known to occur.

Keep in mind, reportable breaches are much more complicated than a non-reportable breach. If you complete and maintain the proper paperwork, you will have nothing to worry about. However, if you fail to report it, fail to investigate it, or even try to hide it (do not do this), the Office of Civil Rights will throw the book at you. Fines start at upwards of \$1 million, giving pharmacies a million reasons to properly document breaches no matter what. However, if you do everything correctly and provide the requested items your fine will be much smaller or no fine at all. Complete the proper paperwork and submit it online



to the Secretary of Health and Human Services and then wait up to 3 years for the review.

2. Inspectors Are Not All-Knowing

Although the inspector has all the power when they walk into the pharmacy, pharmacists must not assume they know everything. Pharmacists and pharmacy staff need to understand the inspection process so they can ensure no mistakes are being made.

In some states, state board inspectors may have limited pharmacy knowledge, or may not have any experience in the pharmacy industry; they work off a checklist and might not fully understand what they are asking. I've been in facilities during inspections and witnessed this first hand. In a few instances, I've even helped with the inspection by teaching the inspector what a question entails and what to look for.

3. By failing to prepare, you are preparing to fail

Not only is preparation essential to passing an inspection, but it also helps put the inspector at ease. It's unfortunate when any employee has to deal with combative and annoyed patrons, customers, and patients. So when this happens to an inspector, it just makes their job more frustrating.

Working with a compliance consultant that prepares and provides clients checklists to ensure all requirements are met makes this process smoother. We happen to provide both checklists and monthly task lists to ensure all compliance requirements are current and there's no scrambling to do when an audit or inspection is on the horizon.

When you can immediately provide the auditor or inspector with the policies, procedures, and documentation they ask for, it shows you are prepared and well organized. The easier you make everything for the auditor or inspector, the quicker they can work through their checklist. This could, not always, help shorten the items they ask for, allow them to be lenient when missing items or errors are found, or possibly allow for longer times to address deficiencies.

Many clients have shared similar stories of being well prepared with policies and procedures at the ready. The inspectors and auditors state they were the only pharmacy in the surrounding area that had all the documentation available. Now, imagine being the pharmacy that is inspected immediately after that bar has been set and not having your documentation readily available?



4. Always Have Everything on Hand

When the PBMs perform onsite audits, they normally give you a notice ahead of time. They primarily look at compliance and prescriptions. It's common for them to ask for the OIG exclusion verification from a random month of the previous year. Remember pharmacies need to run these reports monthly and keep records for 10 years. If you're not doing this, you are in jeopardy of losing all federal reimbursement for that month in question.

There are companies out there that handle this job for you and provide emails stating that none of your employees are on the exclusion list. However, these emails have no real authority. Even if you call the company and have them send the verifications over, you could still be dinged for not having them readily available. If you read the structure of the law and understand how it is enforced, you will see that it must be on file in the pharmacy and include Business Associates (BA's) and certain types of vendors (those you purchase items from that are in turn billed to Medicare or Tri-Care). Don't trust that the auditor will give you a chance to make a call. Have everything on hand, to begin with, in hard copy or electronic file.

5. Do Not Forget OSHA

Several training requirements come from OSHA, including bloodborne pathogen training, hazardous communications training, and fire prevention/extinguisher training. However, OSHA generally doesn't come in to enforce things unless your pharmacy experiences a serious injury or fatality. If that happens, OSHA is guaranteed to take a close look at everything. While these situations are quite rare for pharmacies, it is possible especially when considering compounding and Hazard Drug items. It is better to be safe than sorry, so do not overlook OSHA in this regard.

USP <800> Hazardous Drugs and the presence of hazardous drugs, especially in compounding means there is an additional level of exposure risk and additional precautions that must be followed, and this falls under OSHA requirements as well.

6. The Importance of Line Items

When the DEA performs inspections, one item they look at is the Powers of Attorney (POA). All staff who handle controlled substances inventory coming into the pharmacy must have this POA completed so they can complete the DEA form 222's and CSOC.

A POA allows the employee – usually a pharmacy technician, pharmacist, or a clerk – to



open the shipment received from the wholesaler. The employee then fills in several things on the 222 form, including the date received, quantity received, and individual line items (which must be initialed).

It is common for pharmacy employees to just sign their name at the bottom of these forms, but the DEA Pharmacists Manual states that each line item must be initialed. Each line item that is not initialed carries a \$14,000 fine. Every single form 222 and invoice document must be maintained for two years.

The same information from the form 222's must also be entered into CSOC, which creates some confusion. Both the hard copy form 222 and CSOC requirements are mandatory. Many pharmacists think it's good enough to enter everything into CSOC. While that step is necessary, the 222's must also be initialed and attached to the proper wholesaler invoice. We've noticed that older pharmacists and pharmacy employees do this without issue because it is what they have always done. Younger pharmacists tend to experience issues because they are computer savvy and don't see the importance of the paper records.

Does Your Pharmacy Have an Advocate?

The way you handle each situation described above – as well as, countless other factors – can make a world of difference. You don't get a bonus or gold star for passing an inspection or audit, but failing can mean fines, loss of licenses, and your pharmacy could even be put out of business.

It's all too easy to feel overwhelmed by constantly changing rules and regulations, and the worry that comes with audits and inspections is enough to drive anyone crazy. That's where R.J. Hedges & Associates comes in.

R.J. Hedges has worked with hundreds of facilities to ensure they stay compliant, easily earn Medicare accreditation, and pass audits and inspections. We offer programs that are custom designed to fit with your business. You'll be assigned a dedicated project manager who will guide you through every step, minimizing stress and ensuring you're ready for anything that comes your way.

Contact us today to learn more about how R.J. Hedges can get you on the fast track to passing your next inspection or audit.

Topics: Pharmacy Compliance

