



EDUCATIONAL RESOURCES

Strategies for Responding to State Board Inspections

Denise M. Leard, Esq.

Michael R. Alexander, Esq.

Brown & Fortunato

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE





EDUCATIONAL RESOURCES

Receipt of Initial Complaint Letter/Visit by Board Investigator

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



Receipt of Initial Complaint Letter/Visit by Board Investigator

- In most cases, a pharmacy will first learn that a complaint has been filed with the state board of pharmacy against its license in one of two ways:
 - Notice by letter
 - Unannounced inspection/visit

Receipt of Initial Complaint Letter/Visit by Board Investigator

- The licensee will receive an official letter from the state board of pharmacy notifying it that an investigation has been opened and stating that it can either accept an agreed order being offered by board staff, provide a written response to the allegations, attend an upcoming Informal settlement conference, or request that the case be set for a trial at the state Office of Administrative Hearings; or
- A board investigator will appear unannounced at the pharmacy.

Receipt of Initial Complaint Letter/Visit by Board Investigator

- When you are being investigated or audited by your respective state board, it is important to find the right balance between preserving your rights and interests and not causing more issues by antagonizing the inspectors/investigators.

Receipt of Initial Complaint Letter/Visit by Board Investigator

- A significant part of this is the involvement of a health care attorney. It is important that the pharmacy immediately contact a health care attorney for assistance.
- Without the proper legal guidance, the pharmacy may tender an original response that severely prejudices its case or otherwise waives legal rights that impacts the pharmacy's case moving forward.
- This is particularly true when the first contact with the state board of pharmacy is an unexpected visit from a board investigator.



EDUCATIONAL RESOURCES

Preparing for Possibility of an Inspection

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



Pre-Inspection Checklist

- Being prepared for an inspection before one occurs will assist in the efficiency of the inspection and will help to prevent any additional red flags/concerns from coming up during the inspection.
- Prepare an inspection folder and include in it copies of licenses, certification, key records, and clear instructions on where to locate other key records/information.

Preparation of Pharmacist or Key Employee(s)

- Pharmacy inspections involve the balancing of two critical factors:
 - Maintaining good will/credibility with the state board inspectors.
 - Not waiving your rights or prejudicing your defense by being overly cooperative.
- An owner, manager, or other key employee needs to be available at all times to serve as the investigators' key point of contact.

Preparation of Pharmacist or Key Employee(s)

- Things to **Do** :
 - As soon as possible, notify your health care counsel.
 - Allow access for the site inspection. (Not allowing access is a red flag for investigators who can obtain orders granting them access.)
 - Assist in pulling and locating records.
 - Answer basic questions about simple issues such as the location of records/drugs.
 - Take notes of what questions are asked, what the investigators are focused on, and any issues the investigators flag during the inspection.

Preparation of Pharmacist or Key Employee(s)

- Things **Not to Do**:

- Volunteer information.
- Give an interview without counsel present. If asked, indicate that you are happy to visit with them after you have been able to consult with counsel.

Preparation of Other Employee(s)

- Instruct and periodically remind employees that in the event of an inspection, they are to assist and not obstruct the investigators.
- You can advise them that they are not required to answer substantive questions or to give interviews without first speaking with counsel.
- You cannot instruct them not to give interviews or to answer questions.



EDUCATIONAL RESOURCES

Letter of Investigation

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



Letter of Investigation

- If the pharmacy receives a letter of investigation, it is early in the process.
- The pharmacy can keep its doors open.
- There has been no action against the pharmacy's license.
- One of the most important things is that the investigative process is not open to the public.
- The pharmacy needs to prepare a detailed written response and possibly meet with the board investigator.

Letter of Investigation Response

- Because a Letter of Investigation is early in the process, the pharmacy has an opportunity to limit the scope of the issues the state board is concerned about as well as mitigate any potential for consequences or adverse actions.
- At this stage, state boards are more open to explanations, clarification, etc.
- It is important to maximize the effectiveness of the initial response.
 - This is not to say that state boards will consider additional information/arguments you submit later.
 - Unless there is a compelling reason for why these additional facts/arguments were not in the initial response, any supplement will carry less weight.

Letter of Investigation Response

- If you receive a Letter of Investigation, immediately take the following steps:
 - Notify counsel.
 - Begin gathering any requested records/documentation.
 - Identify additional information/records that either support your good points or provide context/clarification/mitigation on any weak points.



EDUCATIONAL RESOURCES

Site Inspection

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



Unannounced Inspection

- If the state board conducts an unannounced inspection of the pharmacy, there are usually areas of concern that the board have already identified. This does not mean the inspection will be limited to just these specific areas.
- Being organized and prepared for an inspection will hopefully help in preventing the scope of the inspection from expanding.

Site Inspection

- While site Inspections, by nature, are surprising and jarring events, it is important to maintain your composure.
- From the very start of an inspection, there are opportunities to begin working on your response/defense to any adverse finding:
 - A smooth, efficient inspection is critical.
 - As previously noted, the state board will already have areas of concern it is looking into.
 - Do not be surprised if the inspectors note issues.
 - If the inspection is overall smoothly run (i.e., you are not scrambling to locate information, records, etc.), the inspectors will, hopefully, be able to work through the process efficiently—you do not want the inspectors lingering.

Site Inspection

- A site inspection is an opportunity for you to gather information as well.
 - Ask simple questions about what concerns the state board has.
 - NOTE:
 - Do not be pushy about this; the inspectors may choose not to answer.
 - Take notes on what questions the inspectors have, what areas they are focused on, and any issues they identify during the inspection.
- After the inspection, prepare a detailed summary of the inspection to send to your health care counsel.
 - NOTE:
 - Label this summary as “Work-Product/Attorney Client Privilege” in order to flag it as confidential.



EDUCATIONAL RESOURCES

State Board of Pharmacy Investigators

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



State Board of Pharmacy Investigators

- The board investigator may be open and cooperative or may attempt to be intimidating.
- The goal of the investigator is to obtain information from the pharmacy.
- The investigator may ask the pharmacy to compose an affidavit on the spot responding to allegations that the pharmacy may have only just been made aware of.

State Board of Pharmacy Investigators

- If the board of pharmacy investigator is making an unannounced visit, it is not uncommon for him to be accompanied by an agent from the Drug Enforcement Administration.
- Such an appearance may include requesting pharmacy records, obtaining on-the-spot written statements from a pharmacist and other employees, and sometimes request that the pharmacy surrender its DEA controlled substances registration or else face unspecified consequences.



EDUCATIONAL RESOURCES

Common Issues of Review

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



Pharmacy Misconduct

- Examples of misconduct by a pharmacy include, but are not limited to, instances where:
 - The pharmacist fails to counsel the patient about how to take a new prescription (or a prescription with changed instructions) and its possible side effects;
 - A non-pharmacist employee is allowed to counsel the patient regarding the prescription;
 - The pharmacist is not present, and the prescription is filled by a non-pharmacist;

Pharmacy Misconduct

- Examples of misconduct by a pharmacy include, but are not limited to, instances where (cont'd):
 - The pharmacist fails to maintain the confidentiality of the patient's prescription;
 - The pharmacist appears unable to function safely (due to alcohol or drug abuse); or
 - The pharmacy is dirty, cluttered, or looks unsanitary.

Prescription Errors

- Examples of prescription error violations include, but are not limited to, instances where:
 - Incorrect information is entered on the label of the prescription container;
 - A prescription is dispensed with the wrong drug or wrong dosage;
 - A prescription is refilled without proper authorization from the prescribing physician;
 - A generic drug is substituted for a brand name drug without informing the patient of the substitution; or
 - A prescription is filled using drugs whose expiration date has passed.

Other Potential Issues

- As discussed previously, state board investigators are often accompanied by DEA agents.
- If the DEA is involved, there are concerns about the pharmacy's control and/or dispensing of controlled substances.
- This might relate to concerns about improper dispensing of controlled substances, concerns about diversion, and recordkeeping.
 - Overprescribing
 - Out-of-town doctors or customers
 - Drug security/storage
 - Pharmacy security
 - Missing/misplaced/misfiled records



EDUCATIONAL RESOURCES

What happens to a complaint that is filed with the Board of Pharmacy?

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



What happens to a complaint that is filed with the Board of Pharmacy?

- When the board receives a complaint, the board will notify the complainant by letter that the board has received the complaint.
- The complaint will be evaluated, and the pharmacy may be advised of the specific concerns and asked for an explanation of the incident.
- Depending on the type of complaint, the complainant's name can be kept confidential in some instances.

What happens to a complaint that is filed with the Board of Pharmacy?

- Upon completion of an investigation and confirmation that a violation of state pharmacy law has occurred, the board determines the disciplinary action to be taken.
- The action, based on the severity and type of violation, can range from an official warning and/or fine, to suspension, probation, or revocation of the license involved.



EDUCATIONAL RESOURCES

Overview of the Complaint Process

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



Summary of Key Steps in the Complaint Process

- Filing of a formal complaint
- Conference/hearing (formal or informal)
- Resolution
 - Informal settlement
 - Stipulated settlement
 - Board order
- Reportable discipline

Formal Complaint

- The complaint is a formal document saying that the board of pharmacy believes that the pharmacy committed a violation of its duties.
- Working with a health care attorney, the pharmacy needs to prepare a response to the complaint.
- The pharmacy and its health care attorney will collect facts, talk with witnesses, and possibly talk to experts in order to put together a package addressing what the pharmacy did or did not do was justified and within the standard of care of pharmacy practice.

Formal Complaint

- On the basis of the response, the pharmacy and its health care attorney will negotiate with the board of pharmacy and attempt to do one of two things:
 - have the case dismissed or
 - obtain a settlement that is reasonable.

Conference/Hearing Process

- Each state conducts the conference/hearing process differently.
- Some states provide for a two-part process.
 - An informal conference to determine if the matter can be resolved through an Informal Settlement.
 - If the matter is not resolved by the informal conference/settlement (or if the applicable state does not provide for this process), the parties will conduct a formal hearing/conference.

Conference/Hearing Process

- A conference/hearing is generally conducted as follows:
 - The pharmacy representative and/or its attorney will meet with a board panel/representative, as well as general counsel who serves as the board's counsel.
 - The general counsel will typically explain the procedures of the conference.

Conference/Hearing Process

- The board's attorney (i.e., the attorney who sent the preliminary notice letter) will:
 - Present the allegations set forth in the preliminary notice letter and the supporting documentary evidence that would be introduced in a public hearing if scheduling a hearing is necessary and
 - Answer any questions that the board panel may have regarding the allegations against the pharmacy and/or the supporting documentary evidence.
- Any complainant who chooses to attend the informal conference will be given an opportunity to speak to the board panel.

Conference/Hearing Process

- The pharmacy representative and/or its attorney will be given the opportunity to discuss any matter relating to the case and to show compliance with the law.
- The board panel will deliberate to make a recommendation for resolution of the case.
- If the board determines that there has been a violation, it will order discipline authorized by the state Pharmacy Act such as denial of licensure, reprimand, administrative penalty, restriction, probation, suspension, revocation, or retirement.

Settlement and Board Order

- Even in states that do not provide for an informal conference/hearing, the board will generally move to resolve the investigation through a proposed settlement and agreed order.
- The exact terms/nature of the settlement and order will vary from state to state.
- Depending on the severity of the allegations, the proposed resolution can vary from simply fines to license revocation.



EDUCATIONAL RESOURCES

Reportable Disciplinary Action

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE



Reportable Disciplinary Action

- All states enforce a provision that holds the failure to report a disciplinary action against a pharmacist license is grounds for additional discipline.
- The wisest approach is to report whatever discipline a state board of pharmacy takes against a pharmacist's license.
- For example, the California Board of Pharmacy has implemented a tight disciplinary process and, in so doing, has created a pharmacist renewal application that states “mandatory reporting of disciplinary action includes any suspension, revocation, voluntary surrender, probation, or any other restrictions applied to a pharmacist's license.”

Reportable Disciplinary Action

- If a disciplinary action is based on “failure to report” and not new incidents that involve patient safety, the backlash from reporting the additional discipline will normally be minimal (i.e., limited to fines).
- NOTE:
 - Consider involving counsel in reporting any disciplinary actions to other state boards.
 - Depending on how the dispute was resolved, a cover letter containing clarification or explanation is sometime helpful in limiting the impact that the discipline has in other states.



EDUCATIONAL RESOURCES

Questions?

Email us at
customerservice@achcu.com

 PHARMACY



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE





EDUCATIONAL RESOURCES

Thank you

Denise M. Leard, Esq. 

Brown & Fortunato, P.C.

905 S. Fillmore St., Ste. 400

Amarillo, TX 79101

dleard@bf-law.com | 806-345-6318

Michael R. Alexander, Esq.

Brown & Fortunato, P.C.

905 S. Fillmore St., Ste. 400

Amarillo, TX 79101

malexander@bf-law.com | 806-345-6340

 HOME HEALTH



ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE

