



Enforcement and Compounding Committee Report July 9, 2020

Maria Serpa, Licensee Member, Chair
Albert Wong, Licensee Member, Vice-Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member

a. Call to Order and Establishment of Quorum

b. Public Comment on Items Not on the Agenda, Matters for Future Meetings

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

c. Presentation on the Administrative Case Process

Attachment 1

During the meeting members will receive a presentation by Deputy Attorney General Kristina Jarvis on the administrative case process established in the Government Code.

In general terms the formal administrative case process is initiated after an investigation is conducted that reveals violations that, based on the egregious of the violations identified, result in referral of the Office of the Attorney General (AGO) for discipline. Upon referral to the AGO, the assigned attorney will review the investigation and evidence and independently evaluate if violations occurred. Should such a determination be made, the attorney will file an accusation. Following the filing of an accusation, a pleading document that details the allegations of the case. Respondents are provided the option to refute the allegations and indicate their intention to do so by filing a Notice of Defense. Upon receipt of a Notice of Defense, the assigned attorney will request to set the matter for hearing as well as inquire about settlement. Typically, the case is resolved in one of two manners, the disciplinary outcome is reached through a settlement agreement (stipulation) or a hearing is conducted followed by a proposed decision being rendered by an administrative law judge. In either manner, the Board is ultimate decision maker and votes to either adopt or nonadopt a decision. Depending on the outcome of the vote, additional steps occur through the nonadoption process.

Provided below is historical information on accusations filed, disciplinary case outcomes, and nonadoptions for the past five fiscal years.

Accusations	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
Accusations Filed	289	239	267	235	216
Accusations Withdrawn	11	41	26	20	13
Accusations Dismissed	4	5	1	0	2
Accusations Declined	0	0	1	2	0

Provided below is historical information on the number of disciplinary outcomes resulting from accusation matters. Consistent with the provisions of the APA, members vote on each disciplinary outcome.

Disciplinary Outcomes	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
Revocation	139	146	112	140	111
Voluntary Surrender	72	101	78	82	82
Suspension	0	0	0	0	0
Probation with Suspension	20	23	12	8	0
Probation	77	95	105	97	99
Probationary License Issued	13	7	5	4	10
Other	0	2	7	1	63

Further, consistent with the APA, the Board can nonadopt a proposed decision or stipulation. Below is historical information on the number of decisions nonadopted by the Board.

Nonadoptions	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
Stipulated Settlements Nonadopted	10	12	10	10	2
Proposed Decisions Nonadopted	5	1	3	0	1

Provided in **Attachment 1** is a general flowchart of the disciplinary process described above.

d. Discussion and Consideration of Board’s Citation and Fine Program.

Attachment 2

Relevant Law

Business and Professions Code section 4314 establishes the authority for the board to issue citations which may include fines and/or orders of abatement. As included in this section, the order of abatement may include completion of continuing education courses and specifies that any such continuing education courses shall be in addition to those required for license renewal.

Title 16, California Code of Regulations Sections 1775-1775.4 provide the board’s regulations governing its citation and fine program. More specifically, Section 1775 includes the authority of the executive officer or designee to issue citations which may contain either or both an administrative fine and an order of abatement and details the types of violation for which a citation may be issued.

Section 1775.2 establishes the factors to be considered in assessing an administrative fine. Such factors include:

1. The gravity of the violation.
2. The good or bad faith of the cited person or entity.
3. The history of previous violations.
4. Evidence that the violation was or was not willful.
5. The extent to which the cited person or entity has cooperated with the board’s investigation.
6. The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violations.
7. Other matters as may be appropriate.
8. The number of violations found in the investigation.

Section 1775.3 establishes the order of abatement (OOA) compliance requirements.

Background

As part of the May 2018 Board Meeting, members suggested that staff consider using the abatement provisions, especially in cases where the violations involved a medication error. Since that time, board staff have been integrating abatements. Further, as part of the Board’s October 2018 Board Meeting, the board updated its Strategic Plan to include additional strategic goals. Related to this agenda item, Goal 2.10, Evaluation of the Board’s Citation and Fine Program, was added. Since that time, the Committee has received annual reports on the program. During the meeting, members will receive an annual report on the program.

Citation and Fine	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
Citations Issued	1,975	1,936	2,168	1,144	1,426
Average Days to Complete	311	363	381	381	400
Order of Abatements Issued	20	29	30	224	415
Amount of Fines Assessed	\$2,265,150	\$2,355,150	\$2,268,600	\$1,176,450	\$1,462,300
Amount Collected	\$2,119,894	\$2,032,745	\$2,027,656	\$1,210,086	\$963,446

Attachment 2 includes a copy of the relevant laws.

e. Discussion and Consideration of Board’s Inspection Program

Background

Pharmacy inspections are conducted by board inspectors and are triggered for a variety of reasons including receipt of consumer complaints, required annual inspections for specific license types or routine inspections to determine if a pharmacy complies with all state and federal laws and regulations. This process also involves an educational component, wherein licensees have an opportunity to meet and speak with board inspectors, ask questions and receive guidance, and pharmacy law updates. The board established a policy to have all pharmacies inspected at least once every four years. Routine inspections can occur for several reasons. During fiscal year 2019/2020, 1,071 routine inspections were performed, 507 of which were performed independent of any other triggering event, e.g. complaint investigation, sterile compounding inspection, probation inspection, etc.

During the meeting a presentation will be provided detailing inspection information focusing primarily on routine inspections. Information will be provided on the most frequent corrections identified as well as the most frequent violations.

f. Discussion and Consideration of Board's Enforcement Statistics

Full fiscal year information will be provided as a supplemental information, however, as of June 15, 2020, the board received 2421 complaints and has closed 2926 investigations. The board has issued 316 Letters of Admonishment, 1351 Citations and referred 223 cases to the Office of the Attorney General. The board has secured 7 interim suspension orders, been granted 4 Penal Code 23 suspensions, and issued 1 Cease and Desist. Further, the board has revoked 109 licenses, accepted the disciplinary surrender of 95 licenses, denied 10 applications, and imposed other levels of discipline against 137 licensees and/or applicants.

As of June 15, 2020, the board currently has 1371 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

- 42 cases under review for assignment, averaging 8 days
- 756 cases under investigation, averaging 170days
- 266 investigations under supervisor review, averaging 41 days
- 180 investigations under second level review, averaging 42 days
- 127 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 26 days

Annual enforcement statistics will be provided in advance of the meeting.

g. Future Committee Meeting Dates

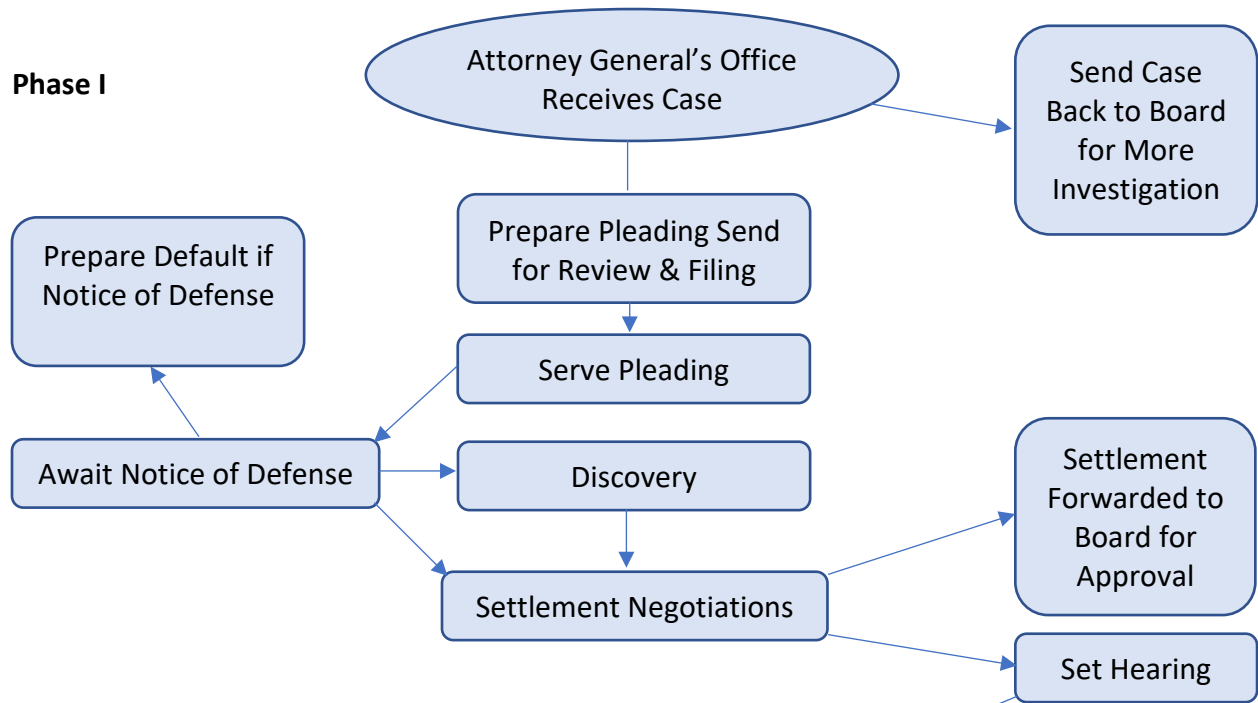
The following are the committee dates scheduled for 2020:

- October 27, 2020

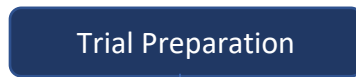
Attachment 1

GENERAL CASE PROCESS

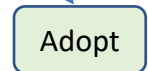
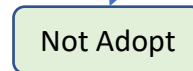
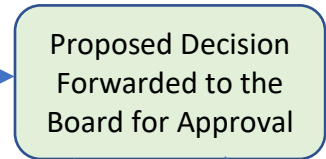
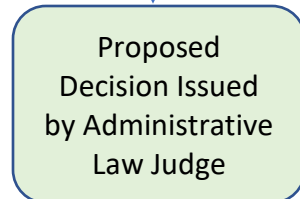
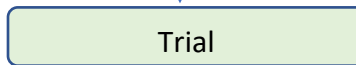
Phase I



Phase II



Phase III



Attachment 2

State of California

BUSINESS AND PROFESSIONS CODE

Section 4314

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

(Amended by Stats. 2007, Ch. 588, Sec. 54. Effective January 1, 2008.)



STATE OF CALIFORNIA
AUTHENTICATED
ELECTRONIC LEGAL MATERIAL

§ 1775. Issuing Citations.

(a) The executive officer or his/her designee may issue a citation which may contain either or both an administrative fine and an order of abatement for:

- (1) A violation of the Pharmacy Law (Business and Professions Code 4000 et seq.).
- (2) A violation of a regulation adopted by the board.
- (3) A violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).
- (4) Defaulting on a United States Department of Health and Human Services education loan.
- (5) A violation of other statutes or regulations for which the board may issue a citation.

(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the individual personally or by certified mail.

(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. If a hearing is not requested pursuant to this article, payment of any fine shall not constitute an admission of the violation charged.

Note: Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Sections 125.9, 148 and 685, Business and Professions Code; and Section 56.36, Civil Code.

§ 1775.1. Amount of Fines.

(a) The fine for violating the Pharmacy Law or regulations adopted pursuant thereto shall not exceed the amount specified in Section 125.9 of the Business and Professions Code, except for a fine issued pursuant to Section 4067 or Section 4127.4 of the Business and Professions Code.

(b) The fine for violating the Confidentiality of Medical Information Act shall not exceed the amount specified in Section 56.36 of the Civil Code.

(c) The fine for defaulting on a United States Department of Health and Human Services education loan shall not exceed \$2,500.

(d) Failure of a person or entity cited to pay a fine within 30 days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the board. When a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

Note: Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Sections 125.9, 148, 685, 4067 and 4127.4, Business and Professions Code; and Section 56.36, Civil Code.

§ 1775.2. Factors Considered.

In assessing the amount of an administrative fine, except violations of the Confidentiality of Medical Information Act and when assessing a fine pursuant to Business and Professions Code section 685, the following factors shall be considered:

- (a) The gravity of the violation.
- (b) The good or bad faith of the cited person or entity.
- (c) The history of previous violations.
- (d) Evidence that the violation was or was not willful.
- (e) The extent to which the cited person or entity has cooperated with the board's investigation.
- (f) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- (g) Other matters as may be appropriate.
- (h) The number of violations found in the investigation.

Note: Authority cited: Sections 125.9, 148, 685 and 4005, Business and Professions Code; and Section 56.36, Civil Code. Reference: Sections 125.9, 148 and 685, Business and Professions Code; and Section 56.36, Civil Code.

§ 1775.3. Compliance with Orders of Abatement.

(a) If a cited person or entity who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request, from the board, an extension of time in which to complete the correction. Such a request shall be in writing and shall be made within the time set forth for abatement.

(b) When an order of abatement is not contested or if the order is appealed and the person or entity cited does not prevail, failure to abate the violation charged within the time specified in the citation shall constitute a violation and failure to comply with the order of abatement. An order of abatement shall either be personally served or mailed by certified mail. Failure to comply with an order of abatement shall constitute a ground for revocation or suspension of the license, permit, or registration.

Note: Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

§ 1775.4. Contested Citations.

(a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act. (Government Code Section 11500 et seq.)

Title 16. Professional and Vocational Regulations
Division 17. California State Board of Pharmacy
Article 9. Citations and Fines
16 CCR § 1775 -1775.4

(b) In addition to requesting a hearing, as provided for in subdivision (a), the person or entity cited may, within 14 calendar days after service of a citation, submit a written request for an informal office conference. The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendar days of receiving the request.

(c) The executive officer or his/her designee shall hold an informal office conference upon request as provided for in subdivision (b) with the person or entity cited and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer or his/her designee may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the informal office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.

(d) The person or entity cited does not waive their request for a hearing to contest a citation by requesting an informal office conference after which the citation is affirmed by the executive officer or his/her designee. If the citation is dismissed after the informal office conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation.

Note: Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code.
Reference: Sections 125.9 and 148, Business and Professions Code.