



ENFORCEMENT COMMITTEE REPORT

March 14, 2019

Allen Schaad, Licensee Member, Chair
Dr. Albert Wong, Licensee Member, Vice Chair
Victor Law, Licensee Member
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Ricardo Sanchez, Public Member

1. Call to Order and Establishment of Quorum

2. 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)]

3. Approval of the December 20, 2018 Enforcement Committee Minutes

Attachment 1

Attachment 1 includes a copy of the draft minutes from the December 20, 2018 Committee Meeting.

4. Presentation, Discussion and Consideration of Ethics Course Provisions in California Code of Regulations (CCR), Title 16, Section 1773.5 CCR

Attachment 2

Relevant Law

CCR section 1773.5 establishes that when directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements as a condition of probation, license reinstatement or as abatement for citation and fine. Board approval must first be obtained prior to the commencement of ethics courses.

Background

The board's ethics program was established via regulation in 2009. The ethics program components established were based upon the Medical Board of California's program. As specified in the regulation an approved course must satisfy several requirements.

Consistent with the provisions of the regulation, the board uses the ethics program in some administrative cases as a condition of probation, as well as part of an abatement order for a citation.

For reference a survey was conducted of various healing arts boards. Each board was asked to provide a sample of an ethics course accepted, the provider and the cost.

Physical Therapy

Sample course: Ethical Decision in Physical Therapy

Length: 2-hour course

Provider: ATrain Education

Cost: \$30

Registered Nursing

Sample course: Righting A Wrong - Ethics & Professionalism in Nursing

Length: 1 hour/week for 3 weeks

Provider: NCSBN Learning Extension

Cost: \$30 each

Vocational Nursing & Psychiatric Technicians

Sample course: Values and Ethics in Mental Health Practice

Length: 6-hour course

Provider: Behavioral Health CE

Cost: \$99

The cost of the courses varies from providers. Most providers offer individual courses to purchase but some providers also offer an annual membership where respondents/nurses can use throughout the year for their continuing education courses.

Medical Board

Sample course: Practical Medical Ethics & Professionalism

Length: 2 days

Provider: Western Institute of Legal Medicine

Cost: \$1849

For Committee Consideration and Discussion

During the meeting, the committee will hear separate presentations from representatives from Professional Boundaries, Inc. and Institute of Medical Quality. Each company has developed coursework that address both the legal and ethical dimensions of pharmacy practice in California. They have been invited here today to present to the committee the content and objectives of their ethics courses, the cost of each course as well as their measurements of the success of the courses.

A copy of the presentation by Professional Boundaries Inc., is provided in **Attachment 2**, as well as a copy of the authorizing regulation CCR section 1773.5. A copy of the presentation by Institute of Medical Quality will be provided the meeting.

5. Discussion and Consideration of Senate Bill 1442 (Wiener, Chapter 569, Statutes of 2018) Relating to Community Pharmacies Staffing

Attachment 3

Background

SB 1442 prohibits a community pharmacy from requiring a pharmacist to work alone. It requires either another employee of the pharmacy or the establishment be made available to assist the pharmacist at all times. Exceptions are detailed in the bill.

At the December 2018 committee meeting, board staff was directed to work with counsel to research the DEA requirements and to determine whether a background check would be required under the Code of Federal Regulations (CFR) or if the board should develop such a requirement. Further, as part of the January 2019 Board Meeting, members received public comment both from pharmacists as well as from individuals representing pharmacies and pharmacy management. In general, the public comments noted challenges with implementation; however, the challenges identified varied based upon their role in the organization.

Recent Update

Title 21 CFR section 1301.90 discusses the screening procedures for employee screening. The committee may wish to consider if, as part of its implementation efforts, a similar background check should be conducted for individuals assisting pharmacists that have not otherwise undergone such a background check. Should the committee determine a background check is appropriate, staff and counsel can draft regulation language for future consideration by the committee and board.

For Committee Consideration and Discussion

During this meeting members will hear from State Senator Jeff Stone regarding implementation of the legislation. In addition, the committee may want to review the federal requirements referenced above.

Attachment 3 contains a copy of the chaptered language for SB 1442 and 21 CFR 1301.90.

6. Presentation on the Board's Routine Pharmacy Inspections

Attachment 4

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. (Data on routine inspections will be provided at a future meeting.)

As part of the committee meeting, Board Inspector Steven Kyle will give a presentation on the routine inspection process.

Attachment 4 contains a presentation on how to prepare for an inspection. It outlines the board's mandate and objectives when conducting inspections. The presentation is being provided to help achieve a better understanding of what licensees can expect during the inspection process.

7. Update on and Discussion of Board's Citation and Fine Program

Attachment 5

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.

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 as demonstrated in the citation data below. Typically, the abatement provides that completion of additional training (typically ranging from 2-6 hours) will result in either the reduction or elimination of the fine. Such an approach creates an incentive for the respondent to seek the additional training being requested.

Citation Data

Citation Types	2016/17	2017/18	7/1/18 – 2/15/19
Citations Issued	1935	2168	806
Citations with OOA	28	30	158
Citations with OOA Accepted	7	24	59
Citations Completed	1855	2115	788
Citations Appealed OC	190	139	121
Citations Appealed AG	61	50	19
Fines Collected	\$2,241,388	\$2,396,828	\$826,891*

*Denotes fines collected through 1/31/19.

For several months the board's president and vice-president have reviewed closed and final citation matters where a fine of \$2,000 or more was assessed. Upon completion of the review these members have provided board staff with recommendations for future application of the factors included in Section 1775.2.

Provided below are summary comments the members have suggested that staff consider when assessing fines.

1. Consider the ability of the respondent to pay and recognize that fines assessed may be more difficult for some respondents to pay.
2. Consider referral to the Attorney General's Office if respondent has been the subject of more than two substantiated investigations.
3. Consider referral to the Pharmacists Recovery Program as well as the AG's office if a respondent refuses to submit to a BAC screen as part of a DUI related incident.
4. Consider referral to the AG's Office in lieu of a citation if the respondent has previous incidents including multiple violations.
5. Consider whether the status of an employee, e.g., floater pharmacist, is a matter of aggravation or mitigation, for example in the cases of a drug loss.
6. Consider the impact to a patient when investigations involve compounding violations.
7. Consider the license history including changes in responsible personnel, e.g. pharmacist-in-charge positions.
8. For medication error cases, consider the type of drug involved and the potential or real harm caused by error.
9. Consider if patient consultation would have stopped the error from occurring, if the prescription was a first-time fill, change in directions, etc.
10. Consider assessing a single fine when multiple violations are related to a single issue, e.g. a medication error.
11. For cases involving failure to report an event to the board, e.g., change of PIC, consider the duration of time.

Counsel reminds all readers that each investigation is unique and must be individually reviewed to determine the appropriate outcome. Board staff evaluate investigation outcomes consistent with

pharmacy law provisions, including those cited in this item of the chair report, as well as board policy in other areas, e.g., the board’s Disciplinary Guidelines.

Attachment 5 includes a copy of BPC section 4314 and a Citation and Fine flowchart.

8. Discussion and Consideration on Efforts to Reduce Investigation Times and Case Resolutions

Background

At the September 14, 2018 Enforcement Committee Meeting the committee discussed average time frames for case investigations. Staff continues to work toward the goal of decreasing the number of aging case investigations outstanding.

One of the committee’s strategic goals is to implement processes to shorten cycle time from initial investigation to case resolution. Below are the benchmarks currently measured by board staff:

1. Assignment – Measures the time frame from the date the complaint is received or initiated.
2. Investigation – Measures the duration from the date the matter is assigned to the date the investigation report is submitted.
3. Review Times – Measures the time from the date the investigation is submitted until review by the supervisor and second level review is completed.
4. Closure Times – Measures the duration from the time the investigation report is reviewed until the case is closed.

Committee Discussion and Consideration

Provided below is a snapshot of the board’s current pending investigations, including the average days by the identified benchmarks as of Feb 01, 2019.

Field Pending Investigations as of February 1, 2019

Pending Case Status	# of Cases	Avg Days at this Status	Avg Case Age
Team Review for Assignment	111	24	47
Under Investigation	962	169	212
Report Review	252	51	302
2nd Level Report Review	118	34	312
Closure Time	155	51	429

The department’s target for intake is the number of days from complaint receipt to the date the complaint is closed or assigned to an investigator. The department’s target average is 20 days.

Average intake for FY 2017-18 for field investigations was 27 days, compared to 24 days for the Fiscal Year (July 01,2019 to Feb 01, 2019).

Average Days for cases under investigation in the field during FY 2017-18 was 235 days versus 169 days for the current Fiscal Year (July 01, 2019 to Feb 01, 2019).

The department’s target for case investigations not transmitted to the Attorney General is 210 days, which includes both intake and investigation. Staff is currently at 193 days.

During this seven-month timeframe, there have four vacant inspector positions that were not filled. Two Supervising Inspectors took extended leave times.

At the September 14, 2018 Enforcement Committee Meeting, staff reported they have reexamined some of their processes, resulting in faster assignment time for field investigations. Chiefs of Enforcement have made case closure time of investigations a priority amongst field staff. The charts below outline aging for pending field cases and the age of field cases upon closure date for fiscal years 16-17, 17-18 and year to date 18-19.

The chart below reveals the aging of cases across the past three fiscal years. The total number of cases as a percentage has increased from 73% to 80% for cases less than a year old. The majority of the current cases the board has pending are less than a year old. For cases in the 1 to 2 year, 2 to 3 year and over 3 year ranges the percentages of cases in these timeframes has decreased over the past three fiscal years.

Age of Field Pending Cases as of Last Day of Fiscal Year

FY16-17

Days Pending	# of Cases	% of Cases
Less than 1 Year	1,442	73.7%
1 to 2 Years	441	22.5%
2 to 3 Years	54	2.8%
Over 3 Years	20	1.0%

FY17-18

Days Pending	# of Cases	% of Cases
Less than 1 Year	1,326	79.3%
1 to 2 Years	282	16.9%
2 to 3 Years	46	2.7%
Over 3 Years	19	1.1%

FY18-19

Days Pending	# of Cases	% of Cases
Less than 1 Year	1,292	80.9%
1 to 2 Years	258	16.2%
2 to 3 Years	41	2.6%
Over 3 Years	6	0.4%

FY18-19 data are as of 2/1/19.

The chart below measures the amount of time it took to close cases for the past three fiscal years from the date the case was received to the date closed, issuance of a citation or letter of admonishment. This chart does not include cases referred to the Attorney General. Cases closed in more than three years for the past three fiscal years have steadily decreased from 7% in FY 16-17 to 1.5% in FY 18-19. In addition, the percentage of cases less than a year old has increased from 54% to 64%. Staff is closing cases at a faster rate than in past fiscal years.

Age of Field Cases Closed Fiscal Year 16-17 through Fiscal Year 18-19

FY16-17

Age	# of Cases	% of Cases
Less than 1 Year	934	54.1%
1 to 2 Years	588	34.0%
2 to 3 years	81	4.7%
More than 3 years	125	7.2%

FY17-18

Age	# of Cases	% of Cases
Less than 1 Year	939	54.0%
1 to 2 Years	714	41.1%
2 to 3 years	59	3.4%
More than 3 years	27	1.6%

FY18-19

Age	# of Cases	% of Cases
Less than 1 Year	559	64.0%
1 to 2 Years	264	30.2%
2 to 3 years	37	4.2%
More than 3 years	13	1.5%

FY18-19 data is as of 2-21-19

Age measured from date received to date closed, or citation or LOA issued.

Does not include cases referred to the AG.

9. Discussion on Attorney General Annual Report on Accusations Prosecuted for Department of Consumer Affairs Client Agencies

Attachment 6

Background

One of the committee's strategic goals is to evaluate the disciplinary process and initiate process improvements to enhance its efficiency and effectiveness. Included as part of the DCA's enforcement performance measures is cycle time for formal discipline. This measures the average duration from the date of intake to the date of case outcome.

Pursuant to legislation in 2015, the Office of the Attorney General is now required to annually publish data on disciplinary matters including both case volume and average days for various benchmarks.

For Committee Discussion

During the meeting, the committee will receive a brief presentation by Supervising Deputy Attorney General (SDAG) Joshua Room on the report recently released by the Office of the Attorney General.

Attachment 6 includes relevant portions of the report.

10. Discussion and Consideration of AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction

Attachment 7

Background

Effective July 1, 2020, under the provisions of Assembly Bill 2138, restrictions are placed on the convictions, crimes, and other acts the board may consider when denying, revoking or suspending a license. The law requires reporting on the board's website of denial summaries as well as a list of crimes that will be considered for denial and how they substantially relate to the qualifications, functions, or duties of the practice of pharmacy.

During the December 2018 committee meeting, members considered making a recommendation for board staff to begin working with the Office of the Attorney General and DCA counsel to identify next steps, including possible statutory changes that could minimize the impacts of this measure as enacted.

The committee directed board staff to begin working with the Office of the Attorney General and DCA counsel to identify next steps including possible statutory changes that could minimize the impacts of this measure, as enacted.

For Committee Discussion and Consideration

Board staff and counsel developed possible statutory changes that may restore some of the flexibility the board needs to retain when making a licensing decision. Some of the recommendations create harmony with federal requirements related to practitioners with access to controlled substances while others represent risks that need to be addressed because of the type of products the board regulates and types of access to information board licensees have.

Further, the DCA Legal Office has offered some recommendations to promulgate regulations also necessary to implement the provisions of this bill. During the meeting DCA counsel will provide suggested regulation language consistent with recommendations from the department for the committee's consideration.

Attachment 7 contains a copy of the chaptered language for AB 2138 and the recommended statutory changes.

11. Presentation and Discussion on Disciplinary Guidelines

Attachment 8

Background

As stated above, one of the committee's strategic goals is to evaluate the disciplinary process and initiate process improvements to enhance its efficiency and effectiveness. The disciplinary guidelines are intended to facilitate due process and uniformity in reviewing applications, investigating alleged violations of pharmacy law, and instituting administrative actions against licensees and applicants. The disciplinary guidelines are designed to assist administrative law judges, attorneys, board members and staff, and others involved in the disciplinary process. The disciplinary guidelines address only the board's review of applications, investigations, and administrative actions and are not a comprehensive overview of the criminal and civil offenses in statute, which may subject a licensee or applicant to criminal prosecution.

For Committee Discussion and Action

To ensure a sufficient time is allocated to review the guidelines, Chairperson Schaad intends to dedicate time at the next several meetings to review portions of the guidelines. For this first discussion it is recommended that members come prepared to discuss the first nine pages.

As a precursor to the discussion SDAG Room will provide members with a brief presentation on the guidelines including how attorneys representing the board use them as a tool in administrative matters.

A copy of the Disciplinary Guidelines is provided in **Attachment 8**.

12. Presentation by the California Pharmacists Association on a Proposal to Modify the Board's Current Enforcement Process

Attachment 9

Background

During the October 2018 Board Meeting, Danny Martinez of the California Pharmacists Association (CPhA) requested the board consider the development of a "pre-discipline" review process.

For Committee Discussion

During the meeting, the committee will receive a brief presentation of Proposal for a Pharmacy Advisory Committee, presented by Danny Martinez, Government Relations and External Affairs for the CPhA.

A copy of the presentation is provided in **Attachment 9**.

13. Review of Final Report Submitted by University of California San Diego's Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)

Attachment 10

Background

During the November 2017 Board Meeting, the board voted to extend the UCSD experimental study involving the use of ADDS technology to dispense new and refill medications to outpatients in an area nonadjacent to a pharmacy counter. As part of that action, the board directed UCSD to provide study updates to the Enforcement Committee every six months. This report to the committee fulfills this requirement.

For Committee Discussion and Consideration

During the meeting, the committee will have the opportunity to review a written update (in the form of a presentation) provided by UCSD on the progress and findings of the study, included as **Attachment 10**. UCSD will continue to study the Kiosk through June 30, 2019 and a final study report will be provided to the board by Fall 2019.

A copy of the presentation is provided in **Attachment 10**.

14. Discussion and Consideration of Proposed Changes to Self-Assessment Forms Incorporated by Reference in Title 16, California Code of Regulations, Section 1715 and 1784

Attachment 11

Relevant Law

Title 16, California Code of Regulations (CCR) Section 1715 establishes the requirement for a pharmacist-in-charge of a pharmacy to complete a self-assessment form. Title 16 CCR section 1784 establishes the requirement for a designated representative-in-charge of a wholesaler to complete a self-assessment form.

Background

The purpose of a self-assessment is to promote compliance of a business regulated by the board through self-examination and education. Because the self-assessment forms are compilations of Pharmacy Law, modifications must be made on an annual basis to incorporate recent changes in the law. Further, because of the mandate for licensees to complete the forms no later than July 1 of each odd-numbered year, it is necessary to update the forms and complete the rulemaking process within a very narrow time period.

To address, in part, the challenges presented with the rulemaking process, during its November 2017 Board Meeting, members voted to change the regulation language itself to establish all of the requirements currently established only by virtue of the form. Further, as part of this, board members voted to amend the existing forms.

The rulemaking package to make such changes is undergoing review by DCA counsel.

For Committee Consideration and Discussion

Recently board staff updated the draft self-assessment forms (17M-13 Rev. 10/16; 17M-14 Rev. 10/16; and 17M-26 Rev. 10/16) to incorporate additional changes to pharmacy law that became effective after the board's last draft revision in November 2017. The revised forms are included in **Attachment 11**.

Should the committee agree with the recommended changes, the revised versions will be brought to the full board for consideration and approval. Depending on the status of the rulemaking package, it is recommended that the most updated version of the forms be included as part of the promulgation.

15. Discussion and Consideration of Title 16, California Code of Regulations, Section 1715.6 Related to the Reporting of Drug Losses

Relevant Law

Title 16, CCR section 1715.6 currently states; *"The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths."*

Title 21 CFR 1301.76(b) states, *"The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft."*

Background

As part of past board discussions related to the board's new inventory reconciliation regulation the issue of drug loss reporting requirements was mentioned. It was brought to the board's attention the difference in the Federal Code of Regulations requirements and California Code of Regulations. During the rulemaking process it was suggested that the board amend its current drug loss requirement (CCR 1715.6) to mirror the DEA requirements. At that time members were advised that such a change could not be implemented as the language lacked the necessary clarity required to comply with the Administrative Procedures Act.

At that time, the board determined it would reassess the issue after the reconciliation regulation took effect and data could be reviewed.

For Committee Discussion and Consideration

As part of its discussion, it may be helpful for the committee to review drug loss reporting information which is provided below.

Fiscal Year Reported	Dosage Units	# Drug Loss Reports
FY 12/13	1,151,704	754
FY 13/14 ¹	1,524,833	1,367
FY 14/15	1,513,696	2,168
FY 15/16	1,646,380	3,481
FY 16/17	2,130,112	7,170
FY 17/18	3,230,016	8,435
July 2018 - Dec 2018	720,392	3,701
Total	11,917,133	27,076

- 1 One very large loss (1.6 million dosage units+) of Benzodiazepines due to an out-of-state lost-in-transit drug loss was not included due to skewing of the data.

The table below reflects the number of reports received between 7/1/18 and mid-December 2018 categorized by the size of the losses.

Loss Size (in dosage units)	Number of Reports
Losses between 0 – 100	3,383
Losses between 100 – 500	204
Losses between 500 – 1000	21
Losses between 1000 – 5000	61
Losses over 5000 – 10000	15
Losses over 10,000	17
Total	3,701

16. Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board’s Ask An Inspector Program

Background

At the January 2019 Board Meeting, the Communication and Public Education Committee provided an overview of the “Ask an Inspector” program”. The “Ask an Inspector” program is staffed by one inspector each week. Inspectors responded to a total of 3,257 inquiries through the program between January 1, 2018 and December 20, 2018. The top ten inquiry types were reported and the highest percentage of questions involved controlled substances, which comprised 22% of the inquires last year.

Committee Discussion and Consideration

Staff drafted the most frequently asked questions resulting from the “Ask an Inspector” program regarding controlled substances. The draft is currently undergoing review by counsel. It will be provided during the meeting for review.

17. Discussion and Consideration of Board’s Enforcement Statistics

Due to the timing of this meeting, enforcement statistics will be provided on the day of the meeting.

18. Future Committee Meeting Dates

Below are the remaining scheduled committee dates for 2019

- July 2, 2019
- September 25, 2019

19. Adjournment

Upon Conclusion of Business

Attachment 1



**ENFORCEMENT COMMITTEE
MEETING MINUTES**

DATE: December 13, 2018

LOCATION: Department of Consumer Affairs
1625 N. Market Blvd
First Floor Hearing Room
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Allen Schaad, Licensee Member, Chair
Albert Wong, Licensee Member, Vice Chair
Victor Law, Licensee Member
Stan Weisser, Licensee Member
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Joshua Room, Supervising Deputy Attorney General
MaryJo Tobola, Senior Enforcement Manager

1. Call to Order, Establishment of Quorum and General Announcements

Chairperson Allen Schaad called the meeting to order at 10:05 a.m. A quorum was established.

2. Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Member of the public, Jason Cain, on behalf of Laura Churns from Alberstons Companies, expressed concern about the lack of clarification provided to licensees on the compounding regulations related to the “batch” definition and staff pharmacist competency for sterile compounding, as well as the lack of clarification to inspectors for consistent enforcement. Mr. Cain requested that the committee consider rescinding all enforcement related regulations between January 1, 2017, when the regulations became effective, through the date in which they are clarified.

3. Discussion and Consideration of Implementation Strategies for Chaptered Legislation

Chairperson Schaad stated that at the October Board and September Enforcement Committee meetings members of the public suggested that the legislation passed in this

year's legislative session be brought to the committee for discussion.

a. AB 2086 (Gallagher) (Chapter 274, Statutes of 2018) Controlled Substances: CURES Database

Chairperson Schaad informed the committee that this bill allows prescribers to request a list of patients for whom they are listed as being the prescriber in the CURES database.

Board staff suggested that the committee consider whether a pharmacist working under a collaboration practice agreement may similarly obtain a list of patients where he/she is listed as the prescriber. Additionally, board staff stated that the Department of Justice (DOJ) CURES database can accommodate such a request, as long as an individual has a DEA number.

As part of the public discussion, Robert Stein of KGI School of Pharmacy stated that it is his understanding that CURES either allows an individual to be a prescriber or a dispenser, not both. Pharmacist Steve Gray stated prescribers have historically been unable to obtain a list.

Board staff will confirm that individuals who are prescribers and dispensers may obtain a list, as long as they have a DEA number. Additionally, staff will obtain clarification from DOJ on what format the list will be provided (i.e. paper, electronic, email, etc..)

b. AB 2783 (O'Donnell) (Chapter 589, Statutes of 2018) Controlled Substances: Hydrocodone Combination Products: Schedules

Chairperson Schaad informed the committee that this measure reclassifies specific hydrocodone combination products as Schedule II controlled substances, making California law consistent with federal law.

As part of the public discussion, Mr. Gray stated not all mid-level practitioners, such as physician assistants and nurse practitioners are aware of the change to Schedule II. Additionally, he stated nurse practitioners may not be aware of the difference between federal and state schedules. In his opinion, the problem exists in that pharmacists are filling prescriptions from prescribers who may not have DEA approval to prescribe that particular schedule of drug. Mr. Gray suggested that the board have a discussion with the boards who regulate all mid-level practitioners to inform them of these changes.

Board staff will advise those boards whose practitioners' prescribing abilities are affected by this law.

c. AB 2789 (Wood) (Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmission

Chairperson Schaad informed the committee that this law requires that by January 1, 2022, all written prescriptions, issued by licensed prescribers in California, be issued as an electronic transmission prescription (e-prescription). Also, by January 1, 2022, all pharmacies, pharmacists, or other practitioners authorized to dispense or furnish a medication must have the capability to receive an e-prescription.

Chairperson Schaad provided a list of exemptions, which included:

- Any medication prescribed under Health & Safety Code §11159.2 (for use by hospice or terminally ill patients)
- Technological/electrical failure making transmission problematic
- Prescription that will be dispensed outside of California
- Issued by hospital emergency department or urgent care clinic AND the patient resides outside of California, or outside the geographical area of the hospital
- The patient is indigent or homeless
- The prescription is issued when a patient's pharmacy is closed
- Prescription issued by veterinarians
- The prescription is for eyeglasses or contact lenses
- The prescriber and dispenser are the same entity
- Any time e-prescribing would cause a delay in therapy
- Prescription is not covered by the National Council for Prescription Drug Programs' SCRIPT standard

The committee discussed who is responsible for ensuring that prescribers provide e-prescriptions to pharmacists. Ms. Virginia Herold confirmed that the board would not provide regulatory oversight to prescribers for this new law. Ms. Herold stated she is confident that pharmacists will work with prescribers in educating them of this new requirement.

As part of the public discussion, Mr. Stein stated that there are concerns regarding a 2017 DEA letter which states that pharmacists could forward unfilled electronic prescriptions from pharmacy to pharmacy, including Schedule II. However, there is no mechanism to do that. Additionally, Mr. Stein requests clarification of the terms "forwarding" and "transferring" as they pertain to CCR section 1717(e). Ms. Herold requested Mr. Stein provide a copy of the 2017 DEA letter to the board.

Also during the public discussion, Mr. Gray, requested clarification of the Health and Safety Code that permits the transfer of any valid prescriptions between pharmacists as it relates to CCR section 1717(e), which limits transferring to refilled prescriptions only. Additionally, Mr. Gray informed the committee there are prescribers who have capability to transfer electronically, but their systems do not meet DEA requirements.

Board staff was directed by the committee to work with counsel on the limitations that exist within the regulation and bring back a recommendation to the committee.

- d. SB 1447 (Hernandez) (Chapter 666, Statutes of 2018) Pharmacy: Automated Drug Delivery Systems and AB 2037 (Bonta) (Chapter 647, Statutes of 2018) Pharmacy: Automated Patient Dispensing Systems

Chairperson Schaad informed the committee that these measures establish requirements for automated drug delivery system (ADDS) registration requirements with a licensing program that recognizes the different uses for such a device. The measure establishes definitions for the two different functions of ADDS: Automated Unit Dose System (AUDS) for administration to patients and Automated Patient Dispensing System (APDS) for dispensing directly to the patients.

Specifically, effective July 1, 2019, this measure prohibits an ADDS from being installed, leased, owned or operated in California unless specific requirements are met. One requirement specifies an ADDS license will only be issued to the holder of a valid and active California pharmacy license. The bill expands the locations for placement and operation of an ADDS to specific locations, including the licensed pharmacy issued the ADDS license, a licensed health facility, a licensed clinic, or a specific medical office. Further, this measure requires the pharmacy issued the ADDS license to own or lease the ADDS machine and own the drugs and devices located within it. The measure requires the pharmacy to supervise the operation of the ADDS. This measure details specific stocking and transfer requirements for the ADDS, requires the pharmacy issued the ADDS license to provide training on the operation and use of that ADDS to specific individuals, and requires the pharmacy to complete periodic self-assessments. The bill requires additional conditions for ADDS used to dispense medication to patients. The bill authorizes a pharmacy inspector employed by the board to enter the location, or proposed location, of an ADDS to inspect the location pursuant to these provisions. Lastly, this measure requires the board to report to the legislature regarding the regulations of ADDS machines on or before January 1, 2024, as part of the board's Sunset evaluation process.

Chairperson Schaad informed the committee that under the provisions of the law, drugs can be stored for a period of up to 48 hours in a secured room within the ADDS location (BPC§4427.4(f)). Chairperson Schaad asked if the committee/board should consider providing more specific storage and recordkeeping requirements?

As part of the public discussion, Mr. Gray asked the board to consider, when an APDS is being stocked by a pharmacist, that drugs may be stored in a secure location, on site, which only the pharmacist can open. Mr. Gray noted that there are similar provisions for deliveries that happen after a pharmacy is closed. Sara Lake, Director of Regulatory Affairs for Asteres, Inc. stated there should not be any circumstance when drugs should not be delivered from the pharmacy directly to the secured machine.

Board staff informed the committee that the legislation, as enacted, allows for the consideration of medication storage outside of any ADDS machine. Staff suggested that the board sponsor legislation, to amend this statute in order to tighten the storage restrictions to apply only to an AUDES, not to an APDS.

The committee directed board staff to research options and present a few policy recommendations to the committee at a later time.

Ms. Anne Sodergren stated that under the provisions of the law, an incident involving an APDS where a complaint, error, or omissions has occurred shall be reviewed as part of the pharmacy's quality assurance program (BPC § 4427.6(i)). Ms. Sodergren asked the committee/board to consider requiring such quality assurance reviews to be separately reported to the board. If so, the board could develop regulations to require the reporting of such incidents to be sent to the board, which would allow the board to collect data to accurately report to the legislature in 2024.

During the public discussion, Mr. Gray stated his support of the development of regulations and urged the committee to provide clear language which would separate this requirement to report incidents from the quality assurance review requirement.

Motion: Direct board staff to work with the committee chair in developing regulation language for consideration regarding the mandatory reporting of Quality Assurance reports to the board. Proposed language will be brought to the January board meeting.

M/S: Weisser/Wong

Support: 5 Oppose: 0 Abstain: 0

Following the vote a member of the public asked for clarification regarding under what conditions an ADDS machine may operate in a licensed clinic. Ms. Herold stated that Section 4186 details conditions under which an ADDS can operate in a licensed clinic. Mr. Gray voiced concern about 4180 Clinics that currently own and operate their own ADDS machines. Mr. Gray requested clarification of implementation of Section 4186 with 4180 Clinics.

SDAG Joshua Room stated that an ADDS in a clinic must be controlled by a pharmacist, but does not have to be owned by a pharmacy.

e. AB 2753 (Low) (Chapter 479, Statutes of 2018) Controlled Substances: CURES Database

Chairperson Schaad informed the committee that this law reduces the number of authorized security printers approved by the DOJ. Further, this measure requires security prescription forms to contain a unique serialized number that must be reported

to CURES and establishes reporting requirements to the DOJ on the delivery of security prescription forms to a prescriber.

Ms. Herold stated that Health & Safety Code section 11162.1 establishes provisions of this law. The board has requested delayed implementation from DOJ, since the actual approved forms will not yet be available by the January 1, 2019 effective date. Providers do not yet have these serialized forms. Effective January 1, 2019 a prescriber may be prescribing on a non-compliant form.

SDAG Room confirmed that printers will not be able to provide compliant forms to prescribers by January 1, 2019. SDAG Room presented the committee with a proposed subscriber alert, which detailed proposed options for pharmacies.

As part of the public discussion, Mr. Stein questioned the use of “if applicable” in the law. SDAG Room clarified that the term “if applicable” is only used in the reporting to CURES requirement, not in the prescribing or dispensing requirement. Further, SDAG Room stated that Health & Safety Code section 11164(a) is the provision requiring that as of January 1, 2019, only a prescription with this security feature is lawful. Mr. Gray encouraged SDAG Room to amend the proposed Subscriber Alert to include the exclusion of Medi-Cal patients. In response, SDAG Room stated that the Subscriber Alert would be limited to issues at hand which was the revised prescription requirements for controlled substances. Jennifer Snyder of the California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS), noted she has had discussions with the author’s office and was informed that it was the intent of the author to allow for a broader application of the “if applicable” term and offered to work with board to find a solution.

Additional public discussion included a recommendation to delay enforcement of the bill, statutory changes and the filing for a court injunction to prevent the law from going into effect. SDAG Room confirmed that an injunction is plausible for an entity other than this state board. Danny Martinez of CPhA stated that in his experience, it is possible to have legislation enacted within just one week, given the gravity of the situation.

Ms. Herold stated that, in the past, the board has exercised enforcement discretion. Ms. Herold stated that historically the board has allowed up to a six-month transition time in order to allow time for compliance to a new regulation. DCA Counsel Laura Freedman explained that any time the Executive Officer (EO) takes an enforcement action, the EO takes into consideration all the facts that are present; in this case, included in those facts would be the availability of compliant forms. SDAG Room supported the EO’s option to not make enforcement of this law a priority for the first six months of 2019.

SDAG Room clarified to the board that the DOJ does not consider itself involved in the enforcement of this requirement in regard to prescribers or dispensers. The DOJ believes its responsibility ends with approving the forms and security printers and the

collection of CURES data. The DOJ does not concern themselves with the intervening transactions.

Motion: Direct staff to release a statement clarifying that the board will not consider this an enforcement priority until July 1, 2019.

M/S: Weisser/Sanchez

Support: 5 Oppose: 0 Abstain: 0

f. AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction

Chairperson Schaad informed the committee that, effective July 1, 2020, this law places restrictions on the convictions, crimes, and other acts the board may consider to deny, revoke or suspend a license. The law requires reporting on the board's website of denial summaries as well as a list of crimes that will be considered for denial and how they substantially relate to the qualifications, functions, or duties of the practice of pharmacy.

Chairperson Schaad stated that staff recommends that they begin working with the Office of the Attorney General and DCA counsel to identify next steps including possible statutory changes that could minimize the impacts of this measure as enacted. Further, it is recommended that staff, in concert with counsel, perform a GAP analysis as the first step towards implementation.

SDAG Room informed the committee that this law makes several changes to the types of convictions that can be used as a basis for denial and allows the board to look into the conduct that led to the convictions. Since this law becomes effective in July 2020, SDAG Room believes that any pending cases as of July 2020 will have this new law applied to it. SDAG advises that some time before July 2020 the board should make adjustments to its criteria, since pending cases which occurred before July 2020 may be subject to this law. SDAG Room clarified that only convictions within the past seven years to be the most relevant types and any conviction(s) that have been dismissed, pursuant to Penal Code section 1203.4, in which the individual has successfully completed probation, may, by petition, be dismissed. The legislature believes completion of probation is indication of sufficient rehabilitation and should no longer be a licensing consideration. SDAG Room anticipates that the DCA and the DOJ will be working on resolving issues on how to handle individuals with multiple convictions. SDAG Room stated that this legislation is consistent with the "Clean Slate" initiatives taking place nationally.

Additionally, SDAG Room stated that he recently had a courtroom appeal that predated this legislation and the courts are already taking these provisions into consideration when making decisions on cases.

DCA Counsel Freedman informed the committee that her office is actively working on general guidelines for all boards. They are working on model language and will be consulting with the DOJ.

President Law asked SDAG Room if DUI convictions would be included in this law. SDAG Room confirmed that a DUI conviction could no longer be considered for license denial if the individual who committed the DUI offense completed probation and petitioned for the conviction to be dismissed.

Member Stan Weisser asked SDAG Room if an applicant is approved for licensure may the board then immediately take disciplinary action and place the license on probation. SDAG Room stated that, in theory, the board could approve the application of an individual who has committed an offense that could no longer be considered, then take disciplinary action against that license based on that prior conviction.

Ms. Sodergren stated that the board is faced with several implementation challenges. The board must draft regulations and educate by providing the types of convictions that could be grounds for denial. Ms. Sodergren asked the committee if they would consider amending this law to allow the Pharmacy Board a provision to take into consideration certain convictions or underlying conduct. Ms. Sodergren informed the board that in its final form, the law allows certain boards provisions to take into consideration, such as fraud convictions. Ms. Sodergren suggested that it might be beneficial to research interest in the legislature to allow for consideration of certain convictions or conduct for the board to rely upon.

As part of the public discussion, Mr. Gray noted that other healing arts boards are also pursuing legislation. Mr. Gray informed the board that there are federal regulations that require the DEA to conduct a background check for any DEA registrant who has access to controlled substances. DEA law states that individuals with a drug-related conviction may not be employed into positions with access to controlled substances. Additionally, federal law prohibits the employment of someone who fills Medicare or Medicaid prescription who are on the Federal Blacklist for having been associated with fraud-related crimes.

Motion: Direct staff to begin working with the Office of the Attorney General and DCA counsel to identify next steps including possible statutory changes that could minimize the impacts of this measure as enacted. Further, it is recommended that staff, in concert with counsel, perform a GAP analysis as the first step towards implementation.

M/S: Weisser/Law

Support: 5 Oppose: 0 Abstain: 0

g. AB 2859 (Cabellero) (Chapter 240, Statutes of 2018) Pharmacy: Safe Storage Products

Chairperson Schaad informed the committee that AB 2859 requires community pharmacies that dispense Schedule II, III, or IV controlled substances (such as opioids) to display safe storage products on the premises and close to the pharmacy. Pharmacies, where a licensed pharmacist is the majority owner and manager of no more than four pharmacies, are exempt from this requirement. These provisions will remain in effect until January 1, 2023.

Chairperson Schaad stated that the language in the bill states that pharmacies are required to display safe storage products but does not specifically state that the pharmacy must offer them for sale. He asked the committee whether members wanted to discuss requiring pharmacies to stock and sell these products or simply display them for informational purposes. Member Weisser stated that he was satisfied with the approved language of the bill.

As part of the public comment, Mr. Gray requested confirmation that the board accepts the general definition of the statute that states that a pharmacy is only required to display the safe storage products, but not sell them. Member Weisser confirmed acceptance of that definition. Secondly, Mr. Gray informed the committee that the statute states that the board may choose to not assess discipline if there is a financial hardship.

DCA Counsel Freedman confirmed that the bill allows a pharmacy to display the products, but does not require a pharmacy to sell the products.

h. SB 212(Jackson) (Chapter 1004, Statutes of 2018) Solid Waste: Pharmaceutical and Sharps Waste Stewardship

Chairperson Schaad informed the committee that this law establishes a statewide program to fund drug takeback and sharps disposal programs throughout California. The provisions take effect on or before January 1, 2021. Under the provisions, the funding will be provided by covered entities, which would typically be manufacturers of drugs sold in California. CalRecycle is required to develop regulations governing this stewardship program by January 1, 2021.

Additionally, Chairperson Schaad informed the committee that under this chapter, the board is required to develop and maintain a list of all covered drugs sold in California, as defined in the measure. Further, the board is required to review each stewardship plan for compliance with applicable federal and state laws governing drug take back programs. Board staff will collaborate with CalRecycle.

Chairperson Schaad informed the committee that, as enacted, the board is required to review a list of covered and not covered products for sale in California. Should the board/committee develop reporting requirements to ensure consistency in the receipt of such data, such an approach could require regulations. The board is provided the authority to adopt regulations for administration of provisions for which it is responsible.

Ms. Sodergren identified challenges to this statute. For example, no real branders exist for basic responsibilities, such as how covered entities are to provide the information to the board; board staff would prefer an electronic standardized format. Therefore, without some type of regulation, staff could request an electronic format, but staff could not require it. Without regulations, it would be very difficult for staff to manage the receipt of information.

Ms. Sodergren informed the committee that Alameda County already has a program. Staff hopes to leverage what Alameda County is doing and use the county information to standardize submissions and develop parameters.

The committee directed staff to move forward to develop standardized submissions and parameters. Staff will provide the committee with recommendations, at a later date.

As part of the public discussion, Jennifer Snyder of the CRA and the NACDS indicated that many of the provisions of the law are problematic. She expressed concern with pharmacies that are included in the definition of covered entities. Ms. Snyder highlighted that there is a requirement that 90 days after the effective date of the bill (January 1, 2019), covered entities will have to submit to the board all of their drugs that they distribute into California and annually thereafter. Ms. Snyder stated that pharmacies in the City and County of San Francisco have successfully submitted this information on an Excel format and Ms. Snyder offered to provide that to the board as an example.

i. SB 1109 (Bates) (Chapter 693, Statutes of 2018) Controlled Substances: Schedule II Drugs: Opioids

Chairperson Schaad informed the committee that SB 1109 requires completion of continuing education (CE) for prescribers on the hazards of opioid use. Further, this law requires that a specified warning notice shall be prominently displayed on the label or container for an opioid dispensed to a patient for outpatient use.

Further, Chairperson Schaad stated as enacted, this CE requirement does not apply to pharmacists who prescribe under a collaborative practice agreement. He asked the members if the board or committee should consider developing a similar requirement for pharmacists performing in such a capacity.

Both Member Weisser and President Victor Law recommended that CE requirement also be developed for pharmacists who prescribe under a collaborative practice agreement.

As part of the public discussion, Danny Martinez of CPhA stated that is his understanding that it was not the authors intent to include pharmacists in this CE requirement. Mr. Martinez questioned whether regulations could be written if the provisions were not directed to pharmacists. Mr. Martinez explained that he believes the author intended to regulate prescribers rather than pharmacists.

President Law has requested a sample of required labels.

MOTION: Board staff will develop a statutory proposal seeking a CE requirement for a pharmacist operating under a collaborative practice agreement, with the authority to work with the chair of the committee. The proposal will be brought to the board at the January 2019 meeting.

M/S: Weisser/Law

Support: 5 Oppose: 0 Abstain: 0

j. SB 1254 (Stone) (Chapter 697, Statutes of 2018) Hospital Pharmacies: Medication Profiles or Lists for High-Risk Patients

Chairperson Schaad informed the committee that SB 1254 requires a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission and discharge. The criteria for determining whether a patient is high-risk will be established by each hospital. Additionally, this law allows for this function to be performed by a pharmacy technician or intern pharmacist, if they have successfully completed training and proctoring by the pharmacy department or another healing arts licensee issued a license pursuant Division 2. Under the provisions, the board has the authority to adopt regulations.

Chairperson Schaad asked the committee if they wished to have staff identify hospitals that have chosen to implement medication reconciliation under the purview of the pharmacy.

Ms. Sodergren explained to the committee that data collected from hospitals could help with the development of policy moving forward.

As part of the public discussion, Mr. Gray opined that this is one of the most important bills of the year and encouraged the board to take this opportunity to take a very strong enforcement position on the implementation of this bill.

Motion: Direct board staff to collect information on how hospitals are implementing the collection of data pursuant to SB 1254.

M/S: Weisser/Law

Support: 5 Oppose: 0 Abstain: 0

k. SB 1442 (Wiener) (Chapter 569, Statutes of 2018) Community Pharmacies: Staffing

Chairperson Schaad informed the committee that this law prohibits a community pharmacy from requiring a pharmacist to work alone. It requires either another employee of the pharmacy or the establishment be made available to assist the pharmacist at all times.

Chairperson Schaad identified some exceptions including:

- Hospital pharmacies and hospital outpatient services
- Government owned pharmacies
- Pharmacies owned by individuals who own up to four pharmacies in California
- Pharmacies owned and operated by a health care service plan that exclusively contracts with no more than two medical groups
- Pharmacies with a drive-through window service when only the drive-through is open and the employer does not require the pharmacist to retrieve items outside the pharmacy for sale
- Pharmacies that do not sell, furnish, or dispense controlled substances, dangerous drugs or dangerous devices at retail

As part of the public discussion, Mr. Martinez and Mr. Gray requested that the board clarify what it means to “assist the pharmacist.” Ms. Snyder provided what she believes is the intent of the legislation: the intent was to identify a staff member (not a pharmacy technician) within the establishment to relieve the pharmacist for short periods of time. Mr. Gray stated that it is his understanding that the intent was to provide an actual assistant to help with administrative duties. Mr. Stein stated there may be staffing issues with separate ownerships between the pharmacy and the retailer. An example he provided is a CVS Pharmacy located inside a Target retail store.

Staff will work with counsel to research the DEA requirements and to see if a background check would be required under the Code of Federal Regulations or if the board should develop such a requirement. Staff will report back with a recommendation at the next meeting.

l. Chaptered Bills Relating to Health Care Coverage: Prescription Drugs

- AB 2863 (Nazarian) (Chapter 770, Statutes of 2018) Health Care Coverage: Prescriptions
- AB 315 (Wood) (Chapter 905, Statutes of 2018) Pharmacy Benefit Management
- SB 1021 (Wiener) (Chapter 787, Statutes of 2018) Prescription Drugs

Chairperson Schaad informed the committee that bills AB 2863, AB 315 and SB 1021 are intended to ensure that patients do not pay more for a drug if they have health insurance, than if they had paid the cash price directly.

As part of the public discussion, Ms. Snyder, requests that the board delay enforcement of provisions in AB 2863 and AB 315 that requires a pharmacy to submit a claim, but noted that submission of the claim is a problem because the systems do not allow for such a submission.

DCA Counsel Freedman recommended allowing staff and counsel more time to review each piece of legislation and their individual impacts. The committee agreed with her recommendation and asked that counsel bring any recommendations to the January Board Meeting.

4. Discussion and Consideration of Amendments to California Code of Regulations, Title 16, Section 1713, Related to Automated Drug Delivery Systems

Chairperson Schaad informed the committee that as discussed earlier in this meeting, recently enacted legislation regarding ADDS alters the condition under which a pharmacy can operate such a device. With the enactment of SB 1447 and AB 2037, the board/committee should consider amending existing regulations for ADDS that dispense medications to patients to reflect current law in this area.

Chairperson Schaad introduced a statement authored by the Ms. Sara Lake. Chairperson Schaad explained to the committee that the statement provided details on proposed regulatory changes, pursuant to the enactment of SB 1447. Chairperson Schaad also introduced a broader set of amendments developed by staff to remove duplication between the regulation and the new law as well as conflicts created by enactment of the new statute.

Chairperson Schaad provided the committee with the suggested recommendation from board staff.

Ms. Sodergren clarified that the suggested recommendation would be to amend CCR section 1713 to reflect the boards current policy with respect to ADDS because there is a conflict between the statute and previous regulations. Staff recommended conforming changes.

Motion: Recommend to the board initiation of a rulemaking to amend Title 16, California Code of Regulations section 1713 and delegate to the Executive Officer the authority to make technical or non-substantive changes consistent with the board’s policy.

M/S: Weisser/Law

Support: 5 Oppose: 0 Abstain: 0

5. Discussion and Consideration of Possible Statutory Amendment to Clarify CURES Reporting Requirement Related to the Dispensing Date

Chairperson Schaad provided background to the committee. He explained that currently, all Schedule II – IV controlled substance prescriptions dispensed in California must be reported to the Prescription Drug Monitoring Program (PDMP) known as CURES.

Records of dispensing must be sent to CURES within seven days of the dispensing of the controlled substance, but there is currently no requirement to send a void/cancel message for prescriptions that were filled in the pharmacy but never picked up.

For committee consideration and discussion Chairperson Schaad explained that while the CURES reporting system is administered by the DOJ, actual submissions by pharmacies are transmitted to a third party, Atlantic Associates (AAI). AAI is tasked with data integrity, formatting checks, identifying duplicate entries, and reconciling “near matches.” AAI then transmits the data for insertion into the CURES database.

Additionally, while some pharmacy systems hold a prescription’s transmission to CURES until the patient actually receives the filled prescription, most systems do not. Thus, CURES reports may contain medication that, in fact, were never actually dispensed to the patient.

Chairperson Schaad welcomed Robert Stein to provide the committee with a presentation relating to this issue.

Mr. Stein presented possible solutions. First, a reverse/cancel transaction obviates the manual processes needed to remove a prescription not conveyed to a patient from CURES. Second, pharmacies with computer systems that include integrated Point of Sale or “closed loop dispensing” may not require the reverse/cancel functionality if the date of sale, physical dispensing to the patient, becomes the “trigger event” to send a prescription record to CURES; however, if the “date of dispensing” is considered to be the date of fill in the pharmacy computer system, some prescriptions may be reported to CURES later than the statutory requirement. Mr. Stein suggested a statutory amendment to Health & Safety Code section 11165 in order to clarify that the time limit to submit the transaction to CURES begins at either the date of prescription processing or the date of actual dispensing to the patient, whichever is later. Third, pharmacy system vendors should be notified that to comply with California reporting requirements, they must modify their systems to send a

void/cancel code to AAI. Fourth, Mr. Stein requested clarifying language throughout statutes and regulations that harmonizes definitions of “fill,” “dispense,” and “sale” dates.

Member Weisser suggested that the information be shared with the DOJ. Ms. Sodergren clarified that the DOJ CURES system has the capability, but the systems at the pharmacies are not capable of sending the void/cancellation to the CURES system.

Ms. Sodergren suggested that staff could publish a newsletter article or send out a subscriber alert advising pharmacies of the problem with pharmacy systems not sending the void/cancellation to the CURES system.

As part of the public discussion, Mr. Gray suggested a legislative change.

6. Discussion and Consideration of Board’s Enforcement Statistics

Chairperson Schaad informed the committee that the board received 1,156 complaints and closed 1,180 investigations. As of November 30, 2018, the board had 1,853 investigations pending.

Chairperson Schaad added that of the investigations closed, 595 complaints were closed without a substantiated violation, including 140 complaints that were determined non-jurisdictional.

In addition, the board issued 625 citations, 94 of which the board offered abatement to either reduce or eliminate the fine. The board referred 108 investigations to the Office of the Attorney General.

Chairperson Schaad concluded that the board resolved 120 administrative cases that resulted in 96 revocations or surrenders of a license, 45 licenses being placed on probation, and issued 20 public reprovals.

7. Future Committee Meeting Dates

Chairperson Schaad informed the committee that the 2019 meeting dates are March 14, 2019, July 2, 2019 and September 25, 2019.

Chairperson Schaad adjourned the meeting at 1:31 PM.

Attachment 2

PBI Education: Courses for Pharmacists

Catherine V. Caldicott, MD, FACP
Senior Faculty and Regulatory Liaison
PBI Education

Prepared for the California State Board of Pharmacy
March 14, 2019

Roadmap

- Who we are
- What we do: Remediation courses
- The Pharmacy Ethics and Professionalism course
 - Pharmacy content
 - Ethics content
- Other courses for pharmacists

About PBI Education

- Founded in 2001
- Mission: To safeguard professionals, professions, and the public they serve
- Live, teleconference, and online continuing education preventive and remedial courses
- ACCME Accredited through UC Irvine School of Medicine
- PE-22 is accredited through CAPE

About PBI Education

Remedial Courses: live, with optional online precourse and telephonic longitudinal follow-up

- ✓Ethics and Professionalism
- ✓Boundaries and Ethics
- ✓Prescribing: Opioids, Pain Management, and Addiction
- ✓Medical Record Keeping
- ✓Laws & Rules (FL only)
- ✓Primer-20 for minor, “nip in the bud” infractions (online plus 1:1 telephonic with faculty)

The Pharmacy Ethics and Professionalism Course

- Pre-course (8 hours): online readings and assignments
- In-person seminar: 2 days, 14 hours
- 6- and 12-month follow up

The Pharmacy Ethics and Professionalism Course

Faculty:

- Jack Raber, Pharm D.
 - Consultant/Owner, Clinipharm Services, Long Beach, CA
 - Teaches pharmacy risk assessment and management at USC School of Pharmacy
- Tom Curtis, JD
 - Chair, Healthcare Practice Group
 - Nossaman LLP, Irvine, CA
- Stephen Schenthal, MD, MSW
 - Founder & CEO, PBI Education

The Pharmacy Ethics and Professionalism Course

- Since 2014
- CAPE approved
- Offered 5-6 x / year
- 12 participants / session cap
- 6- and 12-month follow up survey
- No known recidivism
- Some MAS participation required by other states for compliance w/ probation, assistance in return to practice

The Pharmacy Ethics and Professionalism Course

Precourse

- Reading packet
- Submit board order
- Narrative of violation
- Read and critique pharmacy code of ethics
- Write own code of ethics
- Research violation by reviewing state statutes, regulations
- List and analyze risk factors in their work setting, personal vulnerabilities, resistance to exploring these elements, and accountability that might help prevent future violations

The Pharmacy Ethics and Professionalism Course

Day One:
Pharmacy Content
Facts and Law
What they did wrong

Pharmacy content

- What is a professional?
- Exercising professional judgment
- Review of individual violations
- Rigid thinking vs. critical thinking
- Personality traits of pharmacists
- Professional challenges of pharmacists
- Risk factors for boundary violations
- Law
 - Criminal, civil, administrative
 - Statutes, regs, interpretive guidelines (*The Script*)
 - Non-adoption (if a hearing)

Pharmacy content

- The role of a state pharmacy board
- Methods of discipline
- Definition of unprofessional conduct
- Common reasons for discipline
 - Diversion (self and others), addiction
 - Corresponding responsibility & CA Intractable Pain Act
 - Vetting the prescriber, the prescription (legal and legitimate), the patient; also considering pharmacotherapy and monitoring
 - Internet prescribing

Pharmacy content

- Common reasons for discipline, cont'd.
 - Lack of oversight of the prescription process: boundary violations re: the technician, counseling
 - Employee theft/diversion, reporting, lack of detection systems
 - Best practices for preventing diversion
 - Substandard compounding and illegal manufacturing
 - Fraud, waste, and abuse associated with prescription drug benefits
 - Corruption of the supply chain; the myth of the 5% rule

The Pharmacy Ethics and Professionalism Course

Day Two:

Ethics Content

The Process of a Violation

Why you did what you did

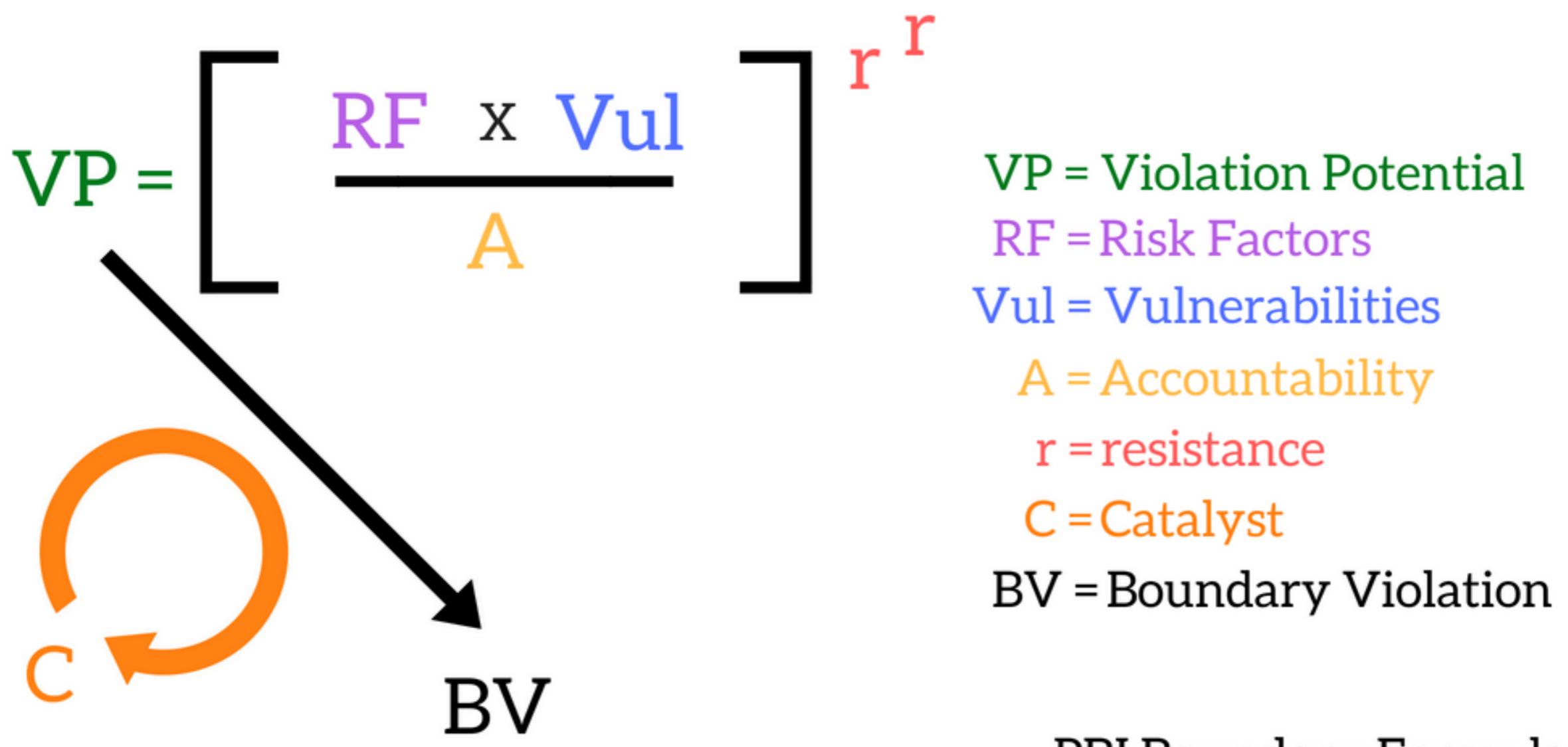
Ethics content

Premise: *Everyone* has the potential to commit an ethics or boundary violation. But not all do. Why do only some stray?

Violations occur in professionals with...

- **Risk Factors:** practice location, discipline, patient population, professional isolation, financial pressures, pressure to become PIC, “worker” vs. professional mentality
- **Vulnerabilities:** personal or psychological issues
- **Accountability measures are inadequate:** supervision; adhering to policies, laws, regs; staying w/in scope of practice, professional boundaries
- **Resistance:** rationalization, denial, other-blaming, defensiveness, justification, repression, etc.
- **Catalyst:** a person who pushes your buttons, a crisis at home or at work, transitions, losses, illness

The Boundary / Ethics Formula ©

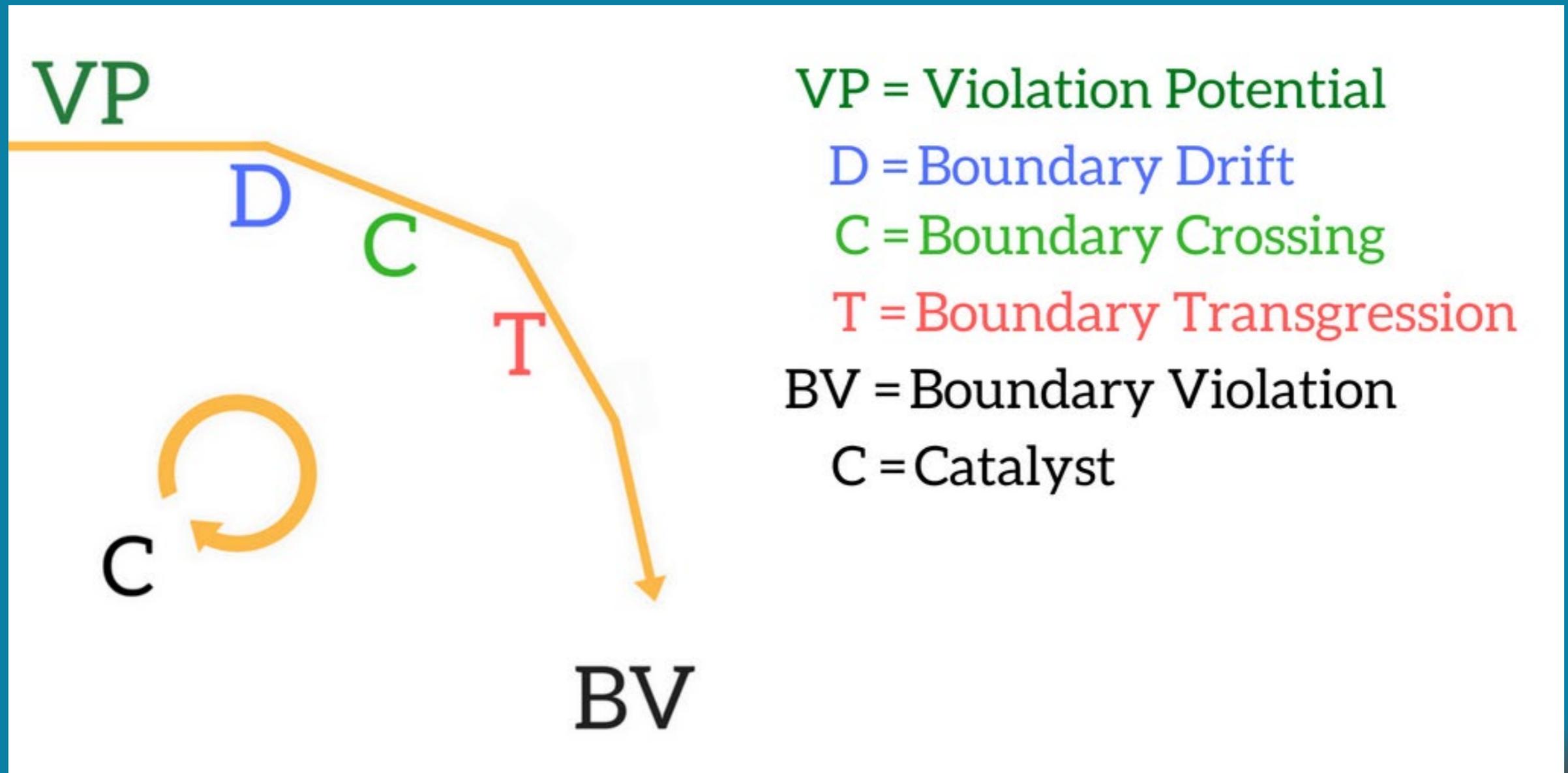


PBI Boundary Formula ©

Lapses Along a Continuum

- A spectrum of severity
- Major violations are usually preceded by smaller misdeeds

The Slippery Slope: Continuum of Impingements



Examples of Line “Impingements”

- **Drift:** Private thoughts about pts for the pharmacist’s own pleasure or benefit, rather than in the service of pt care (e.g., sexual, romantic, rescue, hero, culture-based fantasies)

Behaviors with increasing harms:

- **Crossing:** Stepping outside standard of care, professional role, pharmacy policy, typical practices
- **Transgression:** Sharing personal information, intentionally initiating non-clinical contact or relationship
- **Violation:** Exploitation of trust, knowledge, influence, or emotions derived from the professional relationship

Personalized Protection Plan

- “Oral exam,” peer review
- Includes risk factor and vulnerability modification, increases accountability measures, counterracts resistance(s), plans for catalysts, all to decrease VP
- Stratified
 - Organizational—workplace or employment modifications
 - Professional—conduct, decorum, critical thinking, professional role
 - Personal—physical, mental, emotional health, balance
- Should be updated/modified over time

“Successful Completion”

- Remediating a lapse in professional conduct is a process
- Taking a course is the first step
- A person may have completed the course, but they have only just begun the remediation process

Follow-up

- Questionnaire sent out after 6 and 12 months
- After 6-mo f/u, Letter of Completion issued
- After 12-mo f/u, Certificate of Completion issued
- All questionnaires reviewed for problems, red flags

Participant Comments

- *A transformative experience*
- *Very well balanced between the law aspects and the analysis of personal ethics*
- *It made me take a look at my own risk factors and vulnerabilities that I never knew I had*
- *Has given me the tools to become more competent and to avoid regulatory problems in the future*
- *I will be professional inside and outside the workplace*
- *I am now aware of early warning signs and how they may contribute and lead to violations*

CAPE Comments

From the audit status report:

- *This is a comprehensive, well-done course of laws & professional standards. The didactic portion is very well done..... Examples help illustrate how things could be misinterpreted.*
- *This professional ethics course... covers a wide range of professional ethics and legal subjects. ...It is very in-depth... and it succeeds quite well!*

Other Courses Suitable for Pharmacists

- **Professional Boundaries and Ethics (PB-24)**
- **Medical Ethics and Professionalism (ME-22)**
- **Maintenance and Accountability Seminar (MAS)**

Longitudinal Follow-up

Maintenance and Accountability Seminar (MAS)

- Weekly, hour-long teleconference
- 12-week cycles. Can sign up for multiple cycles
- ~12 course graduate participants, faculty facilitator
- Preliminary data analysis indicates that MAS participation is associated with recidivism prevention

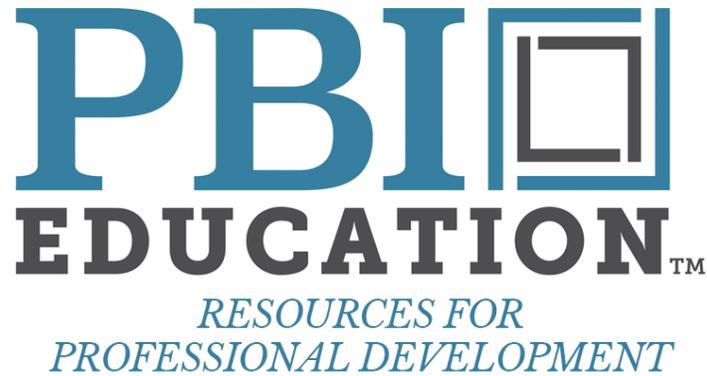
What Participants Say

Why do you keep coming back?

- *To deepen my understanding of risk factors, vulnerabilities, etc.*
- *Because integrating this is a gradual process*
- *To incorporate what I've learned into my world view*
- *To decrease isolation, shame, and embarrassment*
- *It doesn't allow what I've learned to fade away*
- *It reminds me how easy it is to lose the privilege to practice*
- *It decreases the potential for complacency to develop*

Thank you

Questions?



Follow-up questionnaire

PBI Pharmacy Ethics and Professionalism: An Ethics Protection Course

Name : Submission Date :

Course Location : Course date :

Directions: Please answer the following questions at 6 and 12 months following completion of the live workshop and return this form ASAP. You will receive 22 hours category I CME credit if you complete the live course, and send in completed follow-up questionnaires at 6 and 12 months.

1. Has the Medical Ethics Course you took been helpful?

2. What have you changed as a result of taking the Medical Ethics and Professionalism course?

3. Describe which components of your Stratified Ethics Protection Plan (developed in the Pre-course and at the workshop) have been implemented?

4. Which components of the Stratified Ethics Protection Plan have been most helpful?

5. Have there been any other complaints or new concerns about your behavior?

6. Have there been any new citations, arrests, misdemeanor or felony charges?

7. Has there been any new accusation by a regulatory board or professional organization?

8. Have there been any actions against you by the regulatory board or other agencies since you took the workshop?

9. Are you working in your health professional career?

10. Describe how you are taking care of yourself physically?

11. Please check all applicable:

- I exercise at least 2 hours per week
- I am up-to-date with routine medical care
- I eat a healthy diet
- I work less than 50 hours per week
- I am up-to-date with routine dental care
- I get enough sleep to be rested

12. Comments?

13. Do you have meaningful relationships outside work?

14. Do you participate in any group(s)?

15. Please describe how you take care of yourself spiritually?

16. How did codependence play a part in your difficulty and what have you done to address it?

17. How did counter-dependence play a part in your difficulty and what have you done to address it?

18. Did you participate in the Maintenance and Accountability Seminar Series (weekly telephonic group meeting)? If yes, please describe and mention benefits.

19. Is this questionnaire the best way to do the follow-up visits or would you prefer a telephonic or live 6 and/or 12 months follow-up process?

20. Comments?

We recommend you save your work BEFORE clicking "submit" as a precaution. To save your work print out this form or save it as a PDF. To save as a PDF: Click File, then click Print, then update your print options to save as PDF.

Submit

PBI Education | 1301 Riverplace Blvd Suite 800, Jacksonville, FL 32207

tel: 904-800-1237 | email: info@pbieducation.com

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§ 1773.5. Ethics Course Required as Condition of Probation.

16 CA ADC § 1773.5 BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations [Currentness](#)

Title 16. Professional and Vocational Regulations

Division 17. California State Board of Pharmacy

Article 8. Prohibitions and Discipline (Refs & Annos)

16 CCR § 1773.5

§ 1773.5. Ethics Course Required as Condition of Probation.

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

(a) The board will consider for approval an ethics course that at minimum satisfies the following requirements:

(1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.

(2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.

(3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.

(4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.

(5) Content. The course shall contain all of the following components:

(A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.

(B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.

(C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

(D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.

(5) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.

(F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.

(6) Class Size. A class shall not exceed a maximum of 12 participants.

(7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.

(8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.

(9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the case or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

HISTORY

1. New section filed 8-4-2009; operative 9-3-2009 (Register 2009, No. 32).

This database is current through 2/22/19 Register 2019, No. 8

16 CCR § 1773.5, 16 CA ADC § 1773.5

Attachment 3

SB-1442 Community pharmacies: staffing.(2017-2018)

SECTION 1.

The Legislature finds and declares as follows:

(a) Licensed pharmacists are health care professionals whose training and experience play a vital role in protecting public health.

(b) Pharmacists are legally and ethically bound to advise their patients, physicians, and other health practitioners on the selection, dosages, interactions, and side effects of medications as well as monitor the health and progress of those patients to ensure that they are using their medications safely and effectively.

(c) Pursuant to Section 4001.1 of the Business and Professions Code, the highest priority for the regulation of pharmacists is protection of the public.

(d) The duties of a pharmacist include preventing the abuse of prescription opioids. In August 2013, the California State Board of Pharmacy revoked the licenses of both a pharmacy and its pharmacist because the pharmacist failed to comply with corresponding responsibility requirements in the distribution of opioid drugs. Four patients died as a result of the pharmacist's actions.

(e) The California State Board of Pharmacy's decision and order in that case identifies "red flags" that pharmacists are legally obligated to watch for before filling such a prescription. These "red flags" include:

(1) Irregularities on the face of the prescription itself.

(2) Nervous patient demeanor.

(3) The age or presentation of patient (e.g., youthful patients seeking chronic pain medications).

(4) Multiple patients all with the same address.

(5) Multiple prescriptions for the same patient for duplicate therapy.

(6) Requests for early refills of prescriptions.

(7) Prescriptions written for an unusually large quantity of drugs.

(8) Prescriptions written for duplicative drug therapy.

(9) Initial prescriptions written for strong opiates.

(10) Long distances traveled from the patient's home to the prescriber's office or to the pharmacy.

(11) Irregularities in the prescriber's qualifications in relation to the type of medications prescribed.

(12) Prescriptions that are written outside of the prescriber's medical specialty.

(13) Prescriptions for medications with no logical connection to an illness or condition.

(f) In 2013, the Governor signed legislation that significantly expanded the scope of practice of pharmacists. Pharmacists are now, without a prescription from a physician, permitted to vaccinate their patients, aid them in the administration of self-administered hormonal contraception, and provide nicotine replacement products. The California State Board of Pharmacy has by regulation promulgated extensive protocols governing each of these new duties.

(g) For self-administered hormonal contraception, the California Code of Regulations requires a pharmacist to complete the following steps:

(1) Ask the patient to use and complete the self-screening tool.

(2) Review the self-screening answers and clarify responses if needed.

(3) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.

(4) Before furnishing self-administered hormonal contraception, ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.

(5) When a self-administered hormonal contraceptive is furnished, provide the patient with appropriate counseling and information on the product furnished, including:

(A) Dosage.

(B) Effectiveness.

(C) Potential side effects.

(D) Safety.

(E) The importance of receiving recommended preventative health screenings.

(F) That self-administered hormonal contraception does not protect against sexually transmitted infections.

(h) For nicotine replacement products, the California Code of Regulations requires a pharmacist to complete the following steps:

(1) Review the patient's current tobacco use and past quit attempts.

(2) Ask the patient screening questions related to pregnancy, heart attacks, history of heart ailments, chest pain, or nasal allergies.

(3) Review the instructions for use with every patient using a nicotine replacement product.

(i) For vaccines, Section 1746.4 of Title 16 of the California Code of Regulations requires a pharmacist to notify each patient's primary care provider of any vaccine administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider.

(j) Notwithstanding the number, complexity, and importance of a pharmacist's duties, including those new obligations described above, the Legislature has heard uncontradicted testimony that licensed pharmacists are left alone for indeterminate periods of time in the pharmacy and are, simultaneously, required by such establishments to perform nonpharmacist functions such as staffing cash registers and assisting consumers in purchasing prescriptions, groceries, and other nonpharmacy goods. Survey information of pharmacists working in pharmacies reinforces the testimony.

(k) Staffing inadequacies like these interfere with the professional responsibilities of licensed pharmacists, including those requiring time and professional judgment listed above, and pose a risk to the public health because it leaves licensed pharmacists an insufficient amount of time to perform their licensed functions safely and lawfully, exercise their professional discretion, and comply with their legal and ethical obligations to protect the health and well-being of patients.

SEC. 2.

Section 4113.5 is added to the Business and Professions Code, to read:

4113.5.

(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.

(b) This section shall not apply to any of the following:

(1) A hospital pharmacy, as defined in Section 4029 or 4056.

(2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.

(3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.

(4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.

(5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.

(6) A pharmacy that permits patients to receive medications at a drive-through window when both of the following conditions are met:

(A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.

(B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.

(7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.

(d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.

(2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

(e) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Title 21 Code of Federal Regulations

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

EMPLOYEE SCREENING — NON-PRACTITIONERS

Section 1301.90 Employee screening procedures.

It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. It is, therefore, assumed that the following questions will become a part of an employer's comprehensive employee screening program:

Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.

Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

[40 FR 17143, Apr. 17, 1975]

Attachment 4



How to Prepare for a CA Board of Pharmacy Inspection

STEVEN KYLE, INSPECTOR
CA STATE BOARD OF PHARMACY

Be Aware and Take Care: Talk to your Pharmacist!



Statutory Mandate

- ▶ 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.

*California Business and Professions
Code section 4001.1*



Licensees

- ▶ Total Licensees: 139,640 (August 2018)

Individual Licensees

- ▶ Pharmacists: 45,988
- ▶ Advance Practice Pharmacists: 334
- ▶ Intern Pharmacists: 6,800
- ▶ Pharmacy Technicians: 71,360
- ▶ Designated Representatives: 3,359



Site Licenses

- ▶ Community pharmacies: 6,676
- ▶ Correctional facility pharmacies: 58
- ▶ Hospital pharmacies: 468
- ▶ Nonresident: 554
- ▶ Licensed sterile compounding: 875
- ▶ Nonresident sterile compounding: 77
- ▶ Wholesalers: 556
- ▶ Nonresident wholesalers: 750
- ▶ Clinics: 1,351



Objectives

- ▶ Prepare a manual, or regulatory box, to house items Board of Pharmacy Inspectors typically request of the pharmacy
- ▶ Tools to assist with knowledge of pharmacy law
- ▶ Understanding differing levels of education and enforcement if a violation is identified



When Does the CA BOP Inspect?

- ▶ Complaint investigations (internal and external)
- ▶ Routine Inspections (goal is at least every 4 years)
- ▶ New sterile compounding license
- ▶ Annual sterile compounding license renewal
- ▶ Wholesalers
- ▶ Change of Location
- ▶ Probationers, quarterly
- ▶ Assisting other law enforcement agencies
- ▶ As needed



Pharmacy Law Resources

- ▶ California Code of Regulations (CCR)
- ▶ California Business and Professions Code (BPC)
- ▶ California Health and Safety Code (HSC)*

www.pharmacy.ca.gov

<https://leginfo.legislature.ca.gov>

- ▶ Code of Federal Regulations (CFR), Title 21, Part 1300-1399

www.deadiversion.usdoj.gov



What is a Pharmacist-in-Charge?

- ▶ Definition: A pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.
- ▶ Business and Professions Code Section 4036.5 and 4113



Designating a Pharmacist-in-Charge

- ▶ Within 30 days in writing (BPC 4101, 4113).
- ▶ Must be approved (BPC 4113).
- ▶ If not approved by the BOP, 15 days to propose replacement (BPC 4113).
- ▶ Interim PIC, not to exceed 120 days, a pharmacist who is an owner, officer, administrator or employee involved in the daily management (BPC 4113)
- ▶ Must be employed at location (CCR 1709.1).
- ▶ Responsible of daily operations of the pharmacy CCR 1709.1(a).
- ▶ May serve as PIC at two pharmacies, no more than 50 miles apart CCR 1709.1(c).
- ▶ Owner must vest the PIC with adequate authority to assure compliance with the laws governing the operation of the pharmacy (CCR 1709.1).

Be Aware and Take Care: Talk to your Pharmacist!



Cease to act as Pharmacist-in-Charge

- ▶ Notify in writing to BOP within 30 days
(BPC 4101, 4113)
- ▶ Failure to notify the BOP, disciplinary grounds (BPC 4305)
- ▶ What about PIC on leave?



The Inspector Arrives

- ▶ Ask for identification
- ▶ Allow entry into pharmacy (BPC 4008, 4301)



Be Aware and Take Care: Talk to your Pharmacist!

STATE OF CALIFORNIA
COUNTY OF TULARE
1976
COUNTY OF TULARE
U.S. DEPARTMENT OF JUSTICE

RECEIVED
FBI
JUL 20 1976

SEARCHED
SERIALIZED
INDEXED
FILED

SEARCHED
SERIALIZED
INDEXED
FILED

SEARCHED
SERIALIZED
INDEXED
FILED

ATF
1151254472
LABOR 546276





What's Been Observed

Consultation procedure

Would you like counseling
on these prescriptions?

Yes

No

EQUINOX

2 ABC 3 DEF
4 GHI 5 JKL 6 MNO



What's Been Observed

- ▶ Notice to Consumer poster, point to your language sign, pharmacy permit
- ▶ Security features
- ▶ Name tags
- ▶ Privacy (audio and visual)
- ▶ Staffing ratio and duties being performed
- ▶ Professional interactions



Notice to Consumer

This pharmacy must provide any medicine or device legally prescribed for you, unless:

- It is not covered by your insurance
- You are unable to pay the cost of a copayment
- The pharmacist determines doing so would be against the law or potentially harmful to health.

If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

Be Aware and Take Care: Talk to your Pharmacist!



What Do Inspectors Ask For?

SELF-ASSESSMENT !!

- ▶ Best tool to ensure compliance
- ▶ Required for all site license types (community, hospital, compounding, wholesaler, veterinary food-animal drug retailer)
- ▶ Within 30 days of becoming PIC
- ▶ By July 1 of every odd year
- ▶ Maintain for 3 years

Be Aware and Take Care: Talk to your Pharmacist!



Self-assessment example

Yes No N/A

11.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN:



Self-assessment certification

I, (please print) *Pharmacist in Charge*,

RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self assessment form is true and correct.



What Do Inspectors Ask For?

- ▶ Identification and license type of employees
- ▶ Master list of signatures/initials
- ▶ POA
- ▶ Controlled Substance Inventory, last two completed
- ▶ Completed DEA 222/CSOS review
- ▶ DEA 106 for theft/loss
- ▶ CURES confirmation
- ▶ BOP subscriber alert enrollment
- ▶ Samples of invoices
- ▶ Samples of prescription documents

Be Aware and Take Care: Talk to your Pharmacist!



What Do Inspectors Ask For?

- ▶ Policies and Procedures: (Theft/impairment, TCH duties, QA, Temporary absence of RPH, Immunization, EC, Interpretive services, etc.
- ▶ Quality Assurance, Medication Errors Reports
- ▶ Patient centered prescription labels
- ▶ Offsite storage waiver approval
- ▶ CII reconciliation reports



What is Inspected

- ▶ Physical facility: security, cleanliness, orderliness, temperature, water, confidential area etc.





Be Aware and Take Care: Talk to your Pharmacist!

OPEN 2.0 gpm 7.5





What is Inspected

- ▶ Expiration dates, including on labels from Automated dispensing machines
- ▶ Documents and records
- ▶ Procedures, e.g., drug take back

Office DEPOT.

LACTULOSE
1 TABLESPOONFUL BY
MOUTH TWICE DAILY
TAKE 1/2
MOUTH
500 ML



BARBARA BRADLEY (MONTHLY)

NEAR 6 00005 6 122
MORNING NOON EVENING
MORNING NOON EVENING
MORNING NOON EVENING

VOLUME XLXII

PAPER
MART

BUBBLE

#4 9-1/2 INCH X 14-1/2 INCH
KRAFT BUBBLE MAILERS
70 PCS



Centor
A Gerresheimer Company

G-30A
20026446

Screw-Loc® Green Vial

Precise Pak® Child Resistant
Quantity: 135

30 Dram Its: 50mm Screw-Loc®
Child Resistant Closures or
CS-52-1 Caution™ Snap Caps

Customer Care Center (Berlin, OH)
800-321-3391



UPC 96705-01012 QTY 0135



01 1 50 96705 01012 0 30 0135
2016 4 28 0950 272





What Inspectors Typically Do

- ▶ Follow up on complaints and investigation
- ▶ Complete an Inspection Report
- ▶ Document findings
 - ▶ Discussion
 - ▶ Correction
 - ▶ Violation
- ▶ Inspector comments
- ▶ Exit Interview
- ▶ Licensee Comments



What if enforcement action

- ▶ Corrections: provide proof of correction
- ▶ Violations: Accusation vs. LOA, CNF, CF
- ▶ Letters of Admonishment = 3 years
- ▶ Citation with no fine or with fine = 5 years
- ▶ Public Record = Yes
 - ▶ Not Printed in The Script
 - ▶ Not published on www.pharmacy.ca.gov
 - ▶ Not considered discipline but rather enforcement



When is PIC accountable for violation

- ▶ PIC is responsible for pharmacy law compliance
- ▶ Training issues
- ▶ System issues
- ▶ PIC is the person who committed the violation
- ▶ Examples: Consultation violation; Medication errors and PIC can't identify who was the dispensing pharmacist; Large losses of controlled substances diverted from the pharmacy due to lack of security, or systems in place were not followed or not adequate.



Licensed Sterile Compounding Inspections

- ▶ Review of the facility to set standards
- ▶ Review of products to set standards
- ▶ Review of records
- ▶ Review of training of compounding personnel to set standards
- ▶ Review of policy and procedures
- ▶ Can you reverse the process of any completed compounded product?
- ▶ Refer to CCR 1735 and 1751 series of law codes and relevant USP Guidelines

Be Aware and Take Care: Talk to your Pharmacist!



Pharmacy Compliance Manual/Regulatory Box (see *The Script*, June 2017)

- ▶ Self-Assessment(s)
- ▶ Copies of RPH & TCH licenses
- ▶ Master list of RPH & TCH initials/signature
- ▶ Power of Attorney for DEA 222 Form use delegation
- ▶ Drug Invoices (CII separated)
- ▶ Biennial Controlled Substance Inventory
- ▶ Reconciliation reports
- ▶ Executed DEA 222 Forms or CSOS reconciliation
- ▶ DEA 106 Forms for Loss/Theft (report to BOP)
- ▶ Policy and procedures



Pharmacy Compliance Manual/Regulatory Box

- ▶ QA PnP for medication errors and records of past errors
- ▶ PnP for Impairment and Theft (14 days)
- ▶ PnP for Deliveries When Pharmacy is Closed
- ▶ PnP for Immunizations
- ▶ Protocols for timely access when licensee refuses to fill (ethical, moral, religious grounds)
- ▶ How to handle emergency contraceptives: Plan B (OTC), State Protocol, Training, List of Pharmacies referrals, etc.)
- ▶ PnP for Drug Take Back program
- ▶ PnP automated dispensing machine use
- ▶ PnP for assisting patients with low English proficiency. Contact and access codes.

Be Aware and Take Care: Talk to your Pharmacist!



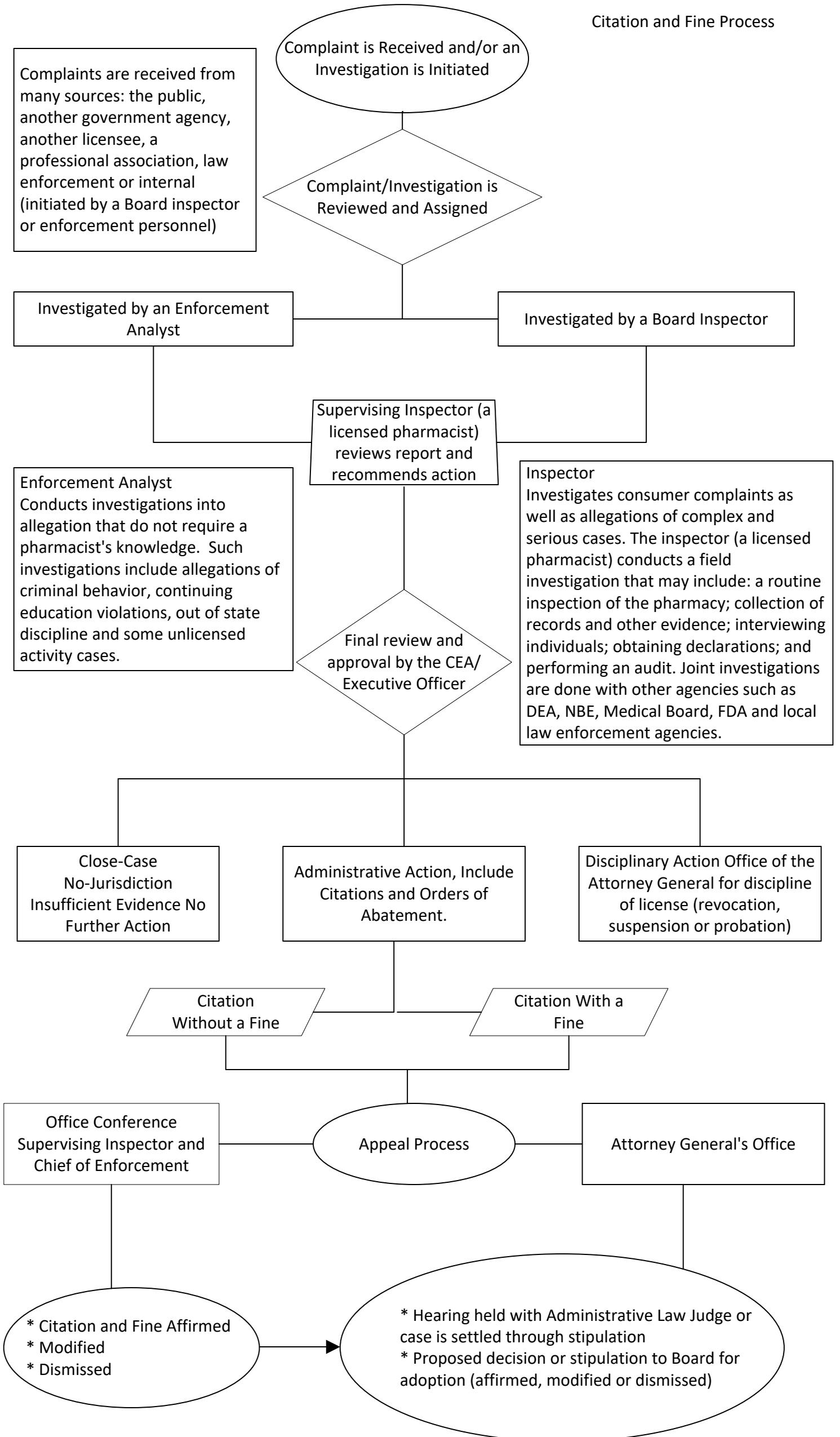
Thank You

▶ Steven.Kyle@dca.ca.gov

Be Aware and Take Care: Talk to your Pharmacist!

Attachment)

Citation and Fine Process



*BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]
(Division 2 enacted by Stats. 1937, Ch. 399.)*

*CHAPTER 9. Pharmacy [4000 - 4427.8]
(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)*

*ARTICLE 19. Disciplinary Proceedings [4300 - 4316]
(Article 19 added by Stats. 1996, Ch. 890, Sec. 3.)*

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.)

Attachment 6

Attorney General's Annual Report on Accusations Prosecuted for Department of Consumer Affairs Client Agencies

January 1, 2019

EXECUTIVE SUMMARY

This is the second annual report by the Office of the Attorney General pursuant to Business and Professions Code section 312.2, which became effective on January 1, 2016, requiring annual reports to be filed by January 1st each year. This report is based on data from Fiscal Year 2017-18. It provides information concerning accusation referrals received and accusations adjudicated for each Department of Consumer Affairs client agency represented by the Licensing Section and Health Quality Enforcement Section of the Office of the Attorney General.

Each client agency is unique and not comparable to others, yet some general observations can be made from the data collected to compile this report. In Fiscal Year 2017-18, approximately 43 percent of the legal work performed by the Licensing Section and Health Quality Enforcement Section was for the prosecution of accusation matters, which are the focus of this report. During the year, 4,409 accusation referrals were received from our Department of Consumer Affairs client agencies. About 2 percent of accusation referrals to the Office of the Attorney General were rejected, and 5 percent of accusation referrals required further investigation.

There were 3,310 adjudications of accusation matters by the Office of the Attorney General during the year. The accusations adjudicated were referred to this office in Fiscal Year 2017-18 or in a prior fiscal year. Multiple adjudications can occur when more than one licensee is included within one matter, each with different adjudication dates and types, or a client agency exercises its discretion to reject an original adjudication. Approximately 55 percent of the total adjudications were by stipulated settlement, 29 percent by default, 13 percent by administrative hearing, and 3 percent resulted from withdrawal of accusations by the agencies.

BACKGROUND

Licensing Section and Health Quality Enforcement Section

The Licensing Section and Health Quality Enforcement Section of the Office of the Attorney General's Civil Law Division specialize in professional and vocational licensing law in California. These sections represent 38 Department of Consumer Affairs agencies that issue multiple types of professional and vocational licenses. They provide legal representation to these agencies in many kinds of licensing matters to protect California consumers and enhance the quality of the professions and vocations. Liaison deputies also regularly consult with agency staff to advise them on jurisdictional, legal, and programmatic issues. Both sections' legal staff also provide training for the Department of Consumer Affairs Division of Investigation, agency investigators, and agency staff.

Both sections prosecute licensing matters, including accusations (license discipline), which comprise about 43 percent of their combined caseload. The balance of prosecution matters consist of statements of issues (appeal hearings when a license application has been denied), interim suspension petitions (hearings before the Office of Administrative Hearings for immediate suspension of a license), injunction proceedings (brought in superior court to stop unlicensed practice), post-discipline matters (when a licensee petitions for reduction of penalty, or reinstatement of a revoked license), citations (appeal hearings when a citation has been issued), Penal Code section 23 petitions (seeking a license restriction during the pendency of a criminal proceeding), subpoena enforcement actions (to obtain records needed for the investigation of complaints), judicial review proceedings (superior court review of final administrative decisions), appeals (usually from superior court review proceedings), and civil litigation related to license discipline (defending agencies in civil lawsuits brought in state or federal courts).

Of these many types of legal actions, Business and Professions Code section 312.2 requests data only for the prosecution of accusation matters. Accusations are the primary component of the enforcement program for each licensing agency. The legal services in other types of licensing matters handled by the Licensing Section and Health Quality Enforcement Section are not included in this report, except where accusations are combined with petitions to revoke probation.

Department of Consumer Affairs Client Agencies

The 38 Department of Consumer Affairs agencies represented by the Licensing Section and Health Quality Enforcement Section each have different licensing laws, programs, and processes unique to their practice areas. A few agencies issue only one type of license, but most issue multiple license types. As a result, they differ in how they refer accusation matters to the Office of the Attorney General; some refer one matter for each licensee, while others refer multiple licensees involved in the same or related acts for which discipline will be sought to be included in a single accusation. About one-third of client agencies represented by the Licensing Section file a single accusation naming all of their licensees involved in the events underlying the disciplinary action. None of the agencies represented by the Health Quality Enforcement Section file a single accusation against multiple licensees. Instead, a separate accusation is filed against each licensee, and when multiple licensees are involved in the same events, the accusations may be consolidated for hearing. Any agency may also refer additional investigations to the Office of the Attorney General for prosecution while an initial accusation matter is pending, and these subsequent investigations are counted as additional *accusation referrals* in this report.

There are also other differences among the agencies. Some agencies have higher default rates than others, and some have higher rates of representation by counsel in their accusation matters. The applicable burden of proof varies based on the type of professional or business license. Generally, when there are specific educational and testing requirements to obtain a license, disciplinary charges must be proven by clear and convincing evidence to a reasonable certainty. Most accusation matters brought by Department of Consumer Affairs agencies are subject to this burden of proof, but a few license types are subject to a lower burden of proof, i.e., preponderance of evidence. Generally, these are licenses that permit operation of a business at a specific location, such as an automotive repair dealership or

pharmacy. Only about a dozen Department of Consumer Affairs agencies are required to file their accusations within a prescribed statute of limitations, which generally range from one year to five years, but may be longer in specific circumstances. All Department of Consumer Affairs client agencies except the Medical Board of California are entitled to recover their costs of investigation and prosecution from respondents. The data included in this report are consistent with each client's licensing programs and practices to the extent possible, but as a result of the wide variances among the many agencies, often are not comparable to each other in any meaningful way.

Investigation Process

Agencies also differ in how they investigate their cases. Investigations are assigned to balance quality and efficiency and avoid insufficient evidence, which causes delay while supplemental evidence is gathered. First and most commonly, agencies investigate their cases using their own staff, including inspectors, sworn and unsworn investigators, investigator assistants, or analysts. Second, certain kinds of cases are required to be referred to the Department of Consumer Affairs Division of Investigation for investigation consistent with Complaint Prioritization Guidelines developed pursuant to Business and Professions Code section 328. Medical Board cases are excluded from the requirements of section 328. From 2006 to December 31, 2018, Medical Board investigations were handled under a third model known as Vertical Enforcement and Prosecution, pursuant to Government Code section 12529.6. Vertical Enforcement required a deputy attorney general to be jointly assigned to the investigation with a Division of Investigation investigator from the Health Quality Investigation Unit. If the investigation resulted in the filing of an accusation, the same deputy attorney general would also be responsible for prosecuting the case for the Medical Board. Some agencies represented by the Health Quality Enforcement Section opted to have some or all of their investigations conducted under the Vertical Enforcement model.

Administrative Adjudication Process

If the investigation reveals evidence that a licensee has violated the agency's practice act, the agency refers the matter to the Office of the Attorney General to initiate a legal proceeding to revoke, suspend, limit, or condition the license, which is called an *accusation*. (Gov. Code, § 11503.)

Upon receipt, a deputy attorney general reviews the transmitted evidence to determine its sufficiency to meet the requisite burden of proof and for any jurisdictional issues. If the evidence is insufficient and circumstances suggest additional avenues for evidentiary development, the deputy may request further investigation from the agency. When evidence is insufficient and further investigation is not recommended, or legal issues prevent prosecution, the Office of the Attorney General declines prosecution, and the case is rejected, or reviewed and returned to the agency.

Based on sufficient evidentiary support, a deputy attorney general prepares an accusation to initiate the agency's adjudicative proceeding. The accusation pleading is sent to the agency for signature by the executive director, executive officer, or other designated *complainant* for the agency. The accusation is *filed* when the complainant signs it, and it is then served by the agency, or returned to the Office of the Attorney General for service on the licensee, known in the accusation proceeding as the *respondent*. When charged in an accusation, a respondent

has a right to an adjudicative hearing under the California Administrative Procedure Act (Gov. Code, tit. 2, div. 3, ch. 5, commencing with §11500). Once served with an accusation, the respondent must file a notice of defense within fifteen days, or is in default. Once the notice of defense has been received, a hearing is scheduled with the Office of Administrative Hearings. If no notice of defense is received, then a default is prepared for presentation to the client agency for its ultimate decision.

The deputy attorney general prosecutes the accusation case before the Office of Administrative Hearings. Upon conclusion of the hearing, the case is submitted to the administrative law judge who presides over the hearing, prepares a proposed decision, and sends it to the agency for its ultimate decision. Of course, a stipulated settlement (such as public reprimand, probation, license surrender, or revocation) can occur at any time and is the most common method of adjudication of accusation matters.

The agency itself makes the final decision in each accusation case. The agency can accept or reject a settlement, and if rejected, the proceedings will continue. After an administrative hearing, the agency can accept the proposed decision issued by the administrative law judge, in which case it becomes the final decision. However, the agency may opt to reduce the penalty, or reject the proposed decision and order the hearing transcript. After review of the transcript and the evidence in the case, it can then adopt the proposed decision or issue its own decision. Most cases are resolved when the agency accepts a stipulated settlement or proposed decision, but if not, additional proceedings ensue, which take more time.

Even after an agency's decision is issued, it may not be final. A respondent may exercise the right to petition for reconsideration, and if granted by the agency, the final decision will be reconsidered. This can also happen if an agency decides a case based upon the default of a respondent for failure to timely file a notice of defense, or failure to appear at a duly noticed hearing. Upon petition by the respondent, the agency can vacate the default decision, and additional proceedings are conducted to ultimately decide the case. Each of these types of *post-submission* events will lengthen the processing of a case and require further adjudication.

Once the agency's decision is final, it is still subject to judicial review in administrative mandamus and appellate proceedings. In very few cases, judicial review results in remand to the agency to conduct further administrative proceedings or reconsider its decision. In these cases, the ultimate, final decision of the agency may be delayed by many months, or even one or more years.

MEASURES REPORTED

The text of Business and Professions Code section 312.2 is set forth in its entirety in the attached appendix. We provide the following interpretation of terms, and description of the manner in which the data was gathered for each of the reporting metrics in subdivisions (a)(1) – (7) and (b)(1) – (6) as follows.

(a)(1) The number of accusation matters referred to the Attorney General.

Accusation matter means an investigation of one or more complaints which the agency has referred to the Office of the Attorney General to review evidence and, if appropriate, prosecute the matter through the disciplinary process as an accusation.

Accusation matters are counted by each investigation report received that bears a distinct investigation number. Some agencies request that more than one respondent be named and prosecuted in a single accusation, in which case the investigation number is counted as an accusation matter for each respondent. Multiple investigations may be referred during the time that the Office of the Attorney General is prosecuting the agency's initial accusation referral, which can span different fiscal years. Each investigation received during the reporting period is counted for each respondent to which it pertains.

(a)(2) The number of accusation matters rejected for filing by the Attorney General.
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Rejected for filing describes the determination made by a deputy attorney general with a supervisor's approval, that an accusation should not be filed. An accusation can be rejected for many reasons, including (1) because the evidence submitted is insufficient to meet the burden of proof to sustain a cause for discipline under the agency's applicable practice act, (2) the events in question are not within the statute of limitations, and/or (3) disciplinary action is not supported by law or public policy. When prosecution is declined, the investigative file is returned to the client agency and the case is closed in the Office of the Attorney General.

A rejection for filing during the reporting period is counted once for each respondent to which the rejection pertains, without regard to the number of investigations referred to the Office of the Attorney General for consideration.

(a)(3) The number of accusation matters for which further investigation was requested by the Attorney General.
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Further investigation requested describes an instance when a deputy attorney general reviews the evidence in the investigation and determines that it is insufficient to meet the burden of proof, but there are avenues available to augment the evidence to support a cause for discipline under the agency's applicable practice act. With supervisory approval, the deputy may request further investigation from the agency or the Division of Investigation, or it is done internally at the Office of the Attorney General. When further investigation is requested in a matter handled by the Licensing Section, the file remains open pending receipt of supplemental investigation, and is documented accordingly. In the Health Quality Enforcement Section, the file is returned to the client agency, and the matter is closed. The file is reopened if the matter is re-referred to the Office of the Attorney General with additional evidence.

Each request for further investigation made during the reporting period is counted in each matter, and is not necessarily associated with the number of referrals received in the matter, or number of respondents to which the further investigation may pertain. There may be only one request for further investigation in a matter that contains more than one respondent or more than one investigation. There may also be more than one further investigation request made pertaining to a single respondent in a matter with only one referral.

(a)(4) The number of accusation matters for which further investigation was received by the Attorney General.

Further investigation received describes the additional investigation received as a result of further investigation requested, as described above. Very rarely, an agency refers a matter back to the Office of the Attorney General with *additional* investigation and requests reconsideration of a previous decision not to prosecute (i.e., rejected). If the matter is accepted for prosecution, this is also recorded as further investigation received. Additional investigation received is distinguished from a *new* referral of an accusation matter from a client agency, which is counted in subdivision (a)(1), but is not counted in (a)(4).

Each supplemental investigation received during the reporting period is counted in each matter and is not necessarily associated with the number of referrals received in the matter or number of respondents to which the further investigation may pertain.

(a)(5) The number of accusations filed by each constituent entity.

Accusation means the initial accusation filed in a matter to initiate proceedings to revoke or suspend a license against one or more respondents, and any subsequent amended accusation filed in the matter. Accusations may be amended during the pendency of a case for a variety of reasons, most commonly because the client agency refers an additional investigation of a new complaint, and the accusation is amended to add new causes for discipline based on the new investigation. *Filed* means the accusation or amended accusation is signed by the agency's designee, known as the complainant, who is usually the executive officer or executive director of the agency. The accusation is filed on the date the document is signed.

Each accusation or amended accusation filed during the reporting period is counted and reported under subdivision (a)(5).

(a)(6) The number of accusations a constituent entity withdraws.

On occasion, the complainant withdraws the accusation after it has been filed, terminating the prosecution of the accusation matter. A common reason for an accusation to be withdrawn is the death of the respondent against whom the accusation is filed. In other cases, the evidentiary basis for the matter may change during litigation, or evidence received from a respondent in the course of discovery may lead to re-evaluation of the merits of the case. The withdrawal of an accusation is counted separately for each respondent named in the accusation.

(a)(7) The number of accusation matters adjudicated by the Attorney General.

Adjudication means the work of the Office of the Attorney General has been completed to bring the case back before the agency's decision maker for its final decision. There are four types of adjudicative events: (1) A default decision and order prepared and sent to the agency because a respondent did not file a notice of defense or failed to appear at a duly noticed

administrative hearing; (2) A stipulated settlement signed by a respondent and sent to the agency to consider accepting as its disposition of the matter for that respondent; (3) The submission of the case at the conclusion of an administrative hearing to an administrative law judge to prepare a proposed decision, and the decision is sent to the agency for its consideration; and (4) Withdrawal of an accusation by the complainant, which terminates the matter. An adjudicative event for each respondent named in an accusation is necessary before the matter is fully adjudicated.

An adjudicative event is counted for each named respondent that occurs during the reporting period. In matters where more than one licensee is named in the accusation, more than one adjudicative event will be counted if it occurs during the reporting period.

Multiple adjudicative events can also occur in cases with only a single respondent. This happens when an agency does not accept a stipulated settlement, does not adopt a proposed decision submitted by an administrative law judge, grants reconsideration of its decision, or when a superior court judge remands the matter to the agency for further consideration. These *post-submission* adjudicative events are counted in reporting the number of accusation matters *adjudicated* in subdivision (a)(7), but because they are not *original* adjudications they are not included in calculating the averages reported in subdivisions (b)(3), (b)(4), and (b)(6).

(b)(1) The average number of days from the Attorney General receiving an accusation referral to when an accusation is filed by the constituent entity.
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The date that each accusation referral is received in the Office of the Attorney General is documented. The calculation of the average reported for subdivision (b)(1) begins on the date of receipt of the first accusation referral in each matter and ends on the date the complainant signs the initial accusation in each matter. Amended accusations received after the client agency's initial referral are not included in the average.

(b)(2) The average number of days to prepare an accusation for a case that is rereferred to the Attorney General after further investigation is received by the Attorney General from a constituent entity or the Division of Investigation.
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Prepare an accusation in subdivision (b)(2) is different from *filing an accusation* in subdivision (b)(1). An accusation is *prepared* (i.e., the preparation is based on an attorney's familiarization with the technical subject matter issues, thorough review of the evidence and expert reports to determine chargeable causes for discipline, then drafting, and supervisorial review of the accusation) by the assigned deputy attorney general and then sent to the complainant at the agency to be reviewed, approved, and signed.

Re-referred means the date when supplemental investigation has been received by the Office of the Attorney General in response to a request for further investigation, or, in rare cases, following rejection of an accusation matter.

The calculation of the average reported for subdivision (b)(2) begins on the date each initial accusation referral was received in the Office of the Attorney General – including time for initial review of the matter, request for further investigation, further investigation conducted, receipt of

the supplemental investigation by the Office of the Attorney General from the agency, re-review by the deputy, and the deputy preparing the accusation – and ends on the date the deputy sends the prepared accusation to the complainant for review and filing in each matter. The average may also include review of additional referrals received while further investigation is being conducted on the initial referral that required it.

Notably, the matters that required further investigation before preparation of an accusation reported in subdivision (b)(2) are included in the average number of days to file accusations reported in subdivision (b)(1). As a consequence, delays in *preparing* accusations for cases that required further investigation generally will increase the average number of days to *file* the agency's accusations reported in subdivision (b)(1).

(b)(3) The average number of days from an agency filing an accusation to the Attorney General transmitting a stipulated settlement to the constituent entity.

Settlements are negotiated according to authorization provided by the complainant based on the agency's published disciplinary guidelines. A stipulated settlement is provided to the agency's decision maker who decides whether to accept the settlement as its disposition of the case against the respondent.

The calculation of the average reported for subdivision (b)(3) begins on the date of filing the initial accusation in each matter, and ends on the date the stipulated settlement for each respondent is sent to the agency for its consideration.

As described in subdivision (a)(7), above, *post-submission* settlements are not included in calculating the average reported in subdivision (b)(3). Only one settlement that occurs during the reporting period for each respondent named in an accusation is included to calculate the average. In matters where more than one respondent is named in the accusation, more than one stipulated settlement will be included in the average if they all occurred during the reporting period.

(b)(4) The average number of days from an agency filing an accusation to the Attorney General transmitting a default decision to the constituent entity.

If a respondent fails to send a notice of defense to the assigned deputy attorney general or agency within 15 days after service of the accusation, or fails to appear at a duly noticed administrative hearing on the accusation, the respondent is in default. The agency can opt to present the case to an administrative law judge without participation by the respondent who has defaulted. However, most often, the agency requests the deputy to prepare a default decision and order for the agency's decision-maker to consider issuing as its final decision against the respondent. Many agencies have delegated authority to their executive officers to adopt default decisions as a matter of course without consideration by the board itself.

The calculation of the average reported for subdivision (b)(4) begins on the date each initial accusation in a matter is filed, and ends on the date of transmission of the default decision and order to the agency for each respondent.

As described in subdivision (a)(7), above, *post-submission* defaults are not included in calculating the average reported in subdivision (b)(4). To calculate the average, only one default that occurs during the reporting period for each respondent named in an accusation is included. In matters where more than one respondent is named in the accusation, more than one default will be included in the average if they all occurred during the reporting period.

(b)(5) The average number of days from an agency filing an accusation to the Attorney General requesting a hearing date from the Office of Administrative Hearings.

After a notice of defense has been received from each respondent named in an accusation, the deputy attorney general assigned to the matter is responsible to coordinate with opposing counsel, unrepresented respondents, prosecution witnesses, and the Office of Administrative Hearings to determine a hearing date when everyone is available. The deputy attorney general prepares a request to set the hearing based on this coordination and sends it to the Office of Administrative Hearings to calendar the hearing.

The calculation of the average reported for subdivision (b)(5) begins on the date the initial accusation in each matter is filed, and ends on the date the request to set a hearing in each case is sent to the Office of Administrative Hearings. Infrequently, a request to set a hearing is done more than once in a case, usually because a continuance has been granted. Only the first request to set a hearing in a case is included in calculating the average.

(b)(6) The average number of days from the Attorney General's receipt of a hearing date from the Office of Administrative Hearings to the commencement of a hearing.
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When the Office of Administrative Hearings receives the request to set hearing sent by the deputy attorney general, the hearing date is set on its calendar and the parties are informed of the hearing date. Unless an intervening motion for a continuance is granted by an administrative law judge, the hearing will commence on that date, and depending on the length of the hearing and intervening factors, may conclude on the same day or at a later date.

The calculation of the average reported for subdivision (b)(6) begins on the date the deputy attorney general receives notice from the Office of Administrative Hearings that the hearing date has been set for each case, and ends on the date the hearing in each case actually commences. As described in subdivision (a)(7), above, any *post-submission* commencement of a hearing is not included in calculating the average reported in subdivision (b)(6). When motions to continue hearings are granted, the commencement of hearings are delayed, and the average number of days will increase as a consequence.

METHODOLOGY

Case Management System

This report is based on data entered by legal professionals in ProLaw, the case management system of the Office of the Attorney General. Each matter received by the Licensing Section and Health Quality Enforcement Section from a client is opened in this system. Rules for the entry of data have been created by the sections, and are managed by the Case Management Section of the Office of the Attorney General, which dictates the definitions, dating, entry, and documentation for each data point.

Section-specific protocols, business processes, and uniform standards across all professionals responsible for data entry ensure the consistency, veracity, and quality of the reported data. The data entered has been verified to comply with established standards. The data markers in administrative cases have been used to generate the counts and averages in this report. Every effort has been made to report data in a transparent, accurate, and verifiable manner. The Office of the Attorney General continues to improve its technology, systems and protocols, and integrate these into its business routines and operations.

Data Presentation

The information required to be reported by Business and Professions Code section 312.2 has been organized on a separate page for each constituent entity in the Department of Consumer Affairs represented by the Licensing Section and Health Quality Enforcement Section of the Office of the Attorney General. Each page includes the number of licenses and types of licenses issued by the agency, which were taken from the 2017 Annual Report of the California Department of Consumer Affairs, containing data from Fiscal Year 2016-17. The report can be found online at: https://www.dca.ca.gov/publications/2017_annrpt.pdf. The following Department of Consumer Affairs website contains links for further information: http://www.dca.ca.gov/about_dca/entities.shtml. Any applicable statute of limitations has been included for each client agency's page, as well as the frequency of more than one respondent being named in the agency's accusations.

Table 1: Business and Professions Code section 312.2, subdivision (a)

Table 1 on the page for each agency provides the *counts* for various aspects of accusation matters, as requested under subdivision (a) of section 312.2, such as the number of accusation referrals received and the number of accusations filed (subd. (a)(1) and (5)). There are some differences in the counts reported for subdivision (a) in this report compared to the first annual report. First, in reporting the number of accusation matters received pursuant to subdivision (a)(1), this year we have reported every accusation referral received for each client agency of the Licensing Section and Health Quality Enforcement Section in a consistent manner across the two sections. In the first annual report, every referral was counted by the Health Quality Enforcement Section. However, due to different business processes and rules for entering data in ProLaw for the Licensing Section, count of *referrals* was based only on new matters opened in ProLaw, and therefore did not include referrals for each licensee named in multiple respondent cases and subsequent referrals received after the initial referral. Effective in Fiscal Year 2017-18, the case management system rules were adapted to provide consistency in the manner in which referrals are counted for both sections. As a result, in this second annual report, the number of referrals reported for all client agencies represented by the Licensing Section exceeds the number of referrals reported last year by 42 percent.

The second difference this year is in the manner of counting accusations pursuant to subdivision (a)(5). This year we have reported the *total* number of accusations filed for each client agency, which include both initial accusations filed to initiate disciplinary proceedings and amended accusations. In the first report, only the Health Quality Enforcement Section reported amended accusations. In this report, we have ensured that the count of

accusations is consistent for all client agencies, including both initial and amended accusations.

Table 2: Business and Professions Code section 312.2, subdivision (b)

Table 2 provides the averages requested under subdivision (b) of section 312.2, which are based on the accusation matters adjudicated during the year, as reported under subdivision (a)(7). We have

included the mean, median, standard deviation, and number of values in the data set from which the averages were determined. The average expresses the central or typical value in a set of data, which is most commonly known as the arithmetic mean. The central value in an ordered set of data is known as the median. The standard deviation (SD) for a data set provides context for averages. A low SD indicates that the data points tend to be close to the mean of the set, while a high SD indicates that the data points are spread out over a wider range of values.

Compared to the median, the mean is more sensitive to extreme values, or *outliers*, and the number of values, or *sample size*. When the mean and median are nearly equivalent, that is a likely indicator that there are no or few extreme values in the data set. However, when there is a large difference between the mean and median, it is likely that there are one or more extreme values skewing the data. For example, for the California Board of Accountancy (page 12), the average number of days from filing an accusation to when a stipulated settlement was sent to the agency was 117 days for the mean and 84 days for the median, with SD of 97, based on 81 stipulations, suggesting the mean is a fair representation of the number of days to reach settlement. In contrast, for the Bureau of Security and Investigative Services (page 445), the average for settlements was 570 days for the mean and 245 days for the median, with SD of 699, based on 22 stipulations. The data for this agency included one case with four respondents, all of whom settled 2,008 days after the accusation was filed. This skewed the data and impacted the mean, as shown by the large 325-day difference between the mean and median, and extremely high SD of 699.¹ This example shows how extreme values influence the mean, especially when the sample size is small, underscoring the importance of considering all results provided when interpreting the data.

There are some differences in the manner in which averages were calculated in this report compared to the first annual report for subdivisions (b)(3) through (6). Data for adjudication of the accusation matter for each respondent named in an accusation whose initial default or settlement was not accepted by the agency as its final decision are not included in these reports. On occasion, an agency grants a petition for reconsideration for a respondent who has defaulted in an accusation matter, vacating the default and allowing the respondent to litigate the case. Similarly, the agency may decide not to accept a stipulated settlement as the final disposition of the case, directing that a different settlement be negotiated, and/or requiring the matter to be set for an administrative hearing before an administrative law judge. In cases where defaults are vacated or proposed stipulated settlements are not adopted by the agency, those subsequent adjudications are not included in the data reported in subdivisions (b)(3) and (4). By excluding subsequent adjudications that are necessitated by agencies' decision making, the average number of days it takes to adjudicate matters by settlement and default is more closely associated with the work of the Office of the Attorney General.

Similarly, under subdivision (b)(6) reporting the average number of days from hearing date received to hearing commenced, we have excluded hearings commenced after reconsideration or non-adoption by an agency.

The individual client agency pages that follow have been organized in alphabetical order for convenience.

¹ The extreme age of that particular matter was due to a series of delaying events. It started as one referral against one licensee, for which further investigation was requested. The additional investigation was extensive and ultimately resulted in a total of nine referrals against four licensees. There was a two-year cessation of that investigation due to redirection of key investigatory staff to internal projects by the agency. A second lengthy delay was caused by an intervening investigation by the district attorney until he decided not to file criminal charges. The case was further delayed intermittently due to attrition of the agency's top two decision makers during critical junctures in the litigation.

California State Board of Pharmacy

The Board of Pharmacy regulated 139,164 licensees in Fiscal Year 2016-17 with more than 25 license types. The Board receives consumer complaints and routinely inspects pharmacies for compliance. Most complaints received by the Board are investigated by the Board's own inspectors, who are licensed pharmacists themselves. There were multiple respondents in about 37 percent of the Board's accusation cases prosecuted by the Office of the Attorney General in Fiscal Year 2017-18.

There is no statute of limitations within which to file accusations for this agency.

The tables below show data for Fiscal Year 2017-18.

Table 1 – Business and Professions Code Section 312.2, Subdivision (a)

Number of	Count
(1) accusation matters referred to the Attorney General.	438
(2) accusation matters rejected for filing by the Attorney General.	10
(3) accusation matters for which further investigation was requested by the Attorney General.	20
(4) accusation matters for which further investigation was received by the Attorney General.	20
(5) accusations filed.	294
(6) accusations withdrawn.	7
(7) accusation matters adjudicated by the Attorney General.	360

Table 2 is based on the adjudicated accusation matters reported under Business and Professions Code section 312.2, subdivision (a)(7) in Table 1.

Table 2 – Business and Professions Code Section 312.2, Subdivision (b)

Average number of days for adjudicated accusation matters	Mean	Median	SD	Count
(1) from receipt of referral by the Attorney General to when an accusation is filed.	228	182	177	266
(2) to prepare an accusation for a case that is rereferred to the Attorney General after further investigation is received.	249	192	136	19
(3) from the filing of an accusation to when a stipulated settlement is sent to the agency.	326	301	218	203
(4) from the filing of an accusation to when a default decision is sent to the agency.	116	88	97	109
(5) from the filing of an accusation to the Attorney General requesting a hearing date.	140	118	95	82
(6) from the Attorney General's receipt of a hearing date to the commencement of a hearing.	144	146	84	28

CONCLUSION

This report for the data in Fiscal Year 2017-18 is based on some differences in calculating counts and averages compared to the first report. We expect consistency in these calculations going forward. Over time, the Office of the Attorney General will be able to derive insights related to performance, productivity, and public protection enhancements with respect to the reported-on prosecutions. The report will allow for statistical and predictive modeling techniques to identify trends and correlations to drive beneficial changes in business processes. The insights and value derived from this data will also provide the basis for the Office of the Attorney General to support the acquisition of additional resources and data tools as needed. We will endeavor to identify any performance gaps as additional relevant data is generated and case delivery mechanisms are examined. We anticipate that this report will facilitate collaboration among the Office of the Attorney General, Office of Administrative Hearings, and Department of Consumer Affairs, all of which join in responsibility for protection of the public through efficiency in adjudicating accusation matters.

This Attorney General's Annual Report on Accusations Prosecuted for Department of Consumer Affairs Client Agencies is also available on the Attorney General's website at <http://oag.ca.gov/publications>.

If you have any questions regarding this report, or if you would like additional information, please contact Sirat Attapit, Director of Legislative Affairs, at (916) 210-6192.

Attachment 7

BUSINESS AND PROFESSIONS CODE - BPC

DIVISION 1.5. DENIAL, SUSPENSION AND REVOCATION OF LICENSES [475 - 499]

(Division 1.5 added by Stats. 1972, Ch. 903.)

CHAPTER 2. Denial of Licenses [480 - 489]

(Chapter 2 added by Stats. 1972, Ch. 903.)

Proposed Amendment to 480.

(a) Notwithstanding any other provision of this code, a board may deny a license regulated by this code on the grounds that the applicant has been convicted of a crime or has been subject to formal discipline only if either of the following conditions are met:

(1) The applicant has been convicted of a crime within the preceding seven years from the date of application that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made, regardless of whether the applicant was incarcerated for that crime, or the applicant has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made and for which the applicant is presently incarcerated or for which the applicant was released from incarceration within the preceding seven years from the date of application. However, the preceding seven-year limitation shall not apply in either of the following situations:

(A) The applicant was convicted of a serious felony, as defined in Section 1192.7 of the Penal Code or a crime for which registration is required pursuant to paragraph (2) or (3) of subdivision (d) of Section 290 of the Penal Code.

(B) The applicant was convicted of a financial crime currently classified as a felony that is directly and adversely related to the fiduciary qualifications, functions, or duties of the business or profession for which the application is made, pursuant to regulations adopted by the board, and for which the applicant is seeking licensure under any of the following:

(i) Chapter 1 (commencing with Section 5000) of Division 3.

(ii) Chapter 6 (commencing with Section 6500) of Division 3.

(iii) Chapter 9 (commencing with Section 7000) of Division 3.

(iv) Chapter 11.3 (commencing with Section 7512) of Division 3.

(v) Licensure as a funeral director or cemetery manager under Chapter 12 (commencing with Section 7600) of Division 3.

(vi) Division 4 (commencing with Section 10000).

(vii) Chapter 9 (commencing with Section 4000) of Division 2.

(C) The applicant seeks licensure under the provisions of Chapter 9 (commencing with Section 4000) of Division 2 and has done any of the following:

(i) Performed an act that would be grounds for denial of a federal registration to distribute controlled substances.

(ii) Performed an act involving fraud in violation of state or federal laws related to healthcare.

(iii) Been convicted of a crime involving identity theft.

(iv) Been convicted of a crime involving the sale of counterfeit products.

(2) The applicant has been subjected to formal discipline by a licensing board in or outside California within the preceding seven years from the date of application based on professional misconduct that would have been cause for discipline before the board for which the present application is made and that is substantially related to the qualifications, functions, or duties of the business or profession for which the present application is made. However, prior disciplinary action by a licensing board within the preceding seven years shall not be the basis for denial of a license if the basis for that disciplinary action was a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code or a comparable dismissal or expungement.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis that he or she has been convicted of a crime, or on the basis of acts underlying a conviction for a crime, if he or she has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code, has been granted clemency or a pardon by a state or federal executive, or has made a showing of rehabilitation pursuant to Section 482.

(c) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis of any conviction, or on the basis of the acts underlying the conviction, that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code, or a comparable dismissal or expungement. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code shall provide proof of the dismissal if it is not reflected on the report furnished by the Department of Justice.

(d) Notwithstanding any other provision of this code, a board shall not deny a license on the basis of an arrest that resulted in a disposition other than a conviction, including an arrest that resulted in an infraction, citation, or a juvenile adjudication.

(e) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license. A board shall not deny a license based solely on an applicant's failure to disclose a fact that would not have been cause for denial of the license had it been disclosed.

(f) A board shall follow the following procedures in requesting or acting on an applicant's criminal history information:

(1) A board issuing a license pursuant to Chapter 3 (commencing with Section 5500), Chapter 3.5 (commencing with Section 5615), Chapter 10 (commencing with Section 7301), Chapter 20 (commencing with Section 9800), or Chapter 20.3 (commencing with Section 9880), of Division 3, or Chapter 3 (commencing with Section 19000) or Chapter 3.1 (commencing with Section 19225) of Division 8 may require applicants for licensure under those chapters to disclose criminal conviction history on an application for licensure.

(2) Except as provided in paragraph (1), a board shall not require an applicant for licensure to disclose any information or documentation regarding the applicant's criminal history. However, a board may request mitigating information from an applicant regarding the applicant's criminal history for purposes of determining substantial relation or demonstrating evidence of rehabilitation, provided that the applicant is informed that disclosure is voluntary and that the applicant's decision not to disclose any information shall not be a factor in a board's decision to grant or deny an application for licensure.

(3) If a board decides to deny an application for licensure based solely or in part on the applicant's conviction history, the board shall notify the applicant in writing of all of the following:

(A) The denial or disqualification of licensure.

(B) Any existing procedure the board has for the applicant to challenge the decision or to request reconsideration.

(C) That the applicant has the right to appeal the board's decision.

(D) The processes for the applicant to request a copy of his or her complete conviction history and question the accuracy or completeness of the record pursuant to Sections 11122 to 11127 of the Penal Code.

(g) (1) For a minimum of three years, each board under this code shall retain application forms and other documents submitted by an applicant, any notice provided to an applicant, all other communications received from and provided to an applicant, and criminal history reports of an applicant.

(2) Each board under this code shall retain the number of applications received for each license and the number of applications requiring inquiries

regarding criminal history. In addition, each licensing authority shall retain all of the following information:

(A) The number of applicants with a criminal record who received notice of denial or disqualification of licensure.

(B) The number of applicants with a criminal record who provided evidence of mitigation or rehabilitation.

(C) The number of applicants with a criminal record who appealed any denial or disqualification of licensure.

(D) The final disposition and demographic information, consisting of voluntarily provided information on race or gender, of any applicant described in subparagraph (A), (B), or (C).

(3) (A) Each board under this code shall annually make available to the public through the board's Internet Web site and through a report submitted to the appropriate policy committees of the Legislature deidentified information collected pursuant to this subdivision. Each board shall ensure confidentiality of the individual applicants.

(B) A report pursuant to subparagraph (A) shall be submitted in compliance with Section 9795 of the Government Code.

(h) "Conviction" as used in this section shall have the same meaning as defined in Section 7.5.

(i) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(j) This section shall become operative on July 1, 2020.

(Repealed and added by Stats. 2018, Ch. 995, Sec. 4. (AB 2138) Effective January 1, 2019. Section operative July 1, 2020, by its own provisions.)

AB-2138 Licensing boards: denial of application: revocation or suspension of licensure: criminal conviction.

SECTION 1.

Section 7.5 of the Business and Professions Code is amended to read:

- 7.5.**
- (a) A conviction within the meaning of this code means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code. However, a board may not deny a license to an applicant who is otherwise qualified pursuant to subdivision (b) of Section 480.
- Nothing in this section shall apply to the licensure of persons pursuant to Chapter 4 (commencing with Section 6000) of Division 3.
- (b) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 2.

Section 7.5 is added to the Business and Professions Code, to read:

- 7.5.**
- (a) A conviction within the meaning of this code means a judgment following a plea or verdict of guilty or a plea of nolo contendere or finding of guilt. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence. However, a board may not deny a license to an applicant who is otherwise qualified pursuant to subdivision (b) or (c) of Section 480.
- (b) (1) Nothing in this section shall apply to the licensure of persons pursuant to Chapter 4 (commencing with Section 6000) of Division 3.
- (2) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:
- (A) The State Athletic Commission.
- (B) The Bureau for Private Postsecondary Education.
- (C) The California Horse Racing Board.
- (c) Except as provided in subdivision (b), this section controls over and supersedes the definition of conviction contained within individual practice acts under this code.
- (d) This section shall become operative on July 1, 2020.

SEC. 3.

Section 480 of the Business and Professions Code is amended to read:

- 480.**
- (a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:
- (1) Been convicted of a crime. A conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action that a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4, 1203.4a, or 1203.41 of the Penal Code.
- (2) Done any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself or herself or another, or substantially injure another.

- (3) (A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.
- (B) The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which application is made.
- (b) Notwithstanding any other provision of this code, a person shall not be denied a license solely on the basis that he or she has been convicted of a felony if he or she has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code or that he or she has been convicted of a misdemeanor if he or she has met all applicable requirements of the criteria of rehabilitation developed by the board to evaluate the rehabilitation of a person when considering the denial of a license under subdivision (a) of Section 482.
- (c) Notwithstanding any other provisions of this code, a person shall not be denied a license solely on the basis of a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code shall provide proof of the dismissal.
- (d) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license.
- (e) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

Attachment ,

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