Compliance Tips on How to Pass State Board of Pharmacy Inspections

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The practice of pharmacy is highly regulated by state pharmacy practice acts that vary considerably by state and change frequently. All pharmacies are subject to state board of pharmacy inspections; however, mail order pharmacies, specialty pharmacies, and chain pharmacies that are operated on a national basis are generally required to comply with multiple state pharmacy practice acts and may be subject to multiple inspections. Compliance deficiencies identified during inspections can result in discipline, including suspension or revocation of pharmacy licenses. In addition, the resultant disciplinary actions may result in payor/pharmacy benefit manager (PBM) contract terminations. Thus, it is important that pharmacy organizations take affirmative actions to ensure that their pharmacies will always pass inspections.

State Board of Pharmacy Inspections

The Right to Inspect

Pharmacy practice acts provide State Board of Pharmacy inspectors with the legal authority to inspect pharmacies to ensure that pharmacies meet minimum standards of operation and practice, as defined by applicable federal and state laws. State Boards of Pharmacy routinely inspect pharmacies for various reasons, including inspections prior to permitting/licensing, inspections after receipt of an application for change of location or change of ownership, routine cyclic inspections to ensure compliance, and enforcement inspections. Routine inspections look for compliance with state statutes and regulations.

Enforcement inspections are triggered by a complaint or threat of danger to the public or as a follow-up to ensure corrective actions were implemented after prior violations had been identified by inspectors. A pharmacy should not refuse an inspection, as such refusal is usually an independent violation of a State

Board of Pharmacy practice act. A State Board of Pharmacy's right to inspect is not unfettered, as pharmacy practice acts set forth certain limits for inspections generally, and it is important that pharmacy organizations understand the breadth and scope of a State Board of Pharmacy's inspection authority.

Pharmacy Inspection Checklists/Forms

Usually, each State Board of Pharmacy has a specific checklist or form that is completed by the inspector on the date of the inspection.[1] State Board of Pharmacy focus areas for inspections may also be ascertained by review of State Board of Pharmacy self-assessment forms.[2] Primary areas reviewed during inspections include, but are not limited to, the following:[3]

Retail and Hospital Outpatient Pharmacies

1. Original pharmacy license and current renewal displayed
2. Current Drug Enforcement Administration (DEA) registration
3. Pharmacist and pharmacy technician nametags, current licensure, and continuing education
4. Pharmacist-in-charge duties
5. Pharmacist duties
6. Pharmacy technician duties
7. Advanced practice pharmacist duties
8. Facility has adequate security (including an alarmed security system and working security cameras; heating and air conditioning available and working; and posted business hours
9. Security and storage of pharmacy area, medications, and records
10. Appropriate and clean pharmacy department workspace—including the size of an area, adequate lighting, access to sinks with hot and cold water, temperature of the refrigeration system, and readily accessible bathroom
11. Appropriate equipment (*e.g.*, counting devices, devices capable of measuring volumes, spatulas, mortar and pestle, electronic balance) necessary to dispense, label, and distribute drugs
12. Appropriate reference books and Board of Pharmacy rules
13. Suitable patient consultation area
14. Proper supervision of pharmacy staff
15. Drug stock is clean, orderly, properly stored, and properly labeled
16. Drugs are purchased from a licensed wholesaler or manufacturer
17. Receipt/distribution of drugs
18. Prescription requirements compliance
19. Prescription labeling, furnishing, dispensing, and storage
20. Prescription transfers
21. Prescription confidentiality
22. Refill authorization and documentation
23. Drug utilization review
24. Prescription Monitoring Program compliance
25. Documented quality assurance/quality improvement and medication errors program
26. Books and recordkeeping—includes prescription dispensing, prescription transfers, patient profiles, purchase invoices and receipts, controlled substances, inventory records, logbook records, returns, and destroyed drugs
27. Appropriate records storage
28. Appropriate DEA forms and controlled substances inventory records
29. Corresponding responsibility for controlled substances prescriptions
30. Policies and procedures
31. Automated dispensing devices
32. Repackaging/prepackaging
33. Outdated, damaged, and recalled drugs are segregated

Compounding Pharmacies

1. Compounding limitations and requirements (preparation timing, storage, office use, Food and Drug Administration (FDA) prohibited, master formula, bulk chemicals, beyond use dates, and stability studies)

2. Recordkeeping (master formula; compound certificate of analysis, compounding log accurately maintained; acquisition, storage, and destruction of chemicals, active chemical acquisitions, and dispensing records)
3. Labeling requirements (active/therapeutic ingredients)
4. Compounding policies and procedures
5. Compounding facilities and equipment functioning and maintained (testing and calibration; cleaning and disinfecting; hood certification)
6. Training of compounding staff (aseptic training)
7. Compounding quality assurance (adverse effects/complaints documented and investigated, and recalls and prescriber/patient notifications conducted when required)
8. Compounding for parenteral therapy
9. Sterile compounding from non-sterile ingredients
10. Sterile compounding area
11. Sterile compounding attire
12. Sterile compounding quality assurance and process validation
13. Beyond use dating for sterile compounded drug preparations
14. Limitations on use of single-dose and multi-dose containers
15. Compounding reference materials
16. Sterile compounding certification/licensure.

Hospital Pharmacies

1. Appropriate licenses and registrations for the pharmacy and the pharmacy staff
2. Pharmacy area separate, secure, with clean pharmacy department workspace—including the size of an area, access to sinks with hot and cold water, temperature of the refrigeration system, and readily accessible bathroom
3. Written policies and procedures
4. Drug distribution and control
5. Drug information
6. Rational drug therapy
7. Controlled substances (DEA registration, DEA Form 222, and controlled substances storage and inventory)
8. Emergency kit and code cart
9. Automated distribution cabinets, floor stock, non-emergency trays, and kits
10. Technician checking validation program
11. Collaborative drug therapy management
12. Medication reconciliation
13. Drug storage
14. Compounding and sterile parenteral products
15. Compounding and non-sterile products
16. Equipment functioning and maintained
17. Delivery of drugs
18. Drug stock
19. Pharmacists duties
20. Pharmacist-in-charge duties
21. Advanced practice pharmacist duties
22. Pharmacy technician duties
23. Pharmaceutical service requirements
24. Medication/chart order
25. Labeling and distribution
26. Duration of drug therapy
27. Confidentiality of chart orders, prescriptions, and patient medical information
28. Quality assurance and medication errors
29. Recordkeeping requirements
30. After-hours supply of medication
31. Emergency room dispensing
32. Discharge medication/consultation services
33. Central filling
34. Centralized packaging

The Multistate Pharmacy Inspection Blueprint Program

The National Association of Boards of Pharmacy (NABP) worked with member State Boards of Pharmacy to establish the Multistate Pharmacy Inspection Blueprint Program (the "Blueprint Program"), a document that provides a minimum set of inspection criteria for inspections.[4] Its goal is to bring uniformity to inspections

(particularly sterile compounding or other non-resident pharmacies that operated on a multi-state basis) while also allowing State Boards of Pharmacy to ensure compliance with their own state-specific requirements and make decisions about licensure of out-of-state pharmacies.[5] The 18 states that participate in the Blueprint Program can access inspection reports completed by other Blueprint Program states and automatically know if a pharmacy has passed another Blueprint Program Inspection.[6]

To become a Blueprint Program state, a State Board of Pharmacy can have the NABP compare its inspection forms to the Blueprint Program to ensure that it covers minimum standards, or it can use NABP's universal inspection form. In order to be deemed a Blueprint Program state and to remain an active participant in the program, states must agree to the following five requirements for conducting inspections:

- *Universal Inspection Form*. Blueprint states must use the NABP Universal Inspection Form. If a state cannot use the Universal Inspection Form, it may instead utilize its own form that has been crosswalked to the Blueprint Program.
- *Initial Training*. Compliance officers or inspectors carrying out Blueprint Program inspections must receive initial training that meets NABP criteria.
- *Ongoing Training*. Inspectors for Blueprint Program states also must participate in annual training, which NABP provides via webinar at no cost to the states.
- *Inspection Frequency*. Blueprint Program states must attest that they will inspect their pharmacies no less than once every 18 months.
- *Inspection Report Sharing*. Blueprint states must share their inspection reports through NABP e-Profile Connect.[7]

How to Prepare for an Inspection

Inspection Policies and Procedures

Pharmacies should establish internal written policies and procedures addressing how to handle inspections. The inspection policies and procedures should address the following issues.

Preparing for Inspection

- Keep a record of all communications with State Boards of Pharmacy.
- Organize all records into the inspection binder referenced below and ensure that the pharmacy is not missing any important documents.
- Prepare staff so they understand what to expect.
- Ensure the pharmacy is clean, the drug refrigerator and other equipment is in operation, and any expired, recalled, or damaged/altered drugs are stored or destroyed.

During the Inspection

- Require the inspector to show his or her State Board of Pharmacy credentials upon arrival at the pharmacy.
- Ask questions about the audit's scope and goals and record the answers given for pharmacy records.
- Establish a designated room or area where the inspector may meet with staff, review documents, or ask questions.
- Require staff to be polite and respectful to the inspector and truthfully respond to questions asked.
- Instruct staff not to speculate if unsure of a response to a question. If the question is unclear, the staff member should ask that it be rephrased.
- Prohibit staff members from admitting any violations of law or regulations.
- Instruct staff to respond only to questions asked and not to offer or otherwise volunteer information in addition to that necessary to respond to the question.

- Require a designated staff member to take notes during the inspection process, including but not limited to, questions asked, statements made, documents requested and reviewed, comments made by the inspector, and responses to the same.
- Do not permit the inspector unsupervised, free access to records, documents, or files.
- Provide copies of any requested documents. Keep the originals and document any records provided.
- Conduct an exit meeting to determine any issues identified in the audit and ask for the list of any discrepancies in writing.
- The pharmacy/pharmacist/manager should not sign any documents that acknowledge any specific findings or commit to any corrective actions prior to consulting with legal counsel.

Follow-up After the Inspection

- The pharmacy/pharmacist/manager should share and discuss the results of the inspection with legal counsel and immediately formulate responses to identified deficiencies, including consideration of policy and procedure, facility, or equipment changes that could address the issues raised by the inspector.
- Investigate any potential problems that arose during the audit. Consult with an attorney to clarify issues and concerns.
- All inspector requests for follow-up submission of additional documents or responses to specific questions should be answered as soon as reasonably possible.
- Once the written inspection report detailing the full audit findings is complete, review it carefully to make sure it matches the notes taken during the inspection.
- Work with legal counsel to prepare and forward a rebuttal response before the specified deadline with copies of any supporting documentation needed.
- If disciplinary action is taken, then consult with legal counsel regarding an administrative hearing or appeal.

Designation of a Key Employee

Identify one employee (usually the pharmacist-in-charge) to field questions from the inspector. This will minimize disruption at the pharmacy and ensure that responses are consistent with pharmacy policies and procedures addressing inspections. The key employee must understand limitations on the breadth and scope of inspection authority and be familiar with all pharmacy policies and procedures. If the key employee is not present or otherwise unavailable on the day of the inspection, inform the inspector and suggest that the inspection would be more productive upon the return of the most knowledgeable employee, or if the inspector could await his or her arrival. Inspectors are not required to delay the inspection, and they may insist on completion of the inspection without delay. Therefore, it is important for pharmacies to always have onsite an individual who is prepared to handle an inspection.

Staff Training

Pharmacy staff should receive training regarding inspection policies and procedures. The inspector will ask questions during the inspection, and staff must understand that the key employee is the person to respond to inspector inquiries. Employees should understand that they are under no obligation to respond to questions asked and that they should not talk to inspectors unless they are specifically instructed by the key employee to respond.

The Inspection Binder

Pharmacies are required to have books and records readily available for review by inspectors. It is our recommendation that pharmacies prepare an electronic binder with the documents required for inspection in one place (the "inspection binder").

Having the important items already organized in an electronic binder will reduce the time the inspector will be conducting the inspection. In addition, an inspection binder organized with the important pharmacy books and records will show the inspector that the pharmacy being inspected is vigilant with respect to demonstrating compliance with pharmacy laws. Likewise, sloppy recordkeeping and missing documents are likely to be perceived as an intentional disregard for pharmacy law compliance and may result in disciplinary action.[8] If hard copies of any documents are stored separately and not available electronically, the inspection binder should note where they are filed or how they may be retrieved. Staff should be trained on how to access the inspection binder in case the key employee is not present during an inspection.

The inspection binder should contain the following documents:

General Pharmacy Records

1. Prior Board of Pharmacy and DEA inspection reports
2. Pharmacy licenses for all states where the pharmacy is licensed
3. Copies of pharmacist and pharmacy technician licenses and continuing education compliance
4. Master list of pharmacist and technician initials
5. DEA 222 forms/power of attorney)
6. DEA 106 forms, theft and loss reports
7. DEA inventory
8. Purchase invoices
9. Records documenting return of drugs to wholesalers or manufacturers, including names of wholesalers
10. Records documenting drugs sent for destruction
11. Pedigrees for drugs purchased
12. Documentation of certification of software system if accepting electronic controlled substance prescriptions
13. Inspection self-assessments

Compounding Records

Compounding pharmacies should have the following items available and ready for inspectors:

1. Most recent self-assessments for both the pharmacy and each sterile compounding permit within the location
2. Most recent state board inspections (by any state where licensed)
3. Any FDA, DEA, or accreditation agency inspections with applicable reports, including any warning letters
4. Compounding policies and procedures (SOPs, etc.)
5. Documentation that all new policies and procedures (or lack thereof) within the last 12 months have been approved
6. Master formula documents
7. Completed recent patient-specific compounding records with associated label(s)
8. Compounding area semi-annual or annual (as applicable) certification reports
9. Quality assurance policies and procedures with documentation (reports) of end product testing (qualitative and quantitative analysis)
10. Non-sterile to sterile compounded product testing documentation (certificate of analysis (CoA)
11. Certificates of analysis for non-sterile components used in compounding for all ISO certified spaces
12. Records of initial training for compounding staff
13. Records of annual competencies for compounding staff
14. Records of the environmental sampling conducted in the pharmacy
15. Daily/weekly/monthly cleaning logs
16. Temperature logs (refrigerator, freezer, incubator, etc., as applicable)
17. Humidity and pressure logs
18. Sample labels
19. Inspection self-assessments

Policies and Procedures

At a minimum, the following policies and procedures and/or records related thereto should be available for review during inspections:

1. Pharmacist-in-charge duties
2. Pharmacist duties
3. Pharmacy technician duties
4. Advanced practice pharmacist duties
5. Quality Assurance Program for medication errors
6. Deliveries when pharmacy is closed
7. Absence of the pharmacist for lunch
8. Impairment of licensees
9. Interpretive services
10. Automated drug delivery system
11. Drug returns from patients
12. Drug Supply Chain Security Act pedigree compliance
13. DEA inventory
14. DEA 222 forms
15. Purchase invoice records
16. Drug returns to wholesalers and destroyed drugs
17. Theft and diversion
18. Protocol/licensee refusals to dispense, based on ethical, moral, and/or religious grounds
19. Advanced pharmacy practice protocols for immunizations, emergency contraception, self-administered hormonal contraception, nicotine replacement therapy, or furnishing naloxone

Disciplinary Actions for Inspection Deficiencies

If the inspector finds deficiencies during the inspection, he or she will usually provide a brief summary of issues during an exit interview and then follow up later with a written investigative report that outlines alleged violations, if any.

Common inspection deficiencies for retail and hospital pharmacies include:

1. Pharmacy technicians not properly identified with name tags and identified as pharmacy technicians (as opposed to pharmacists)
2. Pharmacy technicians not supervised by pharmacist
3. Medication on shelves not properly labeled (including exact number of pills remaining in bottle)
4. Controlled substances not accurately recorded on appropriate forms
5. Not keeping schedule II inventory and dispensing records separate from schedule III-V records
6. Failure to maintain a biennial inventory
7. Controlled substance records (including invoices, inventories, and logs) not properly maintained for required number of years
8. Not having an accurate count for all controlled substances on hand
9. Required DEA forms not maintained, accurate, or complete
10. Inadequate security measures (cameras, alarms, etc.)
11. Failure to control access to secured areas
12. Proper pre-hire screenings not in place (background checks, references, etc.)
13. Proper computer security measures not in place
14. Not properly identifying suspect controlled substance prescriptions
15. No corrective measures in place to ensure legitimacy of a controlled substance prescription
16. Not knowing the requirements for filling a legitimate controlled substance prescription
17. Refrigerator not being maintained at the appropriate temperature
18. Food or other non-medications (*e.g.*, lab samples) being kept in refrigerator with medications[9]

Common inspection deficiencies for compounding pharmacies include noncompliance with facility and equipment standards; master formula requirements; beyond used date assignments; sterile compounding quality assurance and process validation; and failure to maintain appropriate books and records (*e.g.*, compounding log).

The Inspection Report

The inspection report is usually forwarded by the inspector to the State Board of Pharmacy's attorney, who will then make a determination regarding possible disciplinary action. If the inspection report finds minor violations not worthy of formal action, the inspector may prepare a warning notice to document the violations. When a warning notice is issued, a follow-up visit may occur to determine whether the violations have been corrected. For more serious violations not necessitating disciplinary action, the inspector may issue a written order of correction, and the pharmacy will be required to submit and implement a written corrective action plan documenting compliance. When an inspector finds serious violations that he or she believes merits disciplinary action, he or she may recommend to the board that an admonishment letter or citation be issued, disciplinary charges filed, or in the most serious cases, referral made to a local, state, or federal prosecutor for the filing of criminal charges.

Disciplinary Action

Disciplinary action is usually initiated by an administrative complaint or accusation. Possible sanctions for deficiencies include: citation; suspension; revocation; corrective action plan; probation/monitoring; continuing education; fines and reimbursement of prosecution costs; and reports to other states where the pharmacy is licensed. Concurrent sister-state disciplinary actions pose a significant problem for multistate pharmacies, as most pharmacy practice acts permit a sister-state board's imposition of a disciplinary action for disciplinary action taken in another state even though there has been no direct patient impact or harm in their own states.

Conclusion

Pharmacies should engage legal counsel early in the inspection process to help ensure that the inspector does not exceed the scope of his or her warrant or inspection authority set by statute or regulation; determine if/when to object to various aspects of the inspection; ensure pharmacy owners, managers, and staff do not make incriminating statements, and to respond to the inspector. It is important to collect and review all applicable facts before responding to an inspection report and to have legal counsel draft a response to mitigate the impact of the inspector-identified violation(s).

Tools for successfully passing inspections include taking the steps recommended in this article; maintaining knowledge of all applicable pharmacy laws and regulations; and staying abreast of new developments through professional association participation, continuing education, and seminars. Good, organized recordkeeping (including an up-to-date inspection binder) and an inventory management system is the most important step to avoiding any inspection deficiencies. Another good defense against an inspection is a complete understanding of any laws and regulations that the pharmacy needs to maintain compliance with. It is also useful to attend or review minutes from State Board of Pharmacy board meetings and minutes, as they routinely include discussions regarding hot topics for enforcement or State Board of Pharmacy inspection-focused initiatives.

Endnotes

1. See, e.g., Florida (*www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html*); Indiana (*www.in.gov/pla/files/Inspection_Checklist_MCheck.pdf*); Massachusetts (*www.mass.gov/files/documents/2018/03/28/compliance-inspection-tool.docx*); Missouri (pr.mo.gov/boards/pharmacy/Pharmacy-Inspection-Report-Checklist-Sample.pdf); Nevada (bop.nv.gov/Forms/Inspection_Forms); New York (*www.op.nysed.gov/prof/pharm/pharminsestlist.pdf*); North Carolina *www.ncbop.org/phcyinspectionforms.html*); Pennsylvania (*cdn.ymaws.com/www.papharmacists.com/resource/resmgr/Toolkits/Pennsylvania_Pharmacy_Board_Inspection_Guide.pdf*); and South Carolina (*www.scrx.org/assets/resources/pharmacy%20inspection%20form.pdf*).

2. See, e.g., Alaska (*www.commerce.alaska.gov/web/portals/5/pub/pha4150.pdf*); California (*www.pharmacy.ca.gov/licensees/facility/self_assess.shtml*); Illinois (*www.idfpr.com/Forms/PDFs/COMMUNITY%20PHARMACY%20SELF%20INSPECTION%20REPORT.pdf*); New Mexico (*www.rld.state.nm.us/uploads/FileLinks/bde0e0d28ef545cba3d8cd277c39749d/Retail_self_assessment_2015.pdf*); Oregon (*www.oregon.gov/pharmacy/Pages/InspectionForms.aspx*); Utah (dopl.utah.gov/licensing/forms/applications/132_pharmacy_self_inspection.pdf); Washington (*www.doh.wa.gov/Portals/1/Documents/Pubs/690318.pdf*); and Wisconsin (dsps.wi.gov/Credentialing/Health/fm2550.pdf).
3. Ronald Chapman, "Pharmacy Inspections," chapmanlawgroup.com/practice_area/pharmacy-inspections
4. National Association of Boards of Pharmacy Inspection Tools and Services, *Multistate Pharmacy Inspection Blueprint Program*, nabp.pharmacy/member-services/inspection-tools-services/multistate-pharmacy-inspection-blueprint-program.
5. A report from The Pew Charitable Trusts and the National Association of Boards of Pharmacy Feb 2018, *State Oversight of Drug Compounding: Major progress since 2015, but opportunities remain to better protect patients*, *www.pewtrusts.org/-/media/assets/2018/02/drug_safety_assesment_web.pdf*.
6. The following states have signed the Multistate Pharmacy Inspection Blueprint Program Participation Agreement: Arizona, Arkansas, Indiana, Kentucky, Louisiana, Michigan, Mississippi, New Jersey, North Carolina, North Dakota, Ohio, Rhode Island, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wyoming.
7. Next Steps to Inspection Blueprint Uniformity and State Collaboration, NABP Newsletter, Innovations (January 2017), nabp.pharmacy/wp-content/uploads/2016/07/Innovations_January_Final.pdf.
8. Lou Diorio, RPh, FAPhA, *Preparing for a State Board of Pharmacy Inspection*, Pharmacy Purchasing and Products, November 2013 - Vol. 10 No. 11 - Page #80, *www.pppmag.com/article/1418*.
9. George F. Indest III, J.D., M.P.A., LL.M, *Common Deficiencies We See in Pharmacy Inspections*, Thursday, March 21, 2013, *www.thehealthlawfirm.com/blog/posts/common-deficiencies-we-see-in-pharmacy-inspections.html*.

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