Photo courtesy of LDT Health Solutions, Inc

By Lou Diorio, RPh

Preparing for a **State Board of Pharmacy Inspection**

It has been over a year since the terrible tragedy created by the New England Compounding Center (NECC) came to light. All the details have yet to be made public, however, what is known is that the landscape of compounding and pharmacy practice as a whole has been changed forever. In much the same way that the Thalidomide poisonings of the 1960s and the Tylenol contamination of the 1980s shaped the practice of the medical profession, this single event will undoubtedly be considered a watershed event.

The human toll from this event is staggering. As of September 6, 2013, 64 patients have died, and more than 750 have been hospitalized as a result of the estimated 17,000 tainted doses produced by the NECC. In response to this national disaster, the mobilization of resources from every state board of pharmacy has been swift, direct, and far-reaching.

Each state has responded in its own way to scrutinize the compounding activities of their registrants, from tightening controls over extemporaneous compounding in general, to monitoring the preparation of sterile dosage forms in particular. States have moved quickly within their individual regulatory processes to enact emergency regulations limiting the compounding activities of pharmacies engaged in sterile compounding. In many cases, sweeping new powers have been granted to the investigative and enforcement divisions of the boards allowing them to respond instantly to any conditions deemed threatening or dangerous to public health. Unprecedented cooperation between state executives, especially with pharmacies registered as out-of-state providers, has led to an acute awareness of activities within the borders of individual states. The result is almost instantaneous notification in the event of potentially problematic operations, or pharmacies proceeding without the proper levels of safeguards and controls in their compounding process.

It is within this landscape that we must continue to provide safe, quality care to our patients while continuing to adhere to the current regulatory framework. The existing statutes, rules, and regulations all need to be accounted for, but this is not new in our profession. It is, however, a hypersensitive climate where any degree of technical non-compliance will be met with swift and sometimes drastic action on the part of the state board. Their concern is that any degree of noncompliance may mask a more dangerous systemic condition.

So, how can we as pharmacists navigate such a complex and challenging landscape? How can we ensure the safety of our patients while complying with all the overlapping regulations?

Preparing for Inspections

It is both ridiculous and dangerous to believe that a system as complex as a modern compounding pharmacy can operate without systematic controls in place. Likewise, there is no last minute opportunity to prepare for an event as important as an inspection. The profession of pharmacy, by its nature, is fraught with risk on its best day. As such, consistent diligence is the only true path to compliance. Under no circumstances should the daily task of recording all critical pharmacy activities be avoided.

Where to Start

Once an inspector for any regulatory agency arrives at your compounding operation and announces a site inspection, the time is long past to think about preparation. Prior planning will avert confusion at the outset of the inspection and avoid making a long day even longer. Create a compliance binder that contains, among other documents, copies of the pharmacy's state license, any out-of-state licenses or permits, the DEA permit, cleanroom certifications, and any other current operating paperwork that would be routinely requested by an outside agency conducting an inspection. This will not only save you time but will also inspire confidence that your operation is orderly, focused, and practicing under control.

Setting the Tone for a Successful Interaction

Once the inspectors have announced their presence, the first step is to verify their identity. A simple phone call to the regulatory body's office will assure that everything is in order. Next, ask the inspector directly about the nature of their inspection. It is important to note whether the visit is routine, was triggered by another scheduled event, or was prompted by a complaint or injury. Likewise, it is important to be direct with the inspection team and answer their questions openly. However, should a possible liability or injury be involved, the assistance of qualified legal counsel is essential. Generally speaking, you must always provide accurate and honest information, but do avoid expounding on any replies that could lead or expand the questioning beyond the intended focus of the visit. A qualified member of the pharmacy staff should accompany the inspector(s) at all times when they are on site.

Documentation, Manuals, and a Blizzard of Paper

During any regulatory inspection, remember that you are your documentation. Your manuals, records, and reference library will represent your daily practice to the inspecting agency. Daily diligence in record keeping is key to a successful inspection and critical to running a smooth operation. The cornerstone of good practice is to establish policies that set standards for good documentation practices. Sloppy or illegible records, documentation lapses, and poor habits, such as the use of correction fluid (ie, Wite-Out), should be discouraged. Next, having supervisory personnel regularly review these records for accuracy and completeness will go a long way to creating an atmosphere of respect for documentation. Once your staff recognizes that these records may have to be legally defensible in court, it will follow that good habits are essential.

Quite often document requests are not presented in an orderly fashion, nor are they received at the outset of the inspection. Remaining calm and following policy to retrieve, copy, and present these records in an orderly fashion not only helps pharmacy personnel stay focused, but it also may assist the inspectors in reducing their time on premises. Key to managing document requests is to make an extra photocopy of any document, record, or paperwork given to an inspector. This practice will allow the pharmacy to return the original document to its proper place immediately and is a simple method to ensure you maintain a complete record of all information presented to the regulatory authority. It may also aid your

legal counsel in understanding the nature, breadth, and scope of the inquiry, should questions arise or legal action become necessary. If original prescription documents or other original paperwork is requested, refer to your state's practice act for any limits on these requests. In addition, you may wish to contact your counsel for direction before proceeding. Keep in mind that it is your right to request that the inspector allow you to photocopy the document and provide you with a signed receipt before any original document is removed from your premises.

Additional Inspector Requests

In some cases the inspectors will want to photograph, videotape, or collect samples of compounded CSPs. They may even request microbiological samples from your compounding areas. Again, an inspector should never be allowed to wander your premises unescorted, and you should familiarize yourself with the limits of the inspector's powers under your state's practice act. These limits should be communicated to all staff members and accurate notes should be kept of the inspector's comments, activities, and questions along with a full accounting of any documents requested. Having a defined policy and creating a capture form for such occurrences will assist you and your staff in maintaining order as well as having a complete record of the interaction (see **FIGURE 1**). In response to requests for photos or sampling, a polite request for a duplicate set of anything collected should suffice to ensure you have a complete mirror copy of all material provided to the inspection team. It is important to note that inspectors must follow your protocols for hand hygiene, gloving, and garbing in order to

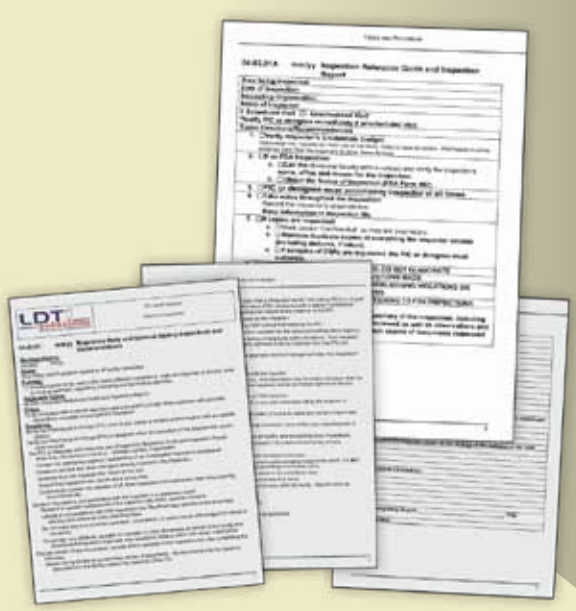
FIGURE 1

Sample Inspection Reference Guide

To manage a regulatory inspection effectively, adherence to internal P&Ps is key. LDT Health Solutions has created a Regulatory Inspections and Communications P&P, which includes:

- Policies and Procedures
- Inspection Reference Checklist (see the sample version at right)
- Inspection Report Guide

This document is designed to help pharmacies approach their regulatory interactions with competence and confidence.



Policy and Procedure

04-03.01A mm/yy Inspection Reference Guide and Inspection Report

Area being inspected: _____

Date of inspection: _____

Inspecting organization: _____

Name of inspector: _____

❑ Scheduled visit ❑ Unscheduled visit*

*Notify the pharmacist in charge (PIC) or designee immediately if unscheduled visit.

Tasks Directions/Recommendations

1. ❑ Verify inspector's credentials (badge):
Discourage the inspector(s) from use of cameras, video, or tape recorders. Permission must be obtained from risk management to allow these devices.

2. ❑ If an FDA inspection:
a. ❑ Call the divisional headquarters contact and verify the inspector's name, office, and reason for the inspection.
b. ❑ Obtain the Notice of Inspection (FDA Form 482).

3. ❑ PIC or designee must accompany inspector at all times.

4. ❑ Take notes throughout the inspection.
❑ Record the inspector's observations.
❑ Keep information in inspection file.

5. ❑ If copies are requested:
a. ❑ Mark copies "confidential" as they are proprietary.
b. ❑ Maintain duplicate copies of everything the inspector obtains (including pictures, if taken).
c. ❑ If samples of CSPs are requested, the PIC or designee must authorize.

6. Answer only specific questions - do not elaborate.

7. Do not concur with any observations made.

8. Do not sign any document acknowledging violations or committing to corrective actions.

9. Do not sign any documents pertaining to FDA inspections.

10. ❑ Prepare report:
The report should include a detailed summary of the inspection, including policies, procedures, and documents reviewed, as well as observations and comments made by the inspector. Attach copies of documents requested by the inspector.

enter your compounding spaces. Government IDs do not supersede your protocols, nor do they permit a compromise of your sterile operations.

Providing Requested Documentation

All requests for copies of documents should be answered as soon as reasonably possible, but keep in mind that in cases where the number or scope of the requests is large, your state pharmacy law establishes a window for the provision of these records to the inspection team, particularly for records that are kept electronically. You do not need to provide all the requested records immediately. A polite reminder to the inspector that you will comply as soon as possible, and that you will have the documents to them within the established regulatory window should be sufficient. Although the inspectors may claim that they will leave the premises more quickly or not return the following day if they receive the requested documents immediately, these assertions are seldom accurate or genuine. Thus, it is unwise to add increased pressure on the pharmacy leadership or staff to provide these documents in an unreasonable timeframe in an already stressful situation.

Determining Appropriate Limits to Access

Your state practice act should outline any limits on access to the pharmacy space, offices, and records. If the limits are unclear or a request appears excessive or odd, consultation with the pharmacy's counsel should be sought. In any event, unless an inspection team is executing a subpoena, search warrant, or other court action, the access need only be provided during the pharmacy's regular, posted business hours. No agency—city, state, or federal—has the right to keep the leadership or staff beyond a reasonable time. Inspections (especially multi-day events) can sometimes run into over time; this creates undue stress on management and staff, and should be avoided.

Responding to Inspector's Suggestions

All suggestions, comments, or interactions with an inspector should be noted. It is important, however, to resist the urge to make any immediate changes to your operation during the inspection to satisfy an inspector's request. A broad plan of corrective action requires careful consideration and, even if necessary, should not be undertaken until the conclusion of the inspection. This approach will allow the plan to reflect input from experts, and the inclusion of good science, proper workflow, and demonstrated best practices, while simultaneously accounting for all the downstream issues that changes to a cleanroom operation may cause.

What to Expect at the Conclusion of the Inspection

At the conclusion of any inspection, it is the responsibility of pharmacy leadership to request a structured and thorough exit conference with the inspector or inspection team. This meeting can be informal, but must be conducted before the inspector leaves the pharmacy premises. This allows all the involved staff to hear the comments and areas of focus directly from the inspector. Ideally, this meeting should be conducted in a quiet space away from the compounding zone or any public areas of the pharmacy. This provides an opportunity to present any additional documents or materials to clarify any misconceptions the team may have developed during the inspection. Do not allow this meeting to turn into a debate with the inspector; questions should only be posed to clarify comments made by the inspection team. Although stressful, staff participation in the exit conference is a valuable learning opportunity, as it underscores the critical nature of pharmacy's daily activities while also driving home the importance of documentation. At the close of this meeting, only pharmacy leadership should accept the written inspection report or other documents mandated or described within your state's practice act. Signing of any paperwork should be done with the understanding that you are acknowledging receipt of the document only, and not acknowledging any specific findings or committing to any corrective actions at this time.

After the Inspection

Following the inspection, pharmacy leadership should convene a staff meeting to review the circumstances of the inspection and to allow the staff to ask questions. This serves to dispel any rumors and reduce staff anxiety. The immediate focus should be on restoring the compounding area to its prime condition and returning any documentation to its proper location. After these immediate issues have been addressed, it is time to review the inspection notes, comments made by the inspectors, and any useful information garnered from the exit conference. Before formal correspondence arrives from the board, the pharmacy should begin to formulate a complete and formal response to any items that could possibly be raised. Investigate possible changes to policy or processes, or the addition of new equipment or automation necessary to address any issues the inspectors may potentially raise. Keep in mind, implementation of any changes should only be made upon careful consideration of all the overlapping issues and never before the final inspection report has be received.

Moving forward, whether there is additional formal board of pharmacy action or not, the pharmacy should continue to maintain an open dialogue with the board to assure that continuous improvement of the operation is the shared goal of both the establishment and the board of pharmacy.

Summary

Visits by regulatory agencies are rarely joyful events; they induce stress even under the best conditions. However, they are a necessary and expected part of pharmacy practice. Constant vigilance is needed to exercise the proper level of control over all areas of your compounding operation. Daily attention to the documents that reflect the care and importance you ascribe to your professional practice will allow these regulatory oversight visits to be as anxiety free as possible. ■

Consider Necessary Changes

After the inspection, pharmacy should explore possible policy or process changes as well as equipment and automation implementations necessary to address the issues the inspector raised. These changes should only be made upon careful consideration of all overlapping issues and never before the final inspection report has been received from the state board.

Photo courtesy of LDT Health Solutions, Inc

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