

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833 Phone: (916) 518-3100 Fax: (916) 574-8618 www.pharmacy.ca.gov



Organizational Development Committee

Seung Oh, Licensee Member, President Jessica Crowley, Licensee Member, Vice-President

a. Budget Report

Fiscal Year 2023/2024

The new fiscal year began July 1, 2023. Although detailed budget information is not yet available, the Board's authorized expenditure is projected to be \$34,129,000. Expenditure and revenue data for the first eight months of the fiscal year are provided below.

Source	Amount	Percentage
Licensing	\$25,448,423	91%
Cost Recovery	\$728,964	3%
Citation Fines	\$1,278,669	4%
Interest	\$441,823	2%

Revenue Sources Table: FY 2023/2024

Further, the Board estimates it has expended \$20,785,000 during the first eight months of the fiscal year. The largest expenditure categories are detailed below.

Expenditures Table: FY 2023/2024

Source	Amount	Percentage
Personnel	\$14,148,000	68%
Pro rata	\$3,276,300	16%
Enforcement	\$2,395,100	12%
Facilities Operations	\$406,500	2%

Fund Condition

Below is a summary of the Analysis of Fund Condition prepared by the Department which includes the fee increase effective January 1, 2025.

Fiscal Year	Fund Balance	Months in Reserve*
2022/2023	\$17,251.000	6.0
2023/2024	\$18,323,000	5.8
2024/2025	\$17,870,000	5.6
2025/2026	\$16,034,000	4.8
2026/2027	\$13,057,000	3.8

Fund	Condition	Table

*Business and Professions Code section 4400 (p) provides that it is the intent of the Legislature that, in setting fees, the Board shall seek to maintain a reserve in the Board's fund equal to approximately one year's operating expenditures.

Attachment 1 includes the Analysis of Fund Condition prepared by the Department and detailed budget charts.

b. Board Member Attendance Information and Mail Vote Information

Board Member Attendance Information

Attachment 2 includes a summary of Board member attendance at Committee and Board meetings for FY 2023/24.

Mail Vote Information

Attachment 3 includes member participation in the mail vote process for FY 2023/24.

c. Personnel Update

As of April 4, 2024, the Board has five vacant positions detailed below.

- 1 Inspector position
- 1 Licensing position
- 2 Enforcement positions
- 1 Chief of Enforcement position

d. Review of Proposed Changes to Board Procedure Manual

<u>Background</u>

The Board's procedure manual serves as a resource guide for members, outlining the processes and protocols governing the Board's operations. It includes:

- 1. An overview of the Board and its general rules of conduct.
- 2. Procedures for meetings.
- 3. Information on travel arrangements and per diem allowances.
- 4. Duties of officers, provisions for election of officers, rules of conduct, and training requirements for Board members.
- 5. Policy positions of the Board.
- 6. Overview of enforcement mechanisms.

For Member Consideration and Discussion

During the meeting, members will review proposed revisions to the manual, with new text indicated by underline and deleted text by strikethrough. If members agree with the proposed changes, staff will finalize updates for release to members and posting on the Board's website.

Suggested Motion: Recommend approval of the updated Board Procedure Manual [insert "as presented" or "consistent with the Board's discussion."

Attachment 4 includes the proposed updated manual without referenced appendices.

e. Future Meeting Dates

Attachment 5 includes a list of meeting dates scheduled for 2024.

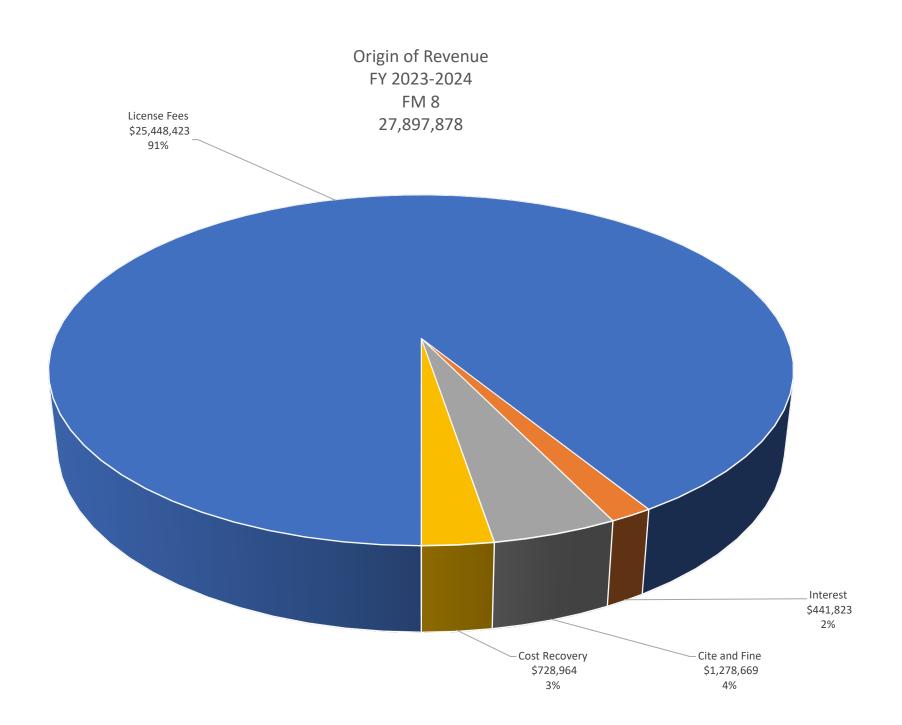
Attachment 1

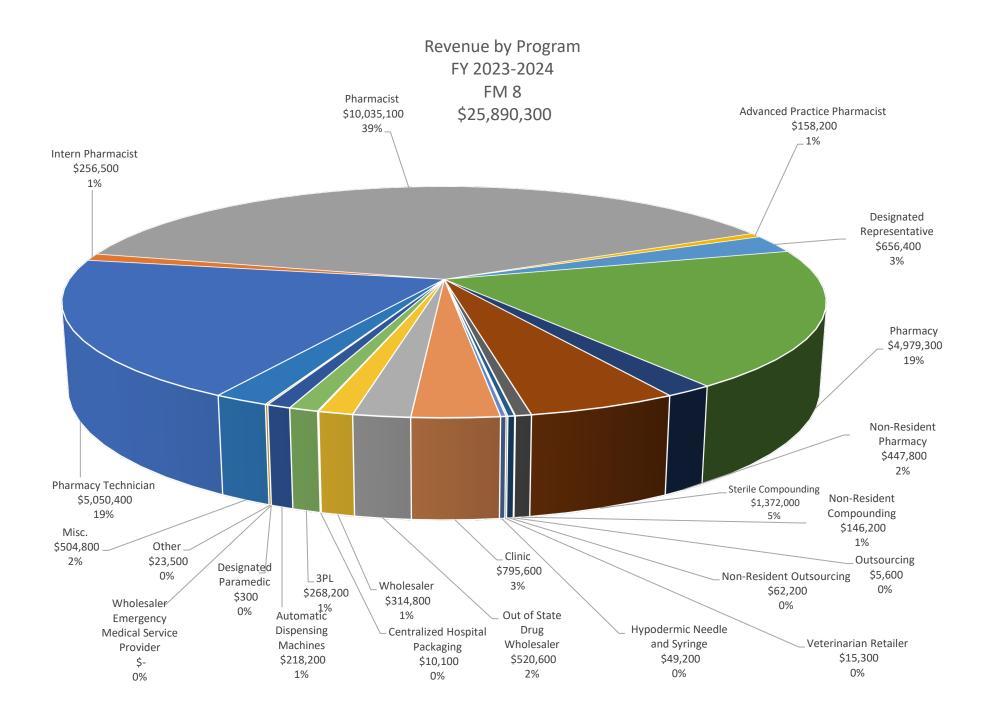
0767 - Pharmacy Board Contingent Fund Analysis of Fund Condition

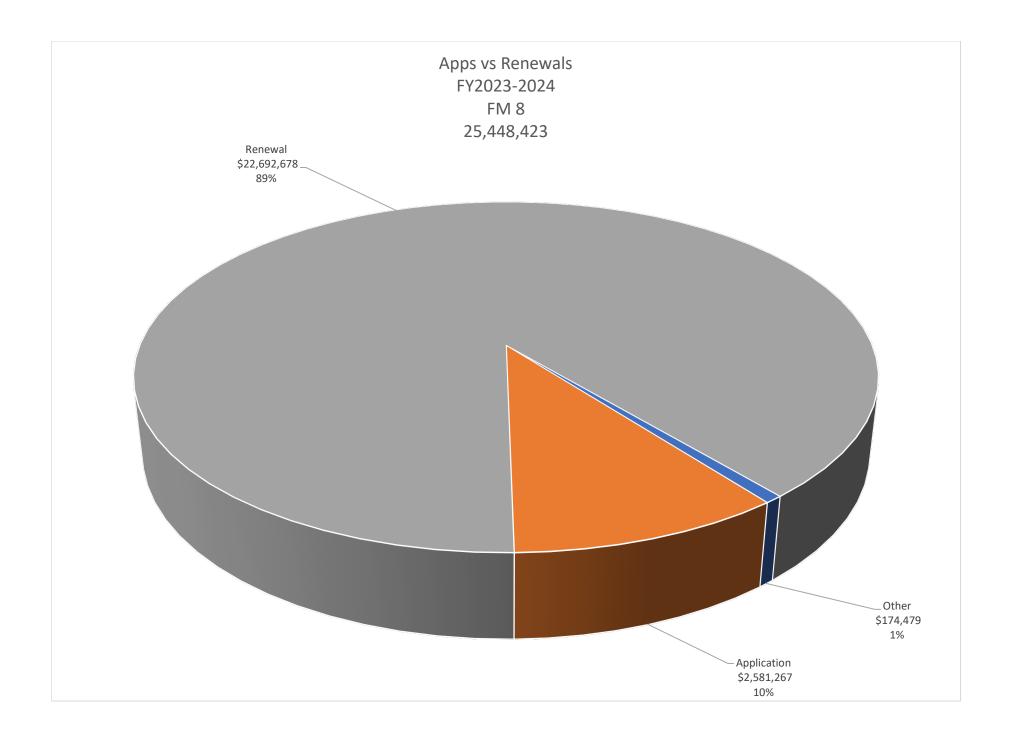
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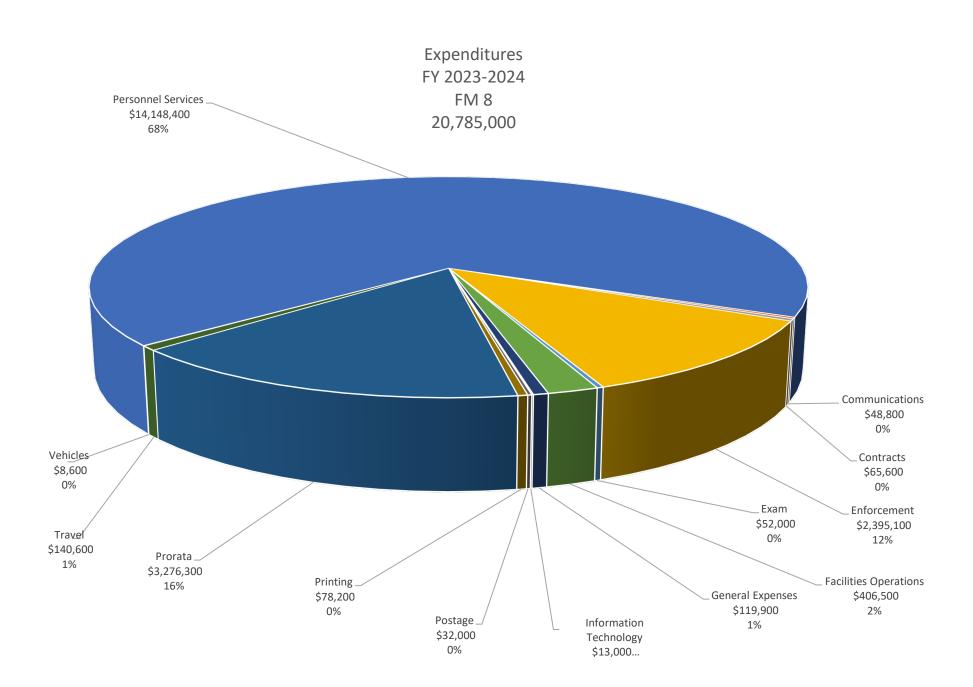
2024-25 Governor's Budget w/FM 8 Projections and Fee Increase					
	ACTUAL 2022-23	CY 2023-24	BY 2024-25	BY +1 2025-26	BY +2 2026-27
BEGINNING BALANCE	\$ 13,847	\$ 17,251	\$ 18,323	\$ 17,870	\$ 16,034
Prior Year Adjustment	\$8	\$ -	\$ -	\$ -	\$ -
Adjusted Beginning Balance	\$ 13,855	\$ 17,251	\$ 18,323	\$ 17,870	\$ 16,034
REVENUES, TRANSFERS AND OTHER ADJUSTMENTS					
Revenues					
4121200 - Delinquent fees	\$ 264	\$ 271	\$ 215	\$ 215	
4121200 - Delinquent fees (Fee Increase effective 1/1/2025)	\$ -	\$ -	\$ -14	\$-28	\$-28
4127400 - Renewal fees	\$ 28,080	\$ 28,000	\$ 28,092	\$ 28,092	\$ 28,092
4127400 - Renewal fees (Fee Increase effective 1/1/2025)	\$ -	\$ -	\$ 774	\$ 1,548	\$ 1,548
4129200 - Other regulatory fees	\$ 1,932	\$ 2,197	\$ 946	\$ 946	\$ 946
4129200 - Other regulatory fees (Fee Increase effective 1/1/2025)	\$ -	\$ -	1 -	\$ 508	\$ 508
4129400 - Other regulatory licenses and permits	\$ 4,516	\$ 4,249	\$ 4,196	\$ 4,196	\$ 4,196
4129400 - Other regulatory licenses and permits (Fee Increase effective 1/1/2025)	\$ -	\$ -	\$ 527	\$ 1,054	\$ 1,054
4143500 - Miscellaneous Services to the Public	\$2	\$1	\$ -	\$ -	\$-
4163000 - Income from surplus money investments	\$ 484	\$ 727	\$ 189	\$ 237	\$ 193
4171400 - Escheat of unclaimed checks and warrants	\$ 25	\$ 20	\$ -	\$ -	\$-
4171500 - Escheat Unclaimed Property	\$3	\$ 30	\$ -	\$ -	\$-
4172500 - Miscellaneous revenues	\$6	\$ 7	\$ -	\$ -	\$ -
Totals, Revenues	\$ 35,312	\$ 35,502	\$ 35,179	\$ 36,768	\$ 36,724
Loan from/to the Pharmacy Board Contingent Fund (0767) from/to the General Fund (0001) per Item 1111-011-0767, Budget Act of 2020	\$ -	\$ -	\$ 2,400	\$ -	\$ -
Totals, Transfers and Other Adjustments	\$ -	\$ -	\$ 2,400	\$ -	\$ -
TOTALS, REVENUES, TRANSFERS AND OTHER ADJUSTMENTS	\$ 35,312	\$ 35,502	\$ 37,579	\$ 36,768	\$ 36,724
TOTAL RESOURCES	\$ 49,167	\$ 52,753	\$ 55,902	\$ 54,638	\$ 52,758
Expenditures:					
. 1111 Department of Consumer Affairs Regulatory Boards, Bureaus, Divisions (State	\$ 29,323	\$ 31,955	\$ 35,481	\$ 36,545	\$ 37,642
Operations)	¢ (50	¢ (50	¢ 400	¢	¢
9892 Supplemental Pension Payments (State Operations)	\$ 659	\$ 659	\$ 492	\$ -	\$ -
9900 Statewide General Administrative Expenditures (Pro Rata) (State Operations)	\$ 1,934	\$ 1,816		\$ 2,059	\$ 2,059
TOTALS, EXPENDITURES AND EXPENDITURE ADJUSTMENTS	\$ 31,916	\$ 34,430	\$ 38,032	\$ 38,604	\$ 39,701
FUND BALANCE	¢ 17.051	¢ 10 202	¢ 17.070	¢ 17004	¢ 12.057
Reserve for economic uncertainties	\$ 17,251	\$ 18,323	\$ 17,870	\$ 16,034	\$ 13,057
Months in Reserve	6.0	5.8	5.6	4.8	3.8
NOTES: 1. Assumes workload and revenue projections are realized in BY +1 and ongoing. 2. Expenditure growth projected at 3% beginning BY +1.					

Prepared 3.26.2024









Attachment 2

Board Member Attendance Board Meetings – FY 2023/24

Board Member	8/30/23	9/12/23	11/1/23	11/2/23	12/13/23	2/8/24
Barker	Х	Х	Х	Х	Х	Х
Cameron-Banks	Х	Х	Х	Х	Х	Х
Chandler		Х			Х	Х
Crowley	Х	Х	Х	Х	Х	Х
De La Paz		Х	Х	Х	Х	Х
Jha	Х	Х	Х	Х	Х	Х
Oh	Х	Х	Х	Х	Х	Х
Patel*	Х	Х				
Serpa	Х	Х	Х	Х	Х	Х
Thibeau	Х	Х	Х	Х	Х	Х
Weisz	Х		Х	Х		Х

Disciplinary Petition Committee Meetings – FY 2023/24

Board Member	3/13/24
Barker	Х
Cameron-Banks	N/A
Chandler	N/A
Crowley	Х
De La Paz	N/A
Jha	Х
Oh	Х
Serpa	Х
Thibeau	
Weisz	

N/A - Denotes not assigned to Disciplinary Petition Committee Meeting

Board Member Attendance Committee Meetings – FY 2023/24

Board Member	7/19/23	1/22/24
Barker	Х	Х
De La Paz	Х	Х
Jha		
Thibeau		Х
Weisz	Х	Х

Communication and Public Education Committee Meetings – FY 2023/24

Licensing Committee Meetings – FY 2023/24

Board Member	7/19/23	10/18/23	1/22/24	4/11/24
Barker	Х	Х	Х	Х
Chandler	Х			Х
Crowley	Х	Х	Х	Х
Oh	Х	Х	Х	Х
Patel*	Х	Х	n/a	n/a
Weisz	Х	Х	Х	Х

Enforcement Committee Meetings - FY 2023/24

Board Member	7/18/23	10/19/23	1/23/24	4/12/24
Barker	Х	Х	Х	Х
Cameron-Banks	Х		Х	Х
Oh	Х	Х	Х	Х
Patel*	Х	Х	n/a	n/a
Serpa	Х	Х	Х	Х
Thibeau	N/A	N/A	N/A	Х

Board Member Attendance Committee Meetings – FY 2023/24

Board Member	7/18/23	4/12/24
Chandler	Х	Х
Crowley	Х	Х
De La Paz	Х	Х
Jha	Х	Х
Oh	Х	N/A
Serpa	X	Х
Thibeau		Х

Legislation and Regulation Committee Meetings - FY 2023/24

Attachment 3

Board of Pharmacy

Mail Vote Participation - FY 2023/24

Board Member	July - Sept	Oct - Dec	Jan - March	<u>Анан</u> Інна	Total
	(61)	(53)	(65)	Apr - Jun	(179)
Barker	49	52	65	0	166
Cameron-Banks	12	4	0	0	16
Chandler	61	45	60	0	166
Crowely	60	53	65	0	178
De La Paz	0	0	0	0	0
Jha*	58	44	58	0	160
Oh	61	53	65	0	179
Serpa	61	53	65	0	179
Thibeau	60	51	65	0	176
Weisz	17	13	34	0	64

*Jha could only participate in 58 mail ballots for Q3

Attachment 4 Updated

Chapter 1

INTRODUCTION

Overview

The California State Board of Pharmacy (board) was created by the California Legislature in 1891 to protect the public by regulating the practice of pharmacy. Section 4000.1 of the California Business and Professions Code specifically establishes 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 is one of the boards, bureaus, commissions, and committees within the Department of Consumer Affairs (DCA), part of the Business, Consumer Services and Housing Agency under the aegis of the gGovernor. The Ddepartment is responsible for consumer protection and representation through the regulation of licensed professionals and the provision of consumer services. While the DCA provides administrative oversight and support services, the board has policy autonomy and sets its own policies, procedures, and regulations.

The board is presently comprised of 13 members; six are public members, and seven are pharmacists, as required by law. The seven pharmacist members and four public members are appointed by the gGovernor. One public member is appointed by the Assembly Speaker and one is appointed by the Senate Rules Committee. Board members may serve up to two four-year terms.

According to California law, at least five of the seven pharmacist members of the board must be pharmacists who are actively engaged in the practice of pharmacy. There must be at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. and a compounding pharmacy specializing in human drug preparations. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. A "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California. *California Business and Professions Code section 4001(c).*

Board members <u>fill-hold</u> non-salaried positions but are paid \$100 per day for each meeting day (or <u>eight</u>&-hour day spent performing board business) and are reimbursed travel expenses.

The board's operations are guided by its <u>five year five-year</u> strategic plan. The strategic plan is revised with the active partnership of all board members, staff, and interested stakeholders.



This procedure manual is provided to board members with <u>as</u> a ready reference of important laws, regulations, DCA policies, and board policies in order to guide the actions of the board members and ensure board effectiveness and efficiency. -The executive officer <u>and bBoard pPresident</u> will coordinate an orientation session with each new board member upon <u>his or hertheir</u> appointment, to assist the new member in learning processes and procedures.

Any questions board members may have, at any_time, can be addressed to the executive officer.

General Rules of Conduct

Board <u>m</u>Members shall not speak to interested parties (such as vendors, lobbyists, legislators, or other governmental entities) on behalf of the board or act for the board without proper authorization.

Members shall maintain the confidentiality of confidential documents and information.

Board <u>m</u>Members shall commit time, actively participate in board activities, participate in enforcement decision making and prepare for board <u>and committee</u> meetings, which includes reading <u>board packetsmeeting materials</u> and all required legal documents.

Board members shall respect and recognize the equal role and responsibilities of all board members, whether public or licensee.

Board members shall act fairly and in a nonpartisan, impartial, and unbiased manner.

Board members shall treat all applicants and licensees in a fair and impartial manner.

Board members' actions shall uphold the board's primary mission - protection of the public.

Board members shall not use their positions on the board for political, personal, familial, or financial gain.

Abbreviations Used in This Manual

B&P	Business and Professions Code
Board	California State Board of Pharmacy
DCA	Department of Consumer Affairs
President	President of the Board of Pharmacy
Vice President	Vice President of the Board of Pharmacy
EO	Executive Officer
SAM	State Administrative Manual



Additional abbreviations and commonly used terms can be found in Appendix A.



Chapter 2

BOARD MEETING PROCEDURES

Frequency of Meetings

(B&P Code Section 4002(b))

The board is required by law to meet at least once every four months and may meet more often as it determines necessary. The board's strategic plan directs four meetings annually. Full board meetings are generally two full-days and are held in northern and southern California on an alternating basis when possible. Additionally, the board, or a committee of the board, shall meet once per quarter to hear petitions for modification of probation and license reinstatement. The bBoard supportswelcomes and encourages public participation throughout at its meetings and provides for public participation via WebEx. The Board may, if necessary to address a time sensitive issue (i.e., in response to a declared disaster, to meet specified times established in the Administrative Procedures Act for enforcement related matters or regulations, etc.) may convene additional board meetings.

The **bB**oard has established the following interim policy until January 1, 2026:

<u>Committee meetings will be convened via teleconference consistent with</u> <u>Government Code s</u><u>Section 11123.5.</u>

- Petitions for modification of probation and license reinstatements will be considered by a committee of the board consistent with Business and Professions Code Section 4309(c).
- Board meetings will be convened with a public location where a quorum of the board is present. Additional members may participate from a non-public remote location consistent with the provisions of Government Code Section 11123.2(j)(1). Where an in-person quorum cannot be achieved, the Board will determine if conditions exist to convene the meeting consistent with Government Code Section 11123.2(j)(2).

Board Member Attendance at Board Meetings

(Board Policy)

Board members shall attend each meeting of the board. If a member is unable to attend, <u>he or shethey</u> must contact the board president <u>or and</u>-the executive officer and ask to be excused from the meeting for a specific reason. Minutes will reflect when a member is not present for a meeting. Two consecutive non-excused absences may result in a request to the appointing authority that the member be replaced.

Board Member Participation

(B & P Code Sections 106 and 106.5)

The Governor appointing authority has the power to remove from office at any time any member of any board appointed by him/herthemthe appointing authority for

4

continued neglect of duties required by law_1 or for incompetence, or unprofessional or dishonorable conduct. The <u>gGovernor</u> may also remove from office a board member who directly or indirectly discloses examination questions to an applicant for examination for licensure.

Public Attendance at Board Meetings Open Meetings Act (Government Code Section 11120 et seg.)

Board meetings are subject to the provisions of the Bagley-Keene Open Meeting Act. This act<u>The Open Meeting Act</u> governs meetings of the state regulatory boards and meetings of committees of those boards where the committee consists of more than two members. It specifies meeting notice and agenda requirements and prohibits discussing or taking action on matters not included on the agenda. Board members will receive training on the Open Meeting Act during the Board Member Orientation given by the DCA.

Appendix B contains detailed information about the Open Meeting Act that has been prepared by the <u>D</u>department's Legal <u>OfficeAffair Division</u>. Updates <u>to on</u> the Open Meetings Act are provided periodically by the <u>D</u>department. Such updates will be provided to board members by <u>the EO's secretaryboard staff</u>.

Attendance at general conferences that involve a discussion of broad issues and which are attended by a broad spectrum of participants are not covered by open meeting laws so long as members of the board do not discuss among themselves matters which are, or potentially may be, before the board. On the other hand, a workshop that is focused specifically on board issues and which involves more than two board members, or where the two members have some authority to act without further action by the full board, must meet the requirements of the <u>Open Meeting</u> <u>Actopen meetings law</u>.

Communications between or among more than two board members may be considered "meetings" if those communications occur in a serial fashion through a series of telephone calls or other communications (such as electronic mail) by which more than two of the board members are involved and board business is discussed (*e.g.*, polling of board members). Such communications are prohibited.

Any general discussion of exams or disciplinary procedures shall be held in public. The board may meet in closed session to discuss examinations where a public discussion would compromise the integrity of the examination or to deliberate on disciplinary cases and to discuss pending litigation.

An annual evaluation of the executive officer is held in closed session.

If the agenda contains matters that are appropriate for closed session, the agenda must cite the <u>particular specific</u> statutory section and subdivision authorizing the closed session.

Quorum

(B&P Code Section 4002(b) and Board Policy)

Seven members of the board constitute a quorum for the transaction of business. The majority of a quorum is necessary to act on behalf of the board.



The board uses the following criteria in counting votes on a given motion or decision (this includes motions during board meetings and mail votes on disciplinary matters).

The board must have a quorum of members present to take an action.

- There must be at least seven members voting <u>in order</u> for the board to take an action or position <u>on</u> an item, <u>unless otherwise delegated by the board</u>.
- A motion passes if a majority of those voting votes for the measure.
- Abstentions count as votes for purposes of establishing a quorum, but do not count as votes for or against the measure. Abstentions simply mean that the abstaining board member will go along with the majority decision of the board.
- For example, if seven members are present, and four members abstain from voting, then:

a vote of 2 Aye, 1 Nay and 4 Abstain would mean that the motion passes (the majority vote is 2 versus 1, with 4 agreeing to go along with the majority of those voting).

- The board president may determine to vote or not vote on any matter before the board.
- In the event of a tie the motion fails.

Should a board member recuse <u>him or herselfthemselves</u> from voting on a matter, that member is no longer counted for purposes of achieving a quorum. If this results in a loss of a quorum, the person may participate under the "rule of necessity", however they should not participate in the discussion and <u>they should</u> abstain from voting. If the reason for the <u>recused_recusal</u> is controversial or substantial (*i.e.*, the member was a witness in the case), the board should wait until another meeting to vote on the matter. This may necessitate a special meeting.

Meeting Rules

(Board Policy)

The board generally uses Robert's Rules of Order as a guide for conducting its meetings, to the extent that this does not conflict with state law (*e.g.*, Bagley–Keene Open Meeting Act). Questions of order are clarified by the board's attorneys.

Agenda Items

(Board Policy)

Any board member may suggest items for a board meeting agenda to the executive officer or during the "Public Comments on Items Not on the Agenda" discussion at every board meeting. The EO sets the agenda at the direction and <u>with the approval</u> of the board president and/or committee chair.

Generally, agenda items for board meetings originate with one of the board's five standing committees (the Enforcement and Compounding Committee, Licensing Committee, Communication and Public Education Committee, Legislation and Regulation Committee, and the Organizational Development Committee). The committee structure is designed to allow for initial discussion and consideration. Recommendations are then formed by the committee and brought to the full board



for considerations as a committee report.

Notice of Meetings (Government Code Section 11120 et seg.)

According to the Open Meetings Act, public meeting notices (including agendas for board meetings) must be sent to persons on the board's mailing list at least 10 calendar days in advance of the meeting. The notice must include a staff person's name, work address and work telephone number who can provide further information prior to the meeting.

All meeting notices for public meetings are also posted on the board's website (<u>www.pharmacy.ca.gov</u>) at least 10 calendar days before the meeting.

The Board supports the efforts of the Diversity, Equity, and Inclusion Steering Committee at the Department of Consumer Affairs and commits to fostering inclusive engagement in its policy decisions, and promoting diversity, equity, and inclusion in the Board's publications and procedures.

Record of Meetings (Board Policy)

Board <u>and committee</u> meeting minutes are a summary, not a transcript, of each <u>board</u>-meeting. The <u>board</u>-meeting minutes shall contain summaries of how each board member voted on motions during the <u>board</u>-meeting.

The minutes are prepared by board staff and submitted for review by board members before the next board <u>or committee</u> meeting. <u>Board meeting Meeting</u> minutes are approved at the next scheduled meeting of the board<u>or committee</u>. The purpose of reviewing and approving the minutes at a <u>board</u>-meeting is not to approve of actions taken by the board at the previous meeting, but rather to determine whether the minutes as drafted accurately reflect the <u>board's</u>-discussion at the previous meeting. When approved, the minutes shall serve as the official record of the meeting.

Electronic Recording of Meetings (Government Code Section 11124.1 and Board Policy)

The public-session portions of a meeting may be electronically recorded if determined necessary for staff purposes. Audio recordings shall be disposed of following board approval of the minutes. Meetings may be webcast-livestreamed for the public to view on the board's website at www.pharmacy.ca.gov. Members of the public may tape record, videotape, or otherwise record a meeting unless too disruptive the board reasonably finds that such recording constitutes a persistent disruption of the proceedings.



(Government Code Sections 11125.7 and 11430.10 and Board Policy)

Due to the need for the board to maintain fairness and neutrality when performing their adjudicative function, the board shall not receive any substantive information from a member of the public regarding any matter that is currently under or subject to investigation or involves a pending criminal or administrative action.

If, during a board meeting, a person attempts to provide the board with substantive information regarding matters that are currently under or subject to investigation or involve a pending administrative or criminal action, the person shall be advised that the board cannot properly consider or hear such substantive information, and the person shall be instructed to refrain from making such comments.

If, during a board meeting, a person wishes to address the board concerning alleged errors of procedure or protocol or staff misconduct, involving matters that are currently under or subject to investigation or involve a pending administrative or criminal action, the board will address the matter as follows:

- Where the allegation involves errors of procedure or protocol, the board may designate either its executive officer or a board employee to review whether the proper procedure or protocol was followed and to report back to the board.
- Where the allegation involves significant staff misconduct, the board may designate one of its members to review the allegation and to report back to the board.

At the discretion of the president or chairperson, speakers may be limited in the amount of time to present to give adequate time to everyone who wants to speak. In the event the number of people wishing to address the board exceeds the allotted time, the president or chairperson may limit each speaker to a statement of his/her name, organization, and whether they support or do not support the proposed action.

Members of the public are welcome to submit written comments in advance of a meeting to the contact person included on the agenda. To ensure member and the public have sufficient time to consider the comments, only comments received within two business days of the start of the meeting will be provided to members and included as part of the meeting materials. At the direction of the Board President or Committee Chairperson comments received after this time may be provided.

Board Voting at National Association of Boards of Pharmacy Meetings (*Board Policy*)

The National Association of Boards of Pharmacy is a professional organization that supports the state boards of pharmacy in protecting public health. The National Association of Boards of Pharmacy member boards of pharmacy are grouped into eight districts that include all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Australia, Bahamas, and nine ten Canadian provinces, and New Zealand.



The board's president shall serve as the official delegate to the annual <u>district and</u> <u>annual</u> meeting of the National Association of Boards of Pharmacy. If the president cannot attend the meeting or is absent for a portion of the meeting, the president shall designate an alternate delegate to the meeting to vote on matters before the NABP's sessions.

Chapter 3

COMMITTEE MEETINGS

Committees of the Board

The board's strategic plan establishes five standing committees through which the board establishes its goals and organizes its activities in pursuit of ensuring the public health, safety, and welfare, and to assure the provision of quality pharmacist's care. These five committees develop policy related to a board mission-related goal. The committees and their goal areas are:

- Licensing Ensuring the professional qualifications of licensees. This
 includes that those entering the practice of pharmacy, as well as those
 continuing to practice, meet minimum requirements for education,
 experience, and knowledge. The board also ensures that facilities licensed by
 the board meet minimum standards.
- Enforcement and Compounding Protecting the public by exercising oversight on all pharmacy activities. This includes preventing violations and effectively enforcing federal and state pharmacy laws when violations occur.
- Communication and Public Education Providing relevant information to consumers and licensees. This includes encouraging the public to discuss their medications with their pharmacist; emphasizing the importance of patients complying with their prescription treatment regiments; and helping pharmacists to become better informed on subjects of importance to the public.
- Legislation and Regulation Advocating legislation and promulgating regulations that advance the vision and mission of the board. These activities ensure better patient care and more effective regulation of the individuals and firms who handle, dispense, furnish, ship, and store prescription drugs and devices in California.
- Organizational Development Achieving the board's mission and goals. This is done through strategic planning, budget management, and staff development activities.

Each of these committees is comprised of at least two-three board members. Staff provides technical and administrative input and support to the committee. The committees are an important venue for ensuring that staff and board members share information and perspectives in crafting and implementing strategic objectives.

The board's committees allow board members, stakeholders, and staff to discuss and conduct problem solving on issues related to the board's strategic goals. They also allow the board to consider options for implementing components for the strategic plan. The committees are charged with coordinating board efforts to reach board goals and achieving positive results on its performance measures.

The board president designates one member of each committee as the committee's chairperson. The chairperson coordinates the committee's work and ensures progress toward the board's priorities. The board president also designates a vice



chairperson for each committee who fulfills the duties of the chairperson in their absence.

Each committeeCommittees typically meets once before a quarterly board meeting. Committee meetings where appropriate. Committee meetings are governed by the same Open Meetings Act requirements as board meetings. The committees refer policy decisions to the full board during a public meeting for a formal decision and vote. During the committee's discussion, the public is encouraged to provide comments. The board meeting agenda will list action items and discussion items of interest for each committee.

All <u>quarterly_committee</u> meetings of the Enforcement and Compounding, Licensing, <u>Legislation and Regulation</u>, and Communication and Public Education Committees are public meetings. This reflects the high interest the public has shown for the agenda items of these committees. -The Legislation and Regulation <u>C</u>eommittee generally holds at least two public meetings each year, typically in the spring and fall in order to recommend positions on introduced legislation (in the spring) or to develop legislative or regulatory proposals (in the fall). The Organizational Development Committee typically does not schedule public meetings as <u>it consists</u> of only two members and items within its purview are not generally appropriate for open meetings (*e.g.*, personnel matters). Nevertheless, a report of items under the Organizational Development Cemmittee's purview is generally provided at each quarterly board meeting.

During any public committee meeting, comments from the public are strongly sought, and the meetings themselves are frequently public forums on specific issues before a committee. Board members who are not members of a committee may attend a public committee meeting as part of the audience.

It is also important to note that any time more than two board members attend a board committee meeting, that committee meeting must have been publicly noticed. The board's legal counsel works with the EO to assure any meeting that fits the requirements for a public meeting is appropriately noticed.

The board also has one standing committee with responsibilities for the California pharmacist licensing examination (the Competency Committee). -This committee is described below.

Competency Committee

The board's Competency Committee is responsible for developing and grading the board's pharmacist licensure examination, the California Practice Standards and Jurisprudence Exam for Pharmacists (known as the CPJE). The committee is comprised of representatives from a cross section of professional practice as well as representatives from California schools of pharmacy. Two board members are appointed to observe the work of the committee by the board president. The board president or their designee is kept apprised of work of the committee.

Membership on this committee is professionally challenging as well as time consuming. The committee members are split geographically between Northern and Southern California. The committee meets seven times annually in two-day meetings. There is an annual meeting where the entire committee meets in one



location to set goals for the year. Membership is generally eight years, and appointment is by the board president.

The Competency Committee is a stand-alone committee that is within the auspices of the board's Licensing Committee. However, meetings of the Competency Committee are not public meetings as these meetings are for examination constructiondevelopment.

Committee Creation and Appointments

(Board Policy)

The president may establish additional committees or subcommittees, whether standing or special, as <u>he or shethey</u> deems necessary. The composition of the committees or subcommittee and the appointment of the members is determined by the board president in consultation with the vice president, and the EO. Any additional committee or subcommittee meetings are governed by the same Open Meetings Act requirements as board meetings.

Attendance at Committee Meetings (Board Policy and Government Code Section 11122.5)

If a board member wishes to attend a meeting of a committee of which he or shethey are is not a member, that board member must obtain permission from the board president or EO to attend. Therefore, requests to attend a committee meeting should be submitted to the EO at least two weeks in advance.

Board members who are not members of a committee may attend a public committee meeting as part of the audience. However, if a quorum of members of the full board are present during a committee meeting, members of the board who are not members of the board committee may attend the committee meeting only as observers.



Chapter 4

TRAVEL & SALARY POLICIES/PROCEDURES

Travel Approval

(DCA Memorandum 91-26)

Board members shall have board president approval for all travel and per diem reimbursement, except for regularly scheduled board and committee meetings to which a board member is assigned.

The DCA Travel Guide information is attached as Appendix C. Board members will be reimbursed for travel expenses incurred while performing approved board business in accordance with these reimbursement criteria.

Travel Arrangements

(Board Policy)

Travel arrangements, including hotel accommodations, flights, and rental cars, are made by the EO's secretary through designated staff through the state's designated travel agency. The EO's secretaryStaff will provide each board member with confirmations for all travel reservations for their review and approval. In the event that the travel reservations need to be modified or canceled the board member shall notify the EO's secretarydesignated staff as soon as possible so that the appropriate steps can be taken to change or cancel the reservations.

State guidelines generally prohibit reimbursement for hotel expenses if the meeting is less than 50 miles from an individual's home address, unless preapproval is secured. Board members who wish to request an exemption to stay at a hotel less than 50 miles from their home must contact the EO's secretarydesignated staff to pursue this exemption at least two weeks before the meeting. The exemption must be approved by the DCA before the meeting.

Out of State Travel

Out-of-state travel for all persons representing California is highly controlled and must be pre-approved by the \underline{gG} overnor's \underline{oG} ffice. For approved out-of-state travel, board members will be reimbursed actual lodging expenses, supported by vouchers, and will be reimbursed for meal and supplemental expenses at the state per diem rate.

Travel Claims

(DCA Memorandum 91–26)

Rules governing reimbursement of travel and meeting expenses for board members are the same as for management level state staff. All expenses must be claimed using the state's electronic travel claim program. The EO's secretaryStaff prepares these electronic travel claims on behalf of board members after all board and committee meetings. All claims will be provided to the board member for review and approval prior to final submission in the electronic travel claim program. Original



receipts are required for reimbursement for lodging<u>, and</u> parking, and gasoline. Board members shall provide the required original receipts to the<u>are to be provided</u> to designated staff-EO's secretary to be included with the travel claim.

In order for travel expenses to be reimbursed, board members must follow the procedures contained in DCA memoranda which are periodically disseminated by the director and are provided to board members on at least an annual basis by the EO's secretaryboard staff. Questions regarding travel reimbursement policies shall be directed to the EO's secretarydesignated staff.

Salary Per Diem

(B&P Code Section 103)

Compensation in the form of salary per diem and reimbursement of travel and other related expenses for board members is regulated by Business and Professions Code Section 103.

In relevant part, this section provides for the payment of salary per diem for board members "for each day actually spent in the discharge of official duties," and provides that the board member "shall be reimbursed for traveling and other expenses necessarily incurred in the performance of official duties."

(Board Policy)

Accordingly, the following general guidelines shall be adhered to in the payment of salary per diem or reimbursement for travel:

- No salary per diem or reimbursement for travel-related expenses shall be paid to board members, except for attendance at official board or assigned committee meetings. Attendance at gatherings, events, hearings, conferences, or meetings other than official board or assigned committee meetings in which a substantial official service is performed shall be approved in advance by the board president.
- The term "day actually spent in the discharge of official duties" shall mean such time as is expended from the commencement of a board or committee meeting until that meeting is adjourned. If a member is absent for a portion of a meeting, hours are then reimbursed for time actually spent. Travel time is not included in this component.
- For board-specified work, board members will be compensated for actual time spent performing work authorized by the board president. This may also include, but is not limited to, authorized attendance at other gatherings, events, meetings, hearings, or conferences; and exam item writing. Work also includes preparation time for board or committee meetings and reading mail ballots for disciplinary actions.
- Reimbursable work does not include miscellaneous reading and information gathering, committee work not related to a meeting, preparation time for a presentation, and participation at meetings not related to official participation of the board.

Board members may submit their hours for which they seek reimbursement to the



EO's secretarydesignated staff on the Board Member Attendance Report. By board policy, board members will be reimbursed for their hours spent at board and committee meetings without submitting a Board Member Attendance Report. However, for reimbursement for all other board-sanctioned activities (including reading mail ballots for disciplinary actions) or performing board business, the hours must be submitted on the Board Member Attendance Report.

At each quarterly meeting of the board, there shall be a report of all per diem reimbursement and travel expenses claimed by each member of the board for the fiscal year.

Business and Professions Code section 103 and a Board Member Attendance Report are provided in Appendix D.



Chapter 5

OTHER POLICIES/PROCEDURES

Requests for Board Representation or Presentation

(Board policy)

If an association or individual requests board participation at an event or meeting, a written request should be submitted to the EO, as to the purpose of the function, and the reason for the request. The board president will approve such requests consistent with the board's strategic plan and if funds are available. Approval to participate will also include the extent of participation (*e.g.*, one time meeting, presentation, or continuous participation on a committee). Continued participation as a board representative should be consistent with the board's strategic plan and may need to be approved by the full board.

Prior authorization for any reimbursement must be obtained or expenses will be the responsibility of the participant.

Board members may participate on their own (*i.e.*, as a citizen or professional) but not as an official board representative unless approved by the board president or the board. However, board members should recognize that even when representing themselves as "individuals," their positions might be misconstrued as that of the board. For that reason, board members are cautioned to not express their personal opinions as a board policy or position or represent that the board has taken a position on a particular issue when it has not. Board members should also make every attempt to provide disclaimers that they are not representing the board.

Resignation of Board Members

(Government Code Section 1750)

In the event that it becomes necessary for a board member to resign, a letter shall be sent to the appropriate appointing authority (gGovernor, Senate Rules Committee, or Speaker of the Assembly) with the effective date of the resignation. Written notification is required by state law. A copy of this letter shall also be sent to the director of the Delepartment, the board president, and the EO.

Duties of Officers of the Board

(B&P Code Section 4002(a))

The board shall elect from its members a president, vice president, and treasurer.

President • Sp

- Spokesperson for the Board of Pharmacy (including but not limited to) – may attend legislative hearings and testify on behalf of the board, may attend meetings with stakeholders and <u>l</u>egislators on behalf of the board, may talk to the media on behalf of the board, and signs letters on behalf of the board
 - Meets and communicates with the <u>e</u>Executive <u>o</u>Officer on a regular basis



		 Communicates with other board members for board business
		 Authors a president's message in every newsletter
1		 Approves board meeting agendas
		• Establishes positions on emergent bills between board meetings. Working with the executive officer negotiates amendments consistent with the Board's direction. Updates board positions in response to changes in pending legislation that requires urgent action.
		Chairs and facilitates board meetings
		Chairs the Organizational Development Committee
		• Signs specified full board enforcement approval orders
		• Grants or denies requests for an extension of time to submit arguments to the board under the Administrative Procedure Act
		 Approves leave requests and FMLA requests for the EO
		 Performs other duties as delegated by the <u>b</u>Board.
	Vice President	 Is the back-up for the duties above in the president's absence
I		 In the absence of the president may perform duties delegated to the president by the <u>b</u>Board.
I		 Is a member of the Organizational Development Committee
	Treasurer	 Maintains the private board member fund for commemorative awards for board staff and board members.
	Past President	• Is responsible for mentoring and imparting knowledge to the new board president
		 May attend meetings and legislative hearings to provide historical background information, as needed
	Committee Chair	 Approves the committee agendas Chairs and facilitates committee meetings
	Vice Committee Chair	 Is the back-up for the duties above in the committee chair's absence

Election of Officers

(<u>B&P Code Section 4002(a) and</u> Board Policy)

The board shall elect the officers at the last meeting of the fiscal year_during the third or fourth quarter of the fiscal year as appropriate, by a majority of the



<u>membership of the board</u>. Officers shall serve terms of one year effective June 1, and may be reelected to consecutive terms.

Officer Vacancies

(Board Policy)

If an office becomes vacant during the year, an election shall be held at the next meeting. If the office of the president becomes vacant, the vice president shall assume the office of the president until an election is held. Elected officers shall then serve the remainder of the term.

Board Member Disciplinary Actions (Board Policy)

A member may be censured by the board if, after a hearing before the board, the board determines that the member has acted in an inappropriate manner.

The president shall sit as chair of the hearing unless the censure involves the president's own actions, in which case the vice president shall preside. In accordance with the Open Meeting Act, the censure hearing shall be conducted in open session.

Board Member Addresses

(DCA Policy)

Board member addresses and telephone numbers are confidential and shall not be released to the public without expressed authority by the individual board member.

A roster of board members is maintained for public distribution and is placed on the board's <u>Web sitewebsite</u>, using the address and telephone numbers of the board.

Written Correspondence and Mailings by Board Members (Board Policy)

If delegated to do so by the president or EO, all correspondence, press releases, articles, memoranda, or any other communication written by any board member in his or hertheir official capacity must be provided to the EO for reproduction and distribution. The EO will maintain a copy and mail and distribute the written material.

Request for Records Access (Board Policy)

No board member may access a licensee's, or applicant's file without the EO's knowledge and approval of the conditions of access. Records or copies of records shall not be removed from the board's office.

Communications with Other Organizations/Individuals/Media (Board Policy)



Interested parties may request to meet with a board member on a matter or matters under the board's jurisdiction. Members must remember that the power of the board is vested in the board itself and not with any individual board member. For that reason, board members are cautioned to not express their personal opinions as a board policy or position or represent that the board has taken a position on a particular issue when it has not.

All communications relating to any board action or policy to any individual or organization, or a representative of the media, shall be made only by the president of the board, his or hertheir designee, or the EO. Any board member who is contacted by any of the above should inform the board president or EO of the contact.

If a board member receives a media call, the member should promptly refer the caller to the board's EO. The board member should then send an email to the executive officer indicating they received a media call and relay any information supplied by the caller.

Executive Officer (EO)

(B&P Code Section 4003)

The EO is appointed by and serves at the pleasure of the board, and is exempt from civil service. The EO shall exercise the powers and perform the duties delegated by the board and vested in <u>him or herthem</u> by California pharmacy law.

Executive Officer

- Responsible for the financial operations and integrity of the board.
 - Official custodian of records.
 - Provides the board with advice during consideration of issues.
 - Liaison between the board and board staff.
 - Provides the board with complete, clear, and accurate reports, minutes, etc.
 - Responds to requests for information from board members.
 - Keeps the board informed of progress of board programs.
 - Implements board policies.

Executive Officer's Annual Evaluation (Board Policy)

<u>Each year dAt the first meeting of each calendar year, the EOConsistent with the</u> policy of the Department of Consumer Affairs, the board conducts an annual assessment of the EO is evaluated by the board president during a closed session meeting of the board. Board members provide information to the president on the EO's performance in advance of this meeting by using the EO evaluation form provided by the Ddepartment. A representative from the department is designated to assist with the facilitation of the assessment process.

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The evaluation process is based on the principle that performance should be evaluated on a regular basis in order to provide recognition of effective performance and as a tool to provide guidance in improving future performance.

If the EO is not at the maximum range of salary, the board may recommend a salary increase for the EO. To qualify for such increases, the EO must meet or exceed performance expectations, as determined by the board. The evaluation form is used to document the board's recommendation for a salary increase. <u>Should the Board determine that the current salary level of the EO position is not appropriate, the Board must follow the Department's process to request a change in the salary level of the EO position.</u>

The EO evaluation form is provided in Appendix E.

Board Staff

(DCA Reference Manual)

Employees of the board, with the exception of the executive officer, are civil service employees. Their employment, pay, benefits, discipline, termination, and conditions of employment are governed by a myriad of civil service laws and regulations and often by collective bargaining labor agreements. Board members shall not intervene or become involved in specific day-to-day personnel transactions. Personnel matters affecting the operation of the board's duties are shared with the president and vice president during Organizational Development <u>Committee</u> meetings.

Board Administration

(DCA Reference Manual)

Board members should be concerned primarily with formulating decisions on board policies rather than decisions concerning the means for carrying out a specific course of action. It is inappropriate for board members to become involved in the details of program delivery. Strategies for the day-to-day management of programs and staff shall be the responsibility of the executive officer.

Contact with Licensees, Applicants, and Respondents

(Board Policy and Government Code <u>Section 11430.10 et seq.</u>)

Board members shall not intervene on behalf of applicants and licensees. They should forward all contacts or inquiries to the EO or board staff without direction on how matter should be handled.

The Government Code contains provisions prohibiting *ex parte* communications. An "*ex parte*" communication is a communication to the decision–maker made by one party to an enforcement action without participation by the other party. While there are specified exceptions to the general prohibition, the key provision is found in subdivision (a) of section 11430.10, which states:

"While the proceeding is pending, there shall be no communication, direct or indirect, regarding any issue in the proceeding, to the presiding officer from an employee or representative or if of agency that is a party or from an interested person outside the



agency, without notice and an opportunity for all parties to participate in the communication."

Board members should not directly participate in complaint handling and resolution or investigations. An applicant who is being formally denied licensure, or a licensee against whom a disciplinary action is being taken, may attempt to directly contact board members.

If the communication is written, the member should read only enough to determine the nature of the communication. Once <u>he or shethey</u> realizes it is from a person against whom an action is pending, <u>he or she should the documents should be</u> reseal<u>ed</u> the documents and <u>send sent them</u> to the EO, or forward the email.

If a board member receives a telephone call from an applicant or licensee against whom an action is pending, <u>he or shethey</u> should immediately tell the person <u>he or</u> <u>shethe member</u> cannot speak to <u>him or herthem</u> about the matter. If the person insists on discussing the case, <u>he or shethey</u> should be told that the board member will be required to recuse <u>himself or herselfthemselves</u> from any participation in the matter. Therefore, continued discussion is of no benefit to the applicant or licensee.

If a board member believes that <u>he or she hasthey</u> received an unlawful *ex parte* communication, <u>he or shethey</u> should contact the board's assigned attorney or EO.

Service of Legal Documents

(Board Policy)

Board members may receive service of a lawsuit against themselves and the board pertaining to a certain issue (*e.g.*, a disciplinary matter, a complaint, a legislative matter, etc.). To prevent a confrontation, the board member should accept service. Upon receipt, the board member should notify the EO of the service and indicate the name of the matter that was served and any other pertinent information. The board member should then mail the entire package that was served to the EO as soon as possible. The board's legal counsel will provide instructions to the board members on what is required of them once service has been made.

Gifts from Licensees or Applicants

(Board Policy)

Gifts of any kind to board members or staff from any licensee or applicant with the board are not permitted.

Additionally, Government Code section 87210 contains specific requirements with respect to gifts. These requirements are among those discussed in the Ethics Course described below.

Government Code section 87210 and related sections are provided in Appendix F.

Conflict of Interest (Government Code Section 87100<u>et seq.</u>)



No board member may make, participate in making, or in any way attempt to use <u>his or hertheir</u> official position to influence a governmental decision in which <u>he or shethey</u> knows or <u>has have</u> reason to know <u>he or shethey</u> <u>has have</u> a financial interest. Any board member, who has a financial interest, shall disqualify <u>himself/herselfthemself</u> from making or attempting to use <u>his/hertheir</u> official position to influence the decision. Any board member who feels <u>he or she isthey are</u> entering into a situation where there is a potential for a conflict of interest should immediately consult the board president or the EO.

Government Code <u>s</u>ection 87100 and related sections are attached as Appendix G.

(Board Policy)

A board member who feels <u>he or she hasthey have</u> a potential conflict of interest in a specific case or issue should make <u>his or hertheir</u> position known when the matter is discussed publicly (*e.g.*, during a board meeting). Further, the member should reinforce this position by physically leaving the room until the discussion regarding the matter is concluded. Whenever possible, a board member should notify the EO when <u>he or shethey</u> believes that the member has a conflict of interest. The EO can help refer the board member to appropriate resources for assistance. For example, the Fair Political Practices Commission is another resource.

Within 30 days of taking or leaving office as a board member, and annually before April 1 of each year, every board member must file a conflict of interest statement with the Fair Political Practices Commission. <u>F</u>filing procedures <u>and are</u> handled <u>and</u> <u>coordinated</u> by the Department of Consumer Affairs. Questions about this process should be directed to the EO.

Ethics Training

(Government Code Sections 11146-11146.4)

Each board member must complete a course on ethics offered through the <u>D</u>department. Upon appointment to the board, a new board member must complete the course within six months. All members must retake the course every two years during their term. Records concerning the attendance of this course must be kept on file for five years. Training information is available on <u>the Attorney General's</u> <u>website at https://oag.ca.gov/ethics()</u>.

Government Code <u>s</u>ections 11146–11146.4 are provided in Appendix H.

Sexual Harassment Prevention Training

(Government Code Section 12950.1)

Each board member must complete a sexual harassment prevention course offered through the <u>D</u>department within six months of assuming office. Board members must complete the sexual harassment prevention course every two years during their term or when directed by the Department of Consumer Affairs.

Defensive Driving Training

Each board member must complete a defensive driving course offered through the



Department of General Services within six months of assuming office. Board members must complete the defensive driving course every four years during their term.

DCA's Board Member Training (B&P Code Section 453)

The Department of Consumer Affairs provides an orientation session for new board members. The California Business and Professions Code requires that this course must be taken within one year of assuming office and within one year of any subsequent reappointment to the board. The training covers the functions, responsibilities, and obligations that come with being a member of a DCA board.

The department also has a <u>Web sitewebsite</u> for board members: <u>https://dca.ca.gov/about_us/board_members/index.shtmlhttp://www.dca.ca.gov/p <u>ubs/board_members/orientation.htm</u></u>

The Honoraria Prohibition

(Government Code Section 8950<u>1 et seq.</u>3)

As a general rule, members of the board should decline honoraria for speaking at, or otherwise participating in, professional association conferences and meetings. A member of a state board is precluded from accepting an honorarium from any source, if the member would be required to report the receipt of income or gifts from that source on his or hertheir statement of economic interest.

Under the Department of Consumer Affairs Conflict of Interest Code, members of the Board of Pharmacy are required to report income from, among other entities, pharmaceutical professional associations and continuing education providers. Therefore, a board member should decline all offers for honoraria for speaking or appearing before such entities.

There are limited exceptions to the honoraria prohibition. The acceptance of an honorarium is not prohibited under the following circumstances: (1) when a honorarium is returned to the donor (unused) within 30 days; (2) when an honorarium is delivered to the State Controller within thirty-30 days for donation to the General Fund (for which a tax deduction <u>i</u>ls not claimed); and (3) when an honorarium is not delivered to the board member, but is donated directly to a bona fide charitable, educational, civic, religious, or similar tax_-exempt, non-profit organization.

In light of this prohibition, members should report all offers of honoraria to the president so that <u>he or shethey</u>, in consultation with the EO and staff counsel, may determine whether the potential for conflict of interest exists.

Government Code <u>s</u>Sections 8950<u>1 and 89502</u>3 areis provided in Appendix I.

Serving as an Expert Witness

During their tenure on the board, members should refrain from acting as pharmaceutical expert witnesses in civil or criminal court cases. The reasons for this



prohibition are twofold.

Acting as an expert witness for compensation would probably constitute a violation of the Standards of Ethical Conduct for gubernatorial appointees. The first ethical standard precludes a gubernatorial appointee from engaging in activity, which has the appearance of using the prestige of the state for the appointee's private gain or advantage. A professional member of the board would be in high demand as an expert witness in litigation relating to pharmacy, simply because of his or her status as a board member. Consequently, the member would likely receive more engagements as an expert witness than if <u>he or shethey</u> were not a member of the board. As such, serving as an expert witness would have the appearance of using the prestige of board-membership for private gain. Parenthetically, although the <u>gG</u>overnor's ethical standards are addressed to the conduct of gubernatorial appointees, all members of the board should be in compliance.

More importantly, acting as an expert witness would jeopardize a board member's ability to participate in the deliberation and resolution of disciplinary actions before the board. As an expert witness in a civil or criminal action against a pharmacist <u>or other applicant or licensee</u>, a board member would be required to learn all the facts of the case at issue. If the <u>pharmacist applicant of licensee</u> who is a party to the civil or criminal comes before the board in a disciplinary action, the board member who served as expert witness would be required to recuse <u>himself or herselfthemself</u> because of considerable *ex parte* knowledge of the case.

Request for Grants

All requests for funding/contributions to board projects shall be approved by the board president. Requests for such grants must be made by the EO at the president's direction. If a board member makes an individual request, a copy of the request shall be forwarded to the EO as soon as possible.

The mechanism for receipt, management, and dispersal of funds shall be prearranged and approved by the board.

Policy Positions of the Board

The following are policies adopted by the board during open meetings.

Policy: Pharmacists as Emergency Responders

Adopted October 25, 2006

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. Skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The board also wishes to encourage an adequate response to any such circumstance



affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at <u>www.medicalvolunteer.ca.gov</u> (California) and <u>www.medicalreservecor.ps.gov</u> (federal).

The board also continues to be actively involved in such planning efforts, at every level. The board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, recordkeeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected. The board encourages its licensees to assist. and follow directions from, local, state, and national health officials. The board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

Furthermore, during a declared disaster or emergency affecting



residents of California, the board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California. The board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California. Finally, the board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

Policy:

Legislative Positions

Adopted April 21, 2009. <u>Replaced July 2022</u> Delegate the power to the board's president and chair of the Legislation and Regulation Committee to take board positions on emergent bills between board meetings.

Policy:

Emergency Meetings for Purposes of Waiving Statutory Requirements

Adopted February 25, 2016

In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open MeetingS Act, the board delegates its authority pursuant to Business and Professions Code section 4062, to the board president for a period of 30 days.

Policy: Extension of Deadline to Submit Arguments to the Board

Adopted October 29, 2013

Allow the board president to grant or deny a request for an extension of time to submit arguments to the board under the Administrative Procedure Act. In the absence or unavailability of the president, the vice-president of the board may act upon the request.

Policy: Sale of Tobacco Products in Pharmacies

Adopted October 29, 2014

The California State Board of Pharmacy recognizes that pharmacists are health care providers and pharmacies are in the business of improving customer health; therefore the board recommends that pharmacies and chain stores that include pharmacies eliminate the sale of tobacco, e-cigarettes and tobacco products, as these products are known to cause cancer, heart disease, lung disease and other health problems.

Policy: Warning Labels on Prescription Labels for Oral Chemotherapy Medications

Adopted January 30, 2019

The California State Board of Pharmacy recognizes that oral chemotherapy treatment is increasingly common among cancer patients and health care providers. However, these medications pose serious risks to humans and the environment if improperly handled or disposed of. Many patients, caregivers and even health care providers may not recognize these drugs or be aware of their hazardous nature. The board supports voluntary efforts by pharmacies and clinics to improve awareness and education about oral chemotherapy medications. In addition, the board encourages pharmacists to provide specific counseling to patients and their caregivers on proper handling and disposal of OC medications.



To help patients, caregivers and health care providers recognize these medications as hazardous, the board encourages pharmacies to affix a standardized "hazardous drug" symbol to prescription labels when appropriate. The addition of the symbol would serve as an important reminder to patients and caregivers about the proper handling and disposal of the drugs.

The following represents an appropriate warning symbol:



Policy: Medication Assisted Treatment (MAT)

Adopted January 30, 2109

California law declares pharmacist health care providers who have authority and ability to provide health care services. Today pharmacists have six to eight years of collegiate education with focused experience in performing medication management. Increasingly this also includes additional residency experience.

Under California law for a number of years and in conjunction with collaborative practice agreements with prescribers, pharmacists have the ability to:

- 1. Design treatment plans
- 2. Initiate adjust and discontinue medications
- 3. Monitor patient progress
- 4. Order and review necessary laboratory tests
- 5. Coordinate care with other medical providers
- 6. Serve as expert consultants to support prescribers in making medication decisions for patients.

This skill set serves a dual purpose of positioning pharmacists so they may provide direct care to patients with opioid addiction and assist other medical providers in caring for this population, thereby expanding access to treatment. In recognition of these factors, the California State Board of Pharmacy advocates for changes in the law that will permit pharmacists to provide medication assisted treatment as part of a collaborative health care team.

Policy: Legislative Positions

Approved July 2022

Delegate the power to the Board's president to take board positions on emergent bills between board meetings. Further, delegation also includes working with the Executive Officer to negotiate amendments consistent with the Board's direction and update Board positions in



response to changes in pending legislation that require urgent action.

Policy:	Digital Signatures
<u> </u>	Approved April 2023
	The Board is aware of some licensees' and applicants' desire to submi
	documents with digital signatures. Government Code Section 16.5
	establishes authority for government agencies to accept digital
	signatures that meet specified conditions. "If a public entity elects to
	use a digital signature, that digital signature shall have the same force
	and effect as the use of a manual signature if and only if it embodies
	all of the following attributes:"
	(1) It is unique to the person using it.
	(2) It is capable of verification.
	(3) It is under the sole control of the person using it.
	(4) It is linked to data in such a manner that if the data is changed, th
	<u>digital signature is invalidated.</u>
	(5) It conforms to regulations adopted by the Secretary of State.
	The Secretary of State has established regulations specifying
	acceptable technologies for acceptance of digital signatures and
	designates Public Key Cryptography as an acceptable technology. (Ca
	<u>Code Regs., tit.2 § 22003.) While the Board has not established any</u>
	formal rules requiring the use of digital signatures, it understands the
	stakeholders are interested in using digital signatures. The Board will
	not require any applicant or licensee to provide information using a
	digital signature in lieu of a wet signature; however, in the interest of
	meeting stakeholder requests, the Board will accept documents that
	are digitally signed using technology known as Public Key
	Cryptography consistent with the regulations established by the
	Secretary of State in Section 22003 as cited above. The Board reminds
	licensees using digital signatures to mail the completed application o
	notification form along with any fees required when applicable to the
	Board's office, 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA
	<u>95833.</u>
Policy:	Compounding Policy Statement
-	Approved September 12, 2023
	<u>Compounding Policy Statement In light of the November 1, 2023,</u>
	compendial date for several USP General Chapters, including General
	Chapter 795 Pharmaceutical Compounding - Nonsterile Preparations,
	797 Pharmaceutical Compounding - Sterile Preparations, 800
	Hazardous Drugs - Handling in Healthcare Settings and 825
	Radiopharmaceuticals - Preparation, Compounding, Dispensing, and
	Repackaging, the California State Board of Pharmacy (Board) wishes to
	update its stakeholders on its policy related to licensees transitioning
	to the updated USP General Chapters as well as actions under
	consideration by the Board.
	There are covered provisions of state and federal law severation the
	<u>There are several provisions of state and federal law governing the</u> practice of pharmacy. Most notably related to compounding are
	provisions in the Federal Food, Drug and Cosmetic Act including
	exemptions provided under Section 503A; California Sherman Food,
	<u>Drug, and Cosmetic Act; and several provisions within the Business</u>

and Professions Code including Sections 4126.8 and 4342.	
As required by law, the Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of Federal Law and USP General Chapters. These efforts resulted in the Board voting, as part of its Ap 2023 Board Meeting, to promulgate new regulations that are in addition to USP Standards. Additional information is available here. The effective date of the newly updated state regulations is yet to be determined.	<u>ril</u>
During this intervening period, the Board encourages licensees to begin transitioning to the new standards established in USP to ensure compliance with state and federal law. It is the Board's expectation that as compounding practices transition to new requirements, including provisions related to establishing beyond use dates (BUDs), that standard operating procedures must be updated and staff appropriately trained prior to implementing new practices and BUDs.	-
Policy: Assembly Bill 1286 Implementation	
Approved December 13, 2023 The California State Board of Pharmacy provides licensees and interested stakeholders with the following information on its policy relating to implementation of provisions contained within Assembly B 1286 (Haney, Chapter 470, Statutes of 2023).	<u>Sill</u>
Assembly Bill 1286 establishes a requirement for the reporting of medication errors that occur in the outpatient setting to an entity approved by the Board under specified conditions. The Enforcement and Compounding Committee will begin its evaluation of entities in the coming months. During this intervening period, reporting of such errors is not required nor will it be retroactive. It is anticipated that reporting of such errors will only be expected after approval of such entity with an appropriate transition period for implementation. Interested stakeholders are encouraged to participate in relevant public meetings.	-
Assembly Bill 1286 also establishes a self-assessment process for surgical clinics. Development of the self-assessment form will be undertaken by the Enforcement and Compounding Committee. Upon development and approval of the self-assessment form, the Board wi advise licensees and make the form available on its website. During this intervening period, completion of the self-assessment form requirement will be delayed. Interested stakeholders are encouraged participate in relevant public meetings.	
Several additional provisions contained in Assembly Bill 1286 become effective January 1, 2024. The Board encourages licensees to begin taking the necessary steps for compliance immediately. The Board recognizes that despite good faith efforts, there may be delays in achieving compliance by January 1, 2024. During the implementation period, the Board will consider actions taken to secure compliance when areas of non-compliance are identified through the inspection of	-

investigation process. The Board encourages licensees to maintain documentation of actions taken to achieve compliance and to present such information to the Board upon request.



Chapter 6

ENFORCEMENT OVERVIEW

Enforcement Options and Sanctions

Enforcement activities are essential for the board to meet its consumer protection mandate. The enforcement program uses a combination of education, communication, and enforcement sanctions to achieve compliance with federal and state pharmacy laws. Where voluntary compliance and education are not enough, the board inspects, mediates, admonishes, cites and fines, and pursues formal disciplinary action.

When the board receives a complaint or uncovers a potential violation of the law through its own efforts, the matter is investigated by staff. Investigations in the field are carried out by the board's inspectors, a statewide-dispersed group of pharmacists who are employees of the board.

During a routine inspection or investigation (which is conducted by a board pharmacist-inspector), if it is believed that a violation of pharmacy law took place, the licensee may be advised of the alleged violation by an "Order of Correction," a written document directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector. This process simply notifies the licensee of the violations of law that the inspector believes have occurred. This notification may not be the board's final or formal determination regarding the matter depending on the seriousness of the alleged violations. An Order of Cerrection order is not a citation nor is it a disciplinary action.

At this time, the licensee is provided an opportunity to provide a written response to the alleged violation. In the written response, the licensee may address the specifics of the violation, as well as provide any mitigation information that the licensee wishes to have included in any investigation report and/or a corrective action plan.

If the "Order of Correction" is for minor violations, and the inspector is satisfied with the pharmacy's compliance, the "Order of Correction" may be the only action taken. If this is the case and the pharmacy doesn't contest the order, then the licensee must maintain in the pharmacy premises a copy of the <u>O</u>order of <u>C</u>orrection and corrective action plan for at least three years from the date the order was issued.

After the inspection or investigation is completed and the inspector makes a determination that the law has been violated, the case is referred to a supervising _inspector for review. If the supervising inspector determines that there was no violation or that the violation was so minor that the only action to take would be the issuance of the "Order of Correction," then the case may be closed and the matter goes no further.

If, after review by the supervising inspector, it is determined that <u>further</u> action may be warranted, the case is referred for a second <u>letter level</u> of review. This second level of review includes a review of the matter as well as a final determination of the

appropriate course of action. In making this determination, the following factors may be taken in consideration:

- Gravity of the violation.
- Good or bad faith of the cited person or entity.
- History of previous violations.
- Evidence that the violations were or were not willful.
- Recognition by the licensee of his/her wrongdoing and demonstration of corrective action to prevent recurrence, *e.g.*, new policies and procedures, protocol, hiring of additional staff, etc.
- Extent to which the cited person or entity has cooperated with the board's investigation and other law enforcement or regulatory agencies.
- Extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- If the violation involves multiple licensees, the relative degree of culpability of each licensee is considered. In the case where a staff pharmacist may have failed to consult, the pharmacist-in-charge and the pharmacy may also be issued a citation and fine, if warranted by the circumstances.
- Any other relevant matters that may be appropriate to consider.

The type of potential actions include:

Further Investigation

It may be decided that there is insufficient evidence to determine if a violation occurred or if any action is warranted. The executive In such cases the matter may be sent back for further investigation.

Case Closure - No Further Action

It may be decided that no action is now warranted. This may occur when it is determined that there was no violation, that the violation was so minor as to not merit an action, or that the mitigating circumstances were such that it would be best not to pursue an action. The matter will then not be taken any further. (The final resolution would be the <u>"Order of Correction."</u>)

Letter of Admonishment

The decision may be made to issue a letter of admonishment. This may occur when it is determined that there was a minor violation, or a violation that mitigating circumstances were such that a letter of admonishment was appropriate. The licensee would be directed to come into compliance within 30 days by submitting a corrective action plan to the board documenting compliance, or the licensee can contest the letter of admonishment to the executive officer or designee for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain <u>in-on</u> the licensed premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment is considered a public record for purposes of disclosure.

Citation and Fine

The executive officer may issue a citation, with or without a fine. The citation will be issued to the licensee and will include a reference to the statute or regulation



violated. It will also include a description of the nature and facts of the violation, as well as a notice to the licensee of the appeal rights. It may or may not include an order of abatement either requesting documentation of the licensee's compliance, or directing the licensee to come into compliance and specifying how that must be done.

Disciplinary Action

The executive officer or designee may determine that the violation is substantial and warrants discipline of the license. The matter is then referred to the Attorney General's Office, where, if appropriate to do so, an accusation is prepared, which identifies the alleged violations of pharmacy law. Disciplinary penalties include interim suspension orders, license revocation, voluntary license surrender, suspension, letters of reproval, and probation.

Appendix J contains an overview of board members' role in disciplinary actions created by the DCA <u>L</u>legal <u>officeAffairs Division</u>.

Mail Ballots

(Government Code Section 115<u>2600 and Board Policy</u>)

The board must approve any decision or stipulation before the formal discipline becomes final and the penalty can take effect. -Proposed stipulations and decisions are securely sent to each board member for his or her vote. For stipulations, a cover memorandum from board staff and sometimes the board's attorney (a deputy attorney general) accompanies the mail ballot. A two-week deadline is generally given for the mail ballots for stipulations and proposed decisions to be completed and returned to the board's office.

After the deadline of 15 days and after seven votes from board members have been received, a decision has been reached. If <u>a</u> majority of the votes are to adopt a decision, the signature pages are sent to the board president, who signs the written decision document.

If two no votes are cast before the deadline, the case is set aside and not processed (even if seven votes have been cast on the decision). Instead, the case is scheduled for discussion during closed session at <u>the nexta subsequent</u> board meeting. Under board policy, when a member wishes to hold a case, the reason for the hold should be provided on the mail ballot. This allows staff the opportunity to prepare the information being requested.

When a ballot is received after the deadline, the vote is retained in the file but is not counted.

A sample mail ballot is provided in Appendix K.

Holding Disciplinary Cases for Discussion at Board Meetings (Board Policy)

When voting on mail ballots for proposed disciplinary decisions or stipulations, a board member may wish to discuss a particular aspect of the decision or stipulation before voting. If this is the case, the ballot should be marked "hold for discussion."



For a case to be held for discussion before the board's vote on the matter (this discussion will occur in closed session), two board members must mark the mail ballot "hold for discussion."

If the matter is held for discussion, staff counsel will preside over the closed session to assure compliance with the Administrative Procedure Act and Open Meeting Act.

If the board member is comfortable voting on the matter, but wishes to discuss the policy behind the decision or case, the ballot should be marked "Policy Issue for Discussion. I have voted above. Issue: _____." The EO will respond directly to the member. If still unresolved or if the matter is to be referred to the board, the policy issue will be placed on the agenda for discussion at the nexta subsequent board meeting.



Attachment 5

Proposed Meeting Dates 2024

May 8 – Disciplinary Petition Committee Meeting

- June 20 Disciplinary Petition Committee Meeting
- July 17 Enforcement and Compounding Committee
- July 17 Legislation and Regulation Committee
- July 18 Licensing Committee
- July 18 Communication and Public Education Committee
- July 31 Aug 1 Board Meeting (Anticipated 1:00 p.m. start time on July 31)
- September 12 Disciplinary Petition Committee Meeting
- October 16 Enforcement and Compounding Committee
- October 17 Licensing Committee
- November 6- Board Meeting (Changed to a one-day meeting)

December 4 – Board Meeting (Sunset Report & Petitioners) Possibly December 5th if deemed necessary

December 18 – Disciplinary Petition Committee Meeting

Revised 4.17.24