

- 7) Provides that, following an administrative hearing, an Administrative Law Judge (ALJ) prepares a proposed decision for consideration by the agency. Authorizes the agency to adopt the proposed decision, reduce or otherwise mitigate the proposed penalty, make technical or other minor changes, reject the proposed decision and remand the case for further proceedings, or reject the proposed decision and decide the case upon the administrative record, with or without taking additional evidence, as specified. (GC § 11517.)
- 8) Authorizes a party aggrieved by a final agency decision to obtain judicial review by filing a petition for writ of administrative mandate. (GC § 11523; Code Civ. Proc. § 1094.5.)

This bill:

- 1) Authorizes the Board, notwithstanding the APA, to negotiate and enter into a stipulated settlement and disciplinary order with a licensee before filing an accusation or other disciplinary pleading.
- 2) Requires, before a pre-accusation settlement may be considered, that Board enforcement staff complete an inspection or investigation, substantiate violations of law, provide the licensee with written findings of those violations, and notify the licensee of potential eligibility for the settlement process.
- 3) Requires the licensee, within 15 days of receiving the findings, to waive the notice and hearing provisions of the APA and elect to participate in the settlement process in lieu of formal administrative adjudication.
- 4) Requires the licensee to submit mitigation and rehabilitation information consistent with the Board's disciplinary guidelines.
- 5) Establishes a settlement committee consisting of the Executive Officer, two Board members, one public member, and one licensee member to review the matter and, in its sole discretion, determine whether to extend a stipulated settlement offer consistent with the Board's disciplinary guidelines.
- 6) Requires any stipulated settlement to be reached within 60 calendar days, unless extended by the committee for good cause or while good-faith settlement discussions are ongoing; requires the Board to file a formal disciplinary pleading if no agreement is reached.
- 7) Requires the stipulated settlement to be approved by the full Board, with members of the settlement committee recused from participating in the Board's consideration of the settlement.
- 8) Provides that an approved stipulated settlement becomes a public record, but if the Board rejects the settlement, the proposed agreement has no force or effect, may not disqualify the Board from further proceedings, and the Board must file the appropriate disciplinary pleading.

- 9) Specifies that the bill does not limit the Board's existing authority to negotiate stipulated settlements after an accusation has been filed.

FISCAL EFFECT: This bill is keyed fiscal by Legislative Counsel. According to the Assembly Committee on Appropriations, the Board states this bill shifts legal workload from the Office of the Attorney General to the Department of Consumer Affairs Legal Office. The Board estimates 90 cases per year and costs of \$284,000 in 2026-27 and \$276,000 in 2027-28 and ongoing for an Attorney III position. The Board states it could incur expenditures on implementation activities that will exceed the Board's usual implementation costs that focus on education. However, the Board is unable to quantify the costs. The DCA Office of Information Services estimates adding new enforcement codes will cost \$1,000, which is absorbable.

COMMENTS:

1. **Purpose.** The Alliance for Pharmacy Compounding is the sponsor of this bill. According to the Author, "This bill remedies a situation that requires formal accusations to be filed against licensees. Instead, this measure will allow the Board of Pharmacy and licensees to enter into stipulated settlements and disciplinary orders before an accusation is filed. This improves efficiency, conserves state resources, and allows the Board to focus its efforts on matters that jeopardize public health and safety." The Author states that "An example of money lost by the BOP in 2022/2023 due to lost ALJ cases are three sterile compounding cases. The BOP brought the same charge of adulteration in all three cases. They lost more money in each subsequent case as each judge granted less in requested recovery costs as the BOP continued to lose on the same adulteration issue."
2. **Background.** The Board regulates over 50,700 pharmacists, 1,300 advanced practice pharmacists, 4,400 intern pharmacists, and 65,700 pharmacy technicians across a total of 32 licensing programs. In addition to regulating professionals, the Board oversees and licenses pharmacies, clinics, wholesalers, third-party logistic providers, and automated drug delivery systems. Pharmacy Law states that "protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount."

The Board has its own enforcement staff, which includes field inspectors responsible for conducting investigations and inspections of pharmacies as well as sterile compounding and outsourcing facilities. The Board's enforcement program is its largest budget expenditure, historically comprising about 64 percent of its total operating expenses. The Board's Enforcement Unit regularly engages in investigations of licensees that may result in disciplinary action, as well as cases involving unlicensed activity. For example, between Fiscal Years 2021-22 through 2023-24, the BOP completed 8,719 investigations, referred 839 investigations for formal discipline, issued 4,092 citations, revoked or accepted surrender of 551 licenses, and placed 344 licensees on probation.

On average, the Board consistently receives around 3,500 complaints from the public or other sources per year. These complaints are then categorized into

priorities based on the potential risk to public health and safety. The highest priority complaints—ranked 1 and 2—involve offenses such as impaired licensee on duty, prescription drug theft, and the unauthorized furnishing of prescription drugs. Priority 3 and 4 complaints are less serious and involve offenses like failure to provide patient consultation, prescription errors, working with an expired license, and general noncompliance issues. These complaints are most likely to result in the issuance of a fine or a letter of admonishment. High-priority complaints are referred to the Attorney General, where the Board files formal accusations seeking discipline against the licensee. Tools such as interim suspension orders are available in appropriate cases to protect the public while disciplinary proceedings are pending.

Most disciplinary actions brought by licensing boards within the Department of Consumer Affairs, including the Board, are conducted pursuant to the APA (Government Code Section 11500 et seq.). Under the APA, an accusation is prosecuted by the Attorney General before an Administrative Law Judge (ALJ) of the Office of Administrative Hearings, who conducts an evidentiary hearing and prepares a proposed decision containing findings of fact, legal conclusions, and a recommended disposition.

The ALJ's proposed decision, however, does not constitute the final disciplinary action of the licensing board. Rather, Government Code section 11517 vests final decision-making authority in the agency. Upon receiving a proposed decision, the licensing board may adopt the proposed decision, reduce or otherwise mitigate the proposed penalty, make technical or other non-substantive changes, reject the proposed decision and remand the matter for further proceedings before the ALJ, or reject the proposed decision and decide the case itself upon the administrative record, with or without taking additional evidence, as authorized by Government Code section 11517(c).

The APA assigns distinct responsibilities to the ALJ and the licensing board. The ALJ serves as an independent hearing officer responsible for conducting the evidentiary hearing and preparing a proposed decision, while the licensing board—whose members are appointed pursuant to statute and charged with administering and enforcing the applicable practice act—retains responsibility for determining the final disposition of disciplinary matters. Accordingly, the APA preserves the board's authority to exercise its independent judgment before issuing a final decision.

When a board rejects a proposed decision and elects to decide the matter itself, the APA establishes additional procedural safeguards. The board must base its decision on the administrative record, may consider additional evidence only as authorized by statute, must provide the parties an opportunity to present written argument before the board, and must issue a written decision supported by findings. The board's final decision is then subject to judicial review through a petition for writ of administrative mandate pursuant to Government Code section 11523 and Code of Civil Procedure section 1094.5. In disciplinary actions involving professional licenses, courts generally exercise independent judgment review where the license constitutes a fundamental vested right.

Licensing boards like the Board have exercised this authority on prior occasions by rejecting proposed decisions pursuant to Government Code section 11517 and issuing final decisions based upon the administrative record. Accordingly, a board's authority to reject an ALJ's proposed decision is an established feature of California's administrative disciplinary process, rather than an extraordinary remedy. The APA reflects a balance between independent adjudication by the Office of Administrative Hearings and the authority of the licensing board to make the final disciplinary decision under Government Code section 11517.

Existing law also authorizes parties to resolve disciplinary matters through stipulated settlements. Under Government Code section 11415.60, agencies may settle adjudicative proceedings before or after issuance of an agency pleading. However, in proceedings to determine whether an occupational license should be revoked, suspended, limited, or conditioned, a settlement generally may not be made before issuance of the agency pleading. In professional licensing disciplinary proceedings, that pleading is typically an accusation, the formal charging document filed by the Attorney General on behalf of the licensing board that identifies the alleged violations of the applicable practice act and serves as the basis for administrative adjudication. As a result, stipulated settlements involving license discipline ordinarily occur *after* an accusation has been filed and before the matter proceeds to an administrative hearing.

The Board settles approximately 80 percent of its disciplinary cases post-accusation. A total of 413 post-accusation case settlements occurred between Fiscal Years 2021-22 through 2023-24. The Board is authorized to seek cost recovery for expenses incurred during a successful investigation in cases where the licensee is ultimately subjected to discipline. However, cost recovery is not always awarded by administrative law judges. The Board was awarded approximately \$1.4 million in cost recovery in Fiscal Year 2023-24.

For most cases resulting in a citation and fine or a letter of admonishment, the Board is limited to issuing fines of \$5,000 to each licensee investigated in a single case. Some specified violations carry higher maximum fines; for example, the Board may issue fines of \$25,000 per prescription for internet sales of drugs where no underlying appropriate examination occurred. When determining what fines to assess, the Board considers the gravity of the violation, history of previous violations, extent to which the cited individual is cooperating with the investigation, and other elements suggesting good or bad faith on behalf of the licensee. As of 2022, the Board has authority to bring an action for up to \$100,000 in fines for repeated violations by pharmacies operating under common ownership or management within a chain community pharmacy, or up to \$150,000 for any violation of the Pharmacy Law demonstrated to be the result of a written policy or which was expressly encouraged by the common owner or manager.

Licensees may appeal a citation issued by the Board by requesting an informal office conference. The office conference allows the licensee the opportunity to present additional or mitigating information to the Board's executive officer or designee and a supervising inspector. Upon conclusion, staff may affirm, modify, or dismiss the citation or affirm or dismiss the letter of admonishment. A licensee may also submit a formal appeal to the Board within thirty days of the issuance of a

citation. Appeals are conducted pursuant to the APA by an administrative law judge who renders a decision, which is presented to the Board for adoption or rejection.

3. **Arguments in Support.** The Alliance for Pharmacy Compounding writes that “Creating a defined interim step would allow the Board and licensees to engage in a more solutions-oriented process, helping to resolve appropriate cases more efficiently while reserving formal referral and litigation for matters that warrant that level of enforcement...It also supports greater consistency and predictability for licensees operating in good faith within a complex regulatory environment. Compounding pharmacies play a critical role in patient care by preparing medications tailored to individual needs, particularly when FDA-approved options are not appropriate or available. A regulatory approach that allows for early engagement and resolution helps ensure that compliant pharmacies can continue to serve patients without unnecessary disruption, while still holding bad actors accountable.”
4. **Policy Comments.** Unlike existing practice, the bill authorizes disciplinary negotiations before an accusation is filed. By the time an accusation is filed, the Board has completed a lengthy investigation, determined that violations of the Pharmacy Law have been substantiated, and referred the matter to the Attorney General for formal disciplinary proceedings. The filing of an accusation marks the beginning of the formal administrative adjudication process, not the beginning of the investigation, and under existing law the parties already retain broad authority to negotiate and resolve disciplinary matters through stipulated settlements without proceeding to an administrative hearing.

The bill expressly overrides Government Code section 11415.60 by authorizing qualifying disciplinary matters to be resolved before an accusation is filed, creating a disciplinary process applicable only to the Board of Pharmacy. Existing law establishes a comprehensive and generally uniform administrative adjudication framework governing disciplinary actions brought by licensing boards within the Department of Consumer Affairs. That framework contemplates the filing of an accusation before a matter is resolved by settlement while still encouraging negotiated resolutions where appropriate. It is unclear why a Board-specific exception to these generally applicable procedural requirements is necessary.

Under current law, an accusation is the formal charging document filed by the Attorney General on behalf of the licensing board identifying the alleged statutory violations supporting the proposed discipline. If a disciplinary matter settles, both the accusation and the stipulated settlement generally become public records. Under AB 2141, however, qualifying matters could be resolved entirely through a pre-accusation stipulated settlement. Although the final stipulated settlement would become a public record if approved by the Board, no formal accusation identifying the alleged violations, legal causes for discipline, or factual basis supporting the Board's enforcement action would ever be filed. As a result, members of the public, employers, and other interested parties may have less information regarding the nature of the violations underlying the Board's disciplinary action.

The APA reflects a longstanding policy of providing a consistent and transparent disciplinary framework applicable to licensing boards throughout the Department of

Consumer Affairs while preserving flexibility for negotiated settlements. AB 2141 would depart from that framework for a single licensing board without making comparable changes applicable to other DCA boards. If enacted, the bill may establish a precedent for future requests from professions seeking board-specific exemptions from the APA based on dissatisfaction with discipline, raising broader questions regarding the consistency, transparency, and uniformity of California's professional licensing disciplinary system.

SUPPORT AND OPPOSITION:

Support:

Alliance for Pharmacy Compounding
California Naturopathic Doctors Association

Opposition:

None received

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