

Alternative Enforcement Model proposal

Presented by

Danny Martinez, Government Relations and External Affairs

California Pharmacists Association

Background

- In March of 2019, CPhA presented a proposal to the Board regarding establishing an “alternate disciplinary process” in response to growing concern from pharmacists about the inequity and unfairness of the disciplinary process. The Board did not pass the proposal but did start a conversation about the disciplinary process and what could be done to make it more equitable.
- In July of 2019, Board staff presented their own proposal to add in a mechanism that would facilitate a “pre-pleading” process, where pharmacists would be able to plead guilty to a charge in a manner that was more expedient than the current process.
 - This was a different direction than what CPhA had in mind initially. Nevertheless, CPhA submitted comments on this proposal along with some recommended changes that attempts to achieve the initial goal: fairness.

Current process (simplified)

- When pharmacies are inspected by the Board's inspectors, there are times where the inspector finds an alleged violation of law that may rise to the level of disciplinary action.
- If the determination has been made by the Board that an accusation is warranted, that is sent to the Attorney General's office for their legal review and analysis.
- If the Attorney General's office is satisfied that there is enough for an accusation to be filed on behalf of the Board, it then completes that process and the pharmacy/pharmacist is then served with the accusation.
- The pharmacy/pharmacist may choose to file a Notice of Defense or accept the accusation and accompanying discipline.
- If a Notice is filed, the process plays out before an administrative judge and a final decision is rendered.

Concerns with the process

- There have been instances in recent months and years where pharmacies/pharmacists either have received accusations from the Attorney General's office or were being cited/admonished, where the accusation was based off of faulty information.
 - In one case, a pharmacist had their license put on probation for violating a statute that was later repealed due to the statute being outdated and inapplicable to compounding practices.
 - In another case, a pharmacist was told their sterilization practices were not allowed under the law, even though there were no regulations or statutes that stated as such and was cited for a law that had nothing to do with the law they were told they were violating.
 - A third case involved a pharmacist who was asked by an inspector to provide various documentation and to sign their name to an admission of violation of the law before the actual investigation of an alleged violation occurred.
- Under current Administrative Procedures Act law, the pharmacy/pharmacist has no opportunity to speak with either Board staff or Board Members about anything related to the accusation, even if they have evidence of faulty information.

Board proposal

- This proposal attempts to meet the concerns previously discussed. However, one of the big sticking points is that in order to participate in this alternative process, a pharmacy/pharmacist must essentially admit guilt up front because this is a pre-pleading settlement.
 - *“Notwithstanding the provisions of Government Code section 11415.60(b), the Board may offer, and a licensee may accept, a stipulated agreement to license discipline without and in advance of the filing of an accusation or other agency pleading, under the following conditions...”*
- Of all the conditions it lists in order to participate in the process, what is missing? The ability to provide evidence that may demonstrate faulty information that was used to “substantiate” a violation of law.

Proposed Solution

- The Board's original proposal presented at the July 25 Full Board meeting in Anaheim was much closer to the solution than this most recent proposal. That original proposal, along with the changes suggested by CPhA, would get to the heart of the matter...an ability to speak with the Board in the event there is faulty information.

Proposal to Add Section 4300.2 (red is CPhA's proposed additions and blue is CPhA's proposed strikeouts)

Notwithstanding the provisions of Government Code section 11415.60, **a committee consisting of the Executive Officer and two Board members, one public member and one professional member**, may offer, and a licensee may accept, **either a stipulated agreement to license discipline or an opportunity to provide mitigation evidence** without and in advance of the filing of an accusation or other agency pleading, under the following conditions:

1. The board **staff** conducted an inspection or investigation as provided for in this chapter and **substantiated alleges** violations of law **that warrant disciplinary action**.
2. The board **staff** advised the licensee of the **substantiated alleged** violations in writing.
3. The licensee, within 15 days of being advised of the **alleged** violations, notified the board in writing of his or her willingness to **conditionally waive the administrative adjudication provisions of the Administrative Procedure Act, including notice and hearing requirements, and to for purposes of considering a pre-filing settlement as an alternative to action taken on the basis of a pleading.** The ~~Executive Officer~~ **committee** retains discretionary authority to extend the deadline to respond in writing beyond 15 days.
 - (i) **The licensee may submit mitigation evidence to the committee for their consideration as an alternative to accepting a settlement.**
4. ~~The~~ **If an** agreed settlement ~~is based on the violations alleged or found includes, and any~~ discipline ~~proposed is~~ **by the Board arising from violations that are substantiated, that discipline shall be** consistent with the board's Disciplinary Guidelines.
5. If no pre-filing settlement between the ~~Executive Officer~~ **committee** and the licensee is agreed to in writing **and in good faith by both parties**, within 60 days of the licensee's notification of waiver, the ~~Executive Officer~~ **committee** may proceed to direct the Attorney General's Office to prepare the appropriate pleading.
6. Any pre-filing settlement agreement reached between the ~~Executive Officer~~ **committee** and a licensee is contingent on approval by the board ~~itself~~. The board ~~itself~~ retains full authority and discretion to adopt, **request modification to**, or reject any such agreement. If the **board requests modification to an** agreement ~~is rejected by the board itself~~, the ~~Executive Officer~~ **committee** may offer a revised pre-filing settlement agreement consistent with any guidance from the board. ~~itself~~ **If the board rejects the agreement**, the ~~Executive Officer~~ **committee** ~~or~~ may proceed to direct the Attorney General's Office to prepare the appropriate pleading. **The board members who participate in the committee shall recuse themselves from voting or participating on the agreement.**

QUESTIONS?