California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ENFORCEMENT COMMITTEE
CHAIR REPORT

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Greg Lippe, Public Member
Stan Weisser, Licensee Member
Ricardo Sanchez, Public Member

The Enforcement Committee met on March 14, 2019.

a. <u>Discussion and Consideration of Ethics Course Provisions in California Code of Regulations, Title 16, Section 1773.5</u>

Attachment 1

<u>Background</u>
In 2009, California Code of Regulations (CCR), Title 16, section 1773.5 established that when directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course as a condition of probation, license reinstatement or as abatement for citation and fine.

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.

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. The following information was collected:

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

Committee Discussion and Action
The Committee heard a presentation from Ms. Leslie Anne Iacopi from the Institute of Medical Quality (IMQ) regarding the content and objectives of their ethics course, the cost of each course, as well as their measurement for success.

As part of the committee discussion, Ms. Iacopi stated the cost of the IMQ ethics course is $1,995, which includes a full two-day program, a follow-up program consisting of a 6-month progress report, a 12-month final report, and all post and pre-tests. The committee requested that a report of the student satisfaction evaluations be provided to the board annually. Board staff was directed to work with IMQ in the development of the student satisfaction annual report.

As part of the public discussion, a member of the public stated it is the common opinion among pharmacy law educators there is not enough time to teach law and ethics in one course. The committee was informed that at some schools of pharmacy a law and ethics course is only a one or two-unit class.

The committee did not take action on this item.

Attachment 1 contains CCR § 1773.5 and a copy of the IMQ presentation, IMQ Professionalism Program for Pharmacists.

b. Discussion and Consideration of Senate Bill 1442 (Weiner, Chapter 569, Statutes of 2018) Relating to Community Pharmacy Staffing

Attachment 2

Background
SB 1442 prohibits pharmacists from working alone. At the last committee meeting, staff was directed to work with counsel to research Drug Enforcement Administration (DEA) requirements and to determine whether a background check would be required under the

Code of Federal Regulations (CFR) or whether the board should develop such a requirement. Title 21 CFR section 1301.90, which discusses the non-practitioner screening procedures for employees and Title 21 CFR section 1301.76, which applies to hospitals, pharmacies and wholesalers, was provided for review.

Committee Discussion and Action

Senator Jeff Stone addressed the committee on the implementation of SB 1442. The Senator shared his own experiences as a intern pharmacist working with a pharmacist who was shot during a robbery and his experiences as a pharmacist, working for Thrifty's in Southern California, tasked with additional retail responsibilities. Senator Stone urged the committee to strongly consider creating a statewide enforcement task force that would conduct after-hour visits and observe activities that happen in pharmacies, especially in the more rural and urban areas, where this abuse occurs more frequently. Senator Stone requested that inspection staff review and understand SB 1442 and ensure that it is appropriately implemented throughout the state in the best interest of patient safety and in the best interest of pharmacists who are being pulled in many different directions.

President Law shared with the Senator that there have been committee discussions regarding the implementation of SB 1442; he asked if the Senator would consider amending the law to clarify that pharmacy technicians are required to provide assistance to the pharmacist. Senator Stone agreed that the most logical person who should be with a pharmacist is a pharmacy technician. Additionally, President Law suggested a second amendment that would allow pharmacies to consolidate their late-night hours to specific stores and staff those designated stores with a pharmacists and pharmacy technicians.

As part of public comment, the committee was informed that, in some cases, retail staff sent to assist in retail pharmacies currently lack the training, knowledge and pharmacy skills necessary to assist the pharmacist or customers. Additionally, the public expressed concern that with the approval of remote dispensing pharmacies, pharmacists will be required to supervise the pharmacy technicians at the remote dispensing pharmacy, in addition to their responsibilities at their actual pharmacy location.

The committee did not take action on this item.

Attachment 2 contains a copy of chaptered language for SB 1442, 21 CFR section 1301.90 and 21 CFR section 1301.76.

c. Summary of a Presentation on the Board's Routine Pharmacy Inspections

Attachment 3

Background

Inspector Steven Kyle presented "How to Prepare for a CA Board of Pharmacy Inspection." As part of his presentation, Inspector Kyle discussed the following areas: when an inspection or investigation is conducted, designating a Pharmacist-In-Charge (PIC),

responsibilities of a PIC, items reviewed during a routine pharmacy inspection, and a review of sterile compounding inspections and pharmacy law resources.

Committee Discussion and Action
As part of the committee discussion, it was suggested that Inspector Kyle's presentation be made available on the board's website for viewing. Board staff confirmed that a video of this module would be posted on the board website.

As part of public comment, a question arose whether inspections are conducted during nights, weekends and/or holidays. Inspector Kyle confirmed that visits are conducted during nights, weekends and/or holidays, as they relate to an investigation.

The committee did not take action on this item.

Attachment 3 contains a copy of the presentation, How to Prepare for a CA Board of Pharmacy Inspection.

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

Attachment 4

Relevant Law
Business and Professions Code (BPC) section 4314 establishes the authority for the board to issue citations which may include fines and/or orders of abatement (OOA). As included in this section, the OOA 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 authorizes 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 orders of abatement compliance requirements.

Background

Goal 2.1 of the board's Strategic Plan calls for evaluation of the board's citation and fine program.

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	**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 (AG) 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 the 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.

Each investigation is unique and must be individually reviewed to determine the appropriate outcome. Board staff evaluate investigation outcomes consistent with pharmacy law provisions, as well as board policy in other areas, e.g., the board's Disciplinary Guidelines.

The data provided in the report demonstrates that OOAs are used with a far greater frequency than in previous years. This is consistent with the board's direction. Whereas, in 2016/17 about 1% of citations were issued with an abatement order, this year about 20% contain such an order.

The committee was informed that typically when issuing an OOA the board is giving the respondent a period of time in which to complete the abatement before the citation is completed, therefore, it would be helpful if staff could provide another follow up report, to see if the actual abatement rate is higher because of the compliance period.

As part of public comment, members of the public expressed concern regarding the expenditure of Cite and Fine monies. In relation, a member of the public asked why the board was not just part of the State General Fund. Supervising Deputy Attorney General (SDAG) Joshua Room provided the following clarification: the board is a Special Fund Agency and does not receive General Funds. Fines collected by the board are not the board's to spend, as special authorization is required to spend those funds, therefore, there is no financial incentive to collect additional fines because the board has no idea whether it will be allowed to spend those funds.

The committee agreed that further discussion regarding the budget building process could be thoroughly discussed as an agenda item at an Organizational Committee Meeting.

The committee did not take action on this item.

Attachment 4 includes a copy of BPC section 4314 and the Citation and Fine flowchart.

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

Background

At the September 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 Action

The committee was provided with a snapshot of the board's current pending investigations, including the average days by the identified benchmarks as of Feb 1, 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 current Fiscal Year (7/1/18-2/1/19).

Average Days for cases under investigation in the field during FY 2017-18 was 235 days versus 169 days for the current Fiscal Year (7/1/18-2/1/19).

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 the seven-month timeframe reviewed by the committee, the board had four vacant inspector positions . Additionally, two supervising inspectors were on leaves of absence.

During a prior meeting of the Enforcement Committee, staff had notes that processes were being reexamined, resulting in faster assignment time for field investigations. Chiefs of Enforcement have made case closure time of investigations a priority amongst field staff.

The committee was provided with the chart below outlining the age of pending field cases over the past three fiscal years. In fiscal year 18/19, 80% of pending cases were under one year old.

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%

*FY 18-19 data are as of 2/1/19

The committee was provided with the chart below outlining the age of field cases closed over the past three fiscal years. This chart does not include cases referred to the Office of the Attorney General. In fiscal year 18/19, 64% of the cases were closed in less than one year.

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%

*FY 2018-2019 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 Office of the Attorney General.

As part of the committee discussion, the committee agreed to continue to monitor this progress.

There was no comment from the public and the committee did not take action on this item.

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

Attachment 5

Background

Strategic Goal 2.5 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 the 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.

Committee Discussion and Action

SDAG Room provided a presentation of the AG's Annual Report. The committee was informed that the report reflects the second reporting year for the Annual Report. This report is an effort by the legislature to collect data on how quickly cases progress. SDAG Room reported that numbers are improving overall. He explained that Board of Pharmacy cases do not move as quickly as some other boards due to the complexity and number of respondents in each case, which slows down the progress. SDAG Room stated currently it is taking about six months for a case to progress from receipt of the case at the AG's office to the filing of an accusation; the goal is to get that time down to three months. The overall goal is to get Board of Pharmacy's cases in and out of the AG's office within one year.

The committee did not take action on this item.

Attachment 5 includes the relevant portion of the AG's Annual Report.

g. 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

1. Consideration of Possible Regulations
2. Consideration of Possible Statutory Changes

Attachment 6

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, 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.

AB 2138 reduces the opportunity for the board to consider some of the criminal activities that people engage in as a cause for discipline or denial of a license. The trigger in the statute is no longer necessarily substantial relationship; there is a hard deadline on when the board can no longer consider the criminal activity. Board staff asked the committee to consider whether AB 2138 is consistent with the board's mandate. Additionally, the board is required to make changes to the board's substantial relationship regulations and update the pharmacy technician application form to conform with the law.

As previously directed by the committee, board staff and counsel have 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 provided suggested regulation language consistent with recommendations from the department for the committee's consideration.

Committee Discussion and Action

The committee considered draft statutory language that would restore the board's ability in some areas to take action on matters beyond what is currently provided. Recommendations included the following:

1. Consideration of convictions of felony financial crimes.
2. Consideration of acts that would be grounds for denial of a federal registration to distribute controlled substances.
3. Consideration of acts that involve fraud in violation of state or federal law related to healthcare.
4. Consideration of convictions related to identify theft.

5. Consideration of convictions related to the sale of counterfeit products.

DCA Counsel Laura Freedman reviewed proposed draft regulation language and options for regulatory amendments that would conform to AB 2138. The committee considered the various proposals.

As part of public comment, it was asked if an applicant would need to disclose a conviction on the application. SDAG Room clarified that an applicant would no longer be required to disclose a conviction, although an applicant could voluntary disclose and show rehabilitation.

Committee Recommendation (Motion): *Recommend the board seek an author to make the statutory amendments, as included in the meeting materials, and include language specific to criminal history.*

Committee Recommendation (Motion): *Recommend the board approve draft regulations to include Section 1 with optional language, subdivision (c), include Option A, without the variation. Make any non-substantive changes consistent with policy.*

Attachment 6 contains a copy of the chaptered language for AB 2138, the recommended statutory changes and draft regulations
as recommended by the committee.

h. <u>Summary of a Presentation and Discussion on Disciplinary Guidelines</u>

Attachment 7

<u>Background</u>
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. These guidelines are designed to assist administrative law judges, attorneys, board members, staff, and others involved in the disciplinary process. These 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.

<u>Committee Discussion and Action</u>
SDAG Room provided members with a presentation on the Disciplinary Guidelines including how attorneys representing the board use them as a tool in administrative matters.

As part of the committee discussion, the committee received information on the Uniform Standards which speak only to substance-using licensees and their specific criteria which were created by a specific organization of executive officers for healthcare.

President Law informed the committee that the current process consists of an inspector completing a report and forwarding the file to a supervising inspector with a recommendation for cite and fine or referral to the AG's Office. Previous discussions have considered that the board should have a process to screen cases before they are issued a cite and fine or referral to the AG's Office to ensure that only cases of the most serious nature are referred to the AG's Office.

As part of public comment, members of the public expressed support of a more thorough review process prior to referral to the AG's Office.

The committee did not take action on this item.

A copy of the Disciplinary Guidelines is provided in **Attachment 7**.

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

Attachment 8

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.

Mr. Martinez presented, Proposal for a Pharmacy Advisory Committee. Mr. Martinez's presentation included a review of the Board of Pharmacy's Enforcement Process, CPhA's proposed changes to the Enforcement Process, and the proposal of a Pharmacy Advisory Committee.

Committee Discussion and Action

Mr. Martinez proposed that prior to initiation of the board's formal disciplinary process (referral to the AG's office), the board should permit licensees to appear before a consortium of their practicing peers in order to help the board prioritize serious issues from less significant issues.

As part of the committee discussion, members expressed various areas of concern. Firstly, the charge of the board is the protection of consumers; to recommend a consortium of only pharmacists is in opposition to that concept. In addition, the membership criteria for CPhA's proposed advisory committee would exclude retired licensees who are still active members in the pharmacy profession.

As part of public comment, speakers stated that CPhA's proposed process would allow a licensee an opportunity to explain their side of the story to committee members before being sanctioned. Additionally, the committee was informed that the states of Iowa, Texas and Florida allow licensees the opportunity to be heard. Another member of the public emphasized the specific need to seek pharmacists who are experts in the area of

collaborative drug therapy pharmacy, to consult and guide the process; he also suggested that there may be more areas in which investigators and board members need guidance, due to lack of in-house experience.

SDAG Room presented a few possible legal objections to the CPhA proposal:

1) Committee members would have access to confidential information generally only shared with board staff who are subject to criminal and civil penalties for the potential release or abuse of private information.
2) The proposal could be considered a violation of statute or an unconstitutional delegation of this body's authority to another body. Creating the committee would require a statutory amendment.
3) By what process is a board of thirteen members going to appoint a subcommittee of five members?
4) The board has been previously briefed on anti-trust possibilities of treading to close to the line of having licensees exclusively policing other licensees under the North Carolina Dental Board case. If the board, which has been consciously constituted of professional and public members, were to delegate some portion of its authority to a subcommittee made up exclusively of members of the profession who might have competitive interests involved in any case, the risks of liability, under the North Carolina case, would increase significantly.

President Law stated that the proposal presented by CPhA was a concept that could be further developed. As the pharmacy profession progresses, there are different areas of specialization that could benefit from peer expertise in order to advise the board during decision making.

The committee directed board staff to work with the chair of the committee to explore alternative solutions.

DCA Counsel suggested that the committee request a future discussion on how the enforcement program is structured. President Law agreed and directed board staff to research other state enforcement models in order to continue the discussion on disciplinary matters.

A copy of the presentation is provided in **Attachment 8**.

j. <u>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)</u>

Attachment 9

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.

Committee Discussion and Action
The committee had 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 9**. 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.

The committee did not take action on this item.

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

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

Attachment 10

Background
Title 16, California Code of Regulations (CCR) section 1715 establishes the requirement for a PIC 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.

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.

During the 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.

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.

Committee Discussion and Action
The committee agreed with the recommended changes, the revised versions are now brought to the full board for consideration and approval.

Committee Recommendation (Motion): *Recommend to the full board approval of the draft self-assessment forms.*

The revised forms are included in **Attachment 10**.

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

Relevant Laws and Background

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."

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 CFR requirements and CCR. 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.

Committee Discussion and Action

As part of its discussion, the committee reviewed 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

As part of public comment, a member of the public expressed concern regarding having to perform inventory and reconciliation every quarter and for every controlled substance. He stated the implication is that on all the other controlled substances, Schedules III, IV and V, there also must be a reconciliation. He requested that the committee revisit the process of reporting drug losses to do what DEA does and establish some criteria for reporting a loss, which varies depending on the schedule of the controlled substance. Additionally, another member of the public encouraged the committee to determine a definition of "significant loss" in numbers.

Board staff suggested, and the board agreed that staff would survey other states for their drug loss reporting requirements and research the types of drugs that are in that 1 to 100 dosage units threshold.

m. <u>Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board's Ask An Inspector Program</u>

This agenda item was moved to the next committee meeting.

n. <u>Discussion and Consideration of Board's Enforcement Statistics</u>

Attachment 11

Since July 1, 2018, the board received 2,229 complaints and closed 2,160 investigations. As of March 31, 2019, the board had 2,022 investigations pending.

Since July 1, 2018, 1,091 investigations were closed without a substantiated violation, including 271 complaints that were determined non-jurisdictional.

Since July 1, 2018, the board issued 879 citations, 136 of which the board offered abatement to either reduce or eliminate the fine. The board referred 193 investigations to the Office of the Attorney General.

Since July 1, 2018, the board resolved administrative cases that resulted in 164 revocations or surrenders of a license, 25 licenses being placed on probation, and issued 28 public reprovals.

The committee did not take action on this item but agreed to discuss any concerns at the next committee meeting.

The enforcement statistics for the first three quarters of FY 2018/2019 are provided in **Attachment 11.**

o. <u>Future Committee Meeting Dates</u>

The next enforcement committee meetings are scheduled for July 2, 2019, and September 25, 2019.

The draft meeting minutes from the March 14, 2019 committee meeting have been provided in **Attachment 12.**

Attachment 1

CCR section 1773.5

IMQ Professional Program for Pharmacist
A hardcopy of this document will be made available at the meeting or upon request.
Requests may be emailed to MaryJo.Tobola@dca.ca.gov

§ 1773.5. Ethics Course Required as Condition of Probation.

16 CA ADC § 1773.5BARCLAYS 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).

Attachment 2

SB 1442
21CFR section 1301.90
21 CFR section 1301.76

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]

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.

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES
SECURITY REQUIREMENTS
§1301.76 Other security controls for practitioners.

(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.
(b) 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. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;
(2) The specific controlled substances lost;
(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
(5) Whether the specific controlled substances are likely candidates for diversion;
(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

(c) Whenever the registrant distributes a controlled substance (without being registered as a distributor as permitted in §§1301.13(e)(1), 1307.11, 1317.05, and/or 1317.10 of this chapter), he/she shall comply with the requirements imposed on non-practitioners in §1301.74(a), (b), and (e).

(d) Central fill pharmacies must comply with §1301.74(e) when selecting private, common or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to the ultimate user. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106. Retail pharmacies must comply with §1301.74

(e) when selecting private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

[36 FR 7778, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15919, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973; 47 FR 41735, Sept. 22, 1982; 56 FR 36728, Aug. 1, 1991; 62 FR 13957, Mar. 24, 1997; 68 FR 37409, June 24, 2003; 70 FR 47097, Aug. 12, 2005; 79 FR 53562, Sept. 9, 2014]

Attachment 3

How To Prepare for a CA Board of Pharmacy Inspection

A hardcopy of this document will be made available at the meeting or upon request. Requests may be emailed to MaryJo.Tobola@dca.ca.gov

Attachment 4

BPC section 4314

Citation and Fine Flowchart
A hardcopy of this document will be made available at the meeting or upon request.
Requests may be emailed to MaryJo.Tobola@dca.ca.gov

BUSINESS AND PROFESSIONS CODE – BPC ARTICLE 19. Disciplinary Proceedings [4300 - 4316] (Article 19 added by Stats. 1996, Ch. 890, Sec. 3.)

(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, and4005 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 abatementpursuant 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 5

Attorney General's Annual Report

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.

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.

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.

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.

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.

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 6

Chaptered Language AB 2138

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.)

Attachment 7

Disciplinary Guidelines

A hardcopy of this document will be made available at the meeting or upon request.

Requests may be emailed to MaryJo.Tobola@dca.ca.gov

Attachment 8

Proposal for a Pharmacy Advisory Committee

A hardcopy of this document will be made available at the meeting or upon request. Requests may be emailed to MaryJo.Tobola@dca.ca.gov

Attachment 9

Study of Expanded Use of ADDS Extension Update

A hardcopy of this document will be made available at the meeting or upon request. Requests may be emailed to MaryJo.Tobola@dca.ca.gov

Attachment 10

Proposed Changes to Self-Assessment Forms

A hardcopy of this document will be made available at the meeting or upon request.

Requests may be emailed to MaryJo.Tobola@dca.ca.gov

Attachment 11

Enforcement Statistics FY 2018/2019

A hardcopy of this document will be made available at the meeting or upon request.

Requests may be emailed to MaryJo.Tobola@dca.ca.gov

Attachment 12

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ENFORCEMENT COMMITTEE
MEETING MINUTES (Draft)

DATE:	March 14, 2019
LOCATION:	Department of Consumer Affairs 1625 N. Market Blvd First Floor Hearing Room Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	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
STAFF MEMBERS PRESENT:	Anne Sodergren, Interim Executive Officer Laura Freedman, DCA Staff Counsel Joshua Room, Supervising Deputy Attorney General MaryJo Tobola, Senior Enforcement Manager Rob Buckner, Criminal Conviction Unit Manager

1. **Call to Order and Establishment of Quorum**
   Chairperson Allen Schaad called the meeting to order at 9:05AM. A quorum was established.

2. **Public Comment on Items Not on the Agenda, Matters for Future Meetings**
   Chairperson Schaad invited public comment.

   Dr. Steven Gray suggested the following items to be considered:
   - The enforcement of the statute that requires pharmacies to provide prescription retail prices upon request by the public, however communicated.
   - Require pharmacies to provide phone numbers that will directly connect the caller to a pharmacy rather than just a call center.
   - Hospitals outsourcing (out of state or out of the country) the required review of hospital orders, in their effort to comply with the Joint Commission's requirement that a pharmacist review the hospital order before the drug is administered to the patient.
   - Clarification of enforcement implementation of the two bills which require pharmacists to tell the patient if the retail price of the medication is less than their copayment.

Kim Allen with Sharp Healthcare requested clarification of SB 1447, which addresses the stocking and restocking of automated drug delivery systems (ADDS). Ms. Allen expressed concern that two Business and Professions Code (BPC) sections conflict with each other. Specifically, BPC Code section 4186 states that an ADDS must be stocked by a pharmacist, but BPC Code section 4427.4 allows ADDS to be stocked by a pharmacist, pharmacy technician or intern pharmacist. Ms. Allen opined that in order to maximize the role of a pharmacist in the pharmacy, the restocking of ADDS should be the responsibility of a pharmacy technician.

Chairman Schaad recommended that the board consider, as a future agenda item, a discussion for clarification of the posting of a pharmacist's address of record on the board website.

Board President and Committee Member Victor Law suggested that the board consider, as a future agenda item, the promulgation of statutory change to discipline the common owner of multiple pharmacies in violation of laws or regulations, rather than disciplining each pharmacy.

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

Chairperson Schaad requested the review and approval of the minutes from the December 20, 2018 Enforcement Committee meeting.

As part of the public comment, Dr. Gray requested that on the bottom of Page 3 of 15, last paragraph, "Health and Safety Code section 4052" be amended to "Business and Professions Code section 4052".

Motion: Approve the minutes with the corrections identified.

M/S: Weisser / Law

Support: 5 Oppose: 0 Abstain: 1

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

Chairperson Schaad provided background and relevant law. In 2009, CCR section 1773.5 established that when directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course 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.

Chairperson Schaad stated that various healing arts boards were asked by board staff to provide a sample of an approved ethics course, the provider, and the cost.

The Committee heard a presentation from Ms. Leslie Anne Iacopi from the Institute of Medical Quality (IMQ) regarding the content and objectives of IMQ's ethics courses, the cost of each course as well as their measurements for success.

Committee Member Stan Weisser asked what the participant cost is for the IMQ ethics program. Ms. Iacopi stated the cost is $1,995, which includes a full two-day program as well as the follow-up

program consisting of a 6-month progress report and a 12-month final report and includes all post and pre-tests.

Chairperson Schaad asked if students are failed from the ethics program. Ms. Iacopi stated that the course design is not intended to fail students, but rather works with their individual issues and focuses on how each participant can move forward and be a better pharmacist.

Chairperson Schaad asked what type of feedback the students provide to IMQ. Ms. Iacopi stated that upon completion of the 12-month report, the board receives a letter from IMQ which verifies the participants completed the 2-day course and and the contents reported in the 6-month progress report and 12-month final report.

Chairperson Schaad asked board staff how course providers are recommended to participants. Interim Executive Officer Anne Sodergren informed the committee that staff suggests programs to licensees that have been used successfully in the past, but licensees are free to locate providers on their own. Providers are then approved by the board if they can demonstrate their program satisfies the requirements of the law.

As part of public comment, Holly Strom shared her support of the IMQ ethics program. Ms. Strom asked the committee what a participant would need to do to get a course provider approved. DCA Counsel Laura Freedman stated that as a condition of probation, staff would approve the course and provider based on the requirement identified in the terms of their probation.

President Law asked Ms. Iacopi if IMQ's student satisfaction evaluations were provided to the board. Ms. Iacopi stated that those surveys were internal, but they could be provided to the board upon request. The committee requested a report of the evaluations be provided to the board annually. Board staff was directed to work with IMQ to obtain annual feedback on student satisfaction.

As part of public comment, Dr. Gray stated his support of the IMQ ethics program. Additionally, Dr. Gray suggested that it would be beneficial for pharmacy students to know what type of disciplinary scenarios result in an ethics course being included as a term of probation. Dr. Gray stated it is the common opinion among pharmacy law educators there is not enough time to teach law and ethics in one course. Dr. Gray expressed concern that at some schools of pharmacy law an ethics course is only a one or two-unit class.

5. <u>Presentation on the Board's Routine Pharmacy Inspections</u>

Chairperson Schaad introduced Board Inspector Steven Kyle. Inspector Kyle presented "How to Prepare for a CA Board of Pharmacy Inspection".

As part of his presentation, Inspector Kyle discussed the following areas: when an inspection or investigation is conducted, designating a pharmacist-in-charge (PIC), responsibilities of a PIC, items

reviewed during a routine pharmacy inspection, and a review of sterile compounding inspections and pharmacy law resources.

Chairperson Schaad requested that questions and comments pertaining to Inspector Kyle's presentation be held until after the next speaker.

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

Chairperson Schaad welcomed and introduced State Senator Jeff Stone who would be commenting on the implementation of SB 1442.

Senator Stone stated that SB 1442 was introduced by Senator Scott Weiner and himself. He shared his own experiences as a intern pharmacist working with a pharmacist who was shot during a robbery and he shared his experience as a pharmacist, working for Thrifty's in Southern California, tasked with additional retail responsibilities.

Senator Stone stated that SB 1442 was written with the belief that pharmacists should not be working alone, especially at night. He explained that although during the night there are smaller volumes of prescriptions being filled, there are many patients picking up prescriptions and requiring consultations. Senator Stone informed the committee that we now see pharmacists who administer immunizations, dispense naloxone, take blood pressures, take blood sugar levels, while also tending to their own personal issues like using the restroom and taking a break. The Senator shared with the committee that a pharmacist confided in him that he will not go to work while he is taking his diuretic medication because he cannot safely leave the pharmacy to use the restroom. Senator Stone shared that pharmacists have voiced their concern over their increased responsibilities in the middle of the night in these types of retail environments. He expressed his concern that pharmacists are working alone at night, answering telephones, ringing up sales, doing immunizations and dealing with patient demands; he warned it is these types of interruptions of routine which could cause errors.

Senator Stone urged the committee to strongly consider creating a statewide enforcement task force that would conduct after-hour visits and observe activities that happen in pharmacies, especially in the more rural and urban areas, where we see this abuse taking place. Additionally, Senator Stone said some employers are not placing adequately trained personnel in the pharmacy who understand how to work the pharmacy computer system, understand how to answer the patient calls or how to track a prescription. He questioned whether a lay person, without pharmacy training or knowledge, should be left alone in a pharmacy while a pharmacist relieves themselves. Senator Stone stated that there may be unintended consequences of this bill. Further, the Senator continued he and Senator Weiner are willing to address these unintended consequences through future legislation.

Senator Stone concluded with his request that inspection staff review and understand SB 1442 requirements and ensure that it is appropriately implemented throughout the state in the best interest of patient safety and in the best interest of pharmacists who are being pulled in many different directions.

Chairperson Schaad thanked Senator Stone for following up on SB 1442. President Law shared with the Senator that there have been many discussions regarding the implementation of SB 1442; he asked if the Senator would consider amending the law to clarify that pharmacy technicians are required to provide assistance to the pharmacist. Senator Stone agreed that the most logical person who should be with a pharmacist is a pharmacy technician. Additionally, President Law suggested a second amendment that would allow pharmacies to consolidate their late-night hours to specific stores and staff those designated stores with a pharmacists and pharmacy technicians. Mr. Weisser also thanked Senator Stone for his advocacy for the consumers of California.

7. <u>Presentation on the Board's Routine Pharmacy Inspections</u>

Chairperson Schaad invited committee and public comments regarding the presentation of routine pharmacy inspections presented earlier by Inspector Kyle.

Mr. Weisser asked Inspector Kyle if he was satisfied with the amount of consultation being provided to patients. Inspector Kyle answered, in his observation, consultation is not enough of a standard practice.

Committee Member Albert Wong suggested that Inspector Kyle's presentation be provided on the Board's website for viewing. Ms. Sodergren confirmed that a video of this module would be provided on the board website.

President Law encouraged pharmacy students to view this module in order to learn inspection expectations.

As part of the public discussion, Joe Grasela asked if out of state pharmacies are inspected. Ms. Sodergren clarified that some out-of-state pharmacies are inspected; outsourcers and sterile compounding are inspected but authority out-of-state is limited. Mr. Grasela stated that he believes that there are many compounding pharmacies that are sending prescriptions into California that are non-sterile and not compliant with California laws. He suggested that the National Association of Boards of Pharmacy conduct out-of-state California inspections. Counsel Laura Freedman suggested that this could be considered as a future agenda item. Mr. Gray asked if inspections are conducted during nights, weekends and/or holidays. Inspector Kyle confirmed that visits are conducted during nights, weekends and/or holidays, as they relate to the investigation. Additionally, Mr. Gray stated that in the area of cite and fines many pharmacy owners are paying the fines for their PICs who are found in violation, which defeats the purpose of sanctioning that specific employee for their mistake. President Law re-stated that his earlier suggestion to cite the owner of the pharmacy.

The committee paused for break at 11:05 a.m. and returned at 11:21 a.m.

8. <u>Discussion and Consideration of Senate Bill 1442 (Wiener, Chapter 569, Statutes of 2018) Relating to Community Pharmacies Staffing</u>

Chairperson Schaad provided information regarding SB 1442 which prohibits pharmacists from working alone. At the last committee meeting, the committee directed staff to work with counsel to research DEA requirements and to determine whether a background check for non-licensed personnel would be required under the Code of Federal Regulations (CFR) or whether the board should develop such a requirement. Ms. Sodergren informed the board that Title 21 CFR section

1301.90, which discusses the non-practitioner screening procedures for employees, had been provided for their review.

As part of public comment, Title 21 CFR section 1301.76 which is the basis for section 1301.90, was provided to the committee by Dr. Gray. Dr. Gray clarified that section 1301.76 applies to institutional practitioners, meaning hospitals, pharmacies and wholesalers. As part of public comment, a pharmacist working in a retail store stated that, in his experience, the staff sent to assist in retail pharmacies currently lack the training, knowledge and pharmacy skills necessary to assist the pharmacist or customers. Additionally, it was suggested that when inspectors conduct inspections, a copy is made of the employee schedules to verify who is assigned to the pharmacy to verify compliance with SB 1442.

Dr. Wong voiced his concern that pharmacies are unwilling or unable to staff appropriately. Dr. Wong stated he believed that Primary Benefit Manager (PBM) reimbursements are the root of this inability to staff appropriately.

Ms. Sodergren informed the committee that she is aware of at least one complaint alleging non-compliance with SB 1442.

Dr. Gray stated that with the approval of remote dispensing pharmacies, pharmacists will be required to supervise the pharmacy technicians at the remote dispensing pharmacy, in addition to their responsibilities at their actual pharmacy location. With the increased pharmacist responsibility there could be security issues in addition to concerns regarding consultation and service.

9. <u>Update on and Discussion of Board's Citation and Fine Program</u>

Chairperson Schaad stated that Goal 2.1, of the board's Strategic Plan calls for evaluation of the board's citation and fine program.

Chairperson Schaad explained that the chair report details several provisions of pharmacy law that govern the board's citation and fine program. During the discussion, Chairperson Schaad hoped to focus on two areas: post evaluation of order of abatement provisions since the board's May 2018 meeting and review of the policy considerations and guidance staff have been provided, by both the president and vice president, as it relates to completed citations issued with a fine of $2,000 or greater.

Chairperson Schaad directed the committee to the citation and fine data in the chair report. The data provided in the report demonstrated that orders of abatement are used with a far greater frequency than in previous years. This is consistent with the board's direction. Whereas, in 2016/17 about 1% of citations were issued with an abatement order, this year about 20% contain such an order. It appears abatements acceptance is relatively low.

Ms. Sodergren explained that typically when issuing an order of abatement, the board is giving the respondent a period of time in which to complete the abatement before the citation is completed, therefore, it would be helpful if staff could provide another follow up report to see if the actual abatement rate is higher because of the compliance period.

President Law informed the committee that since he and Vice President Greg Lippe have been reviewing citations, the number of citations has decreased.

As part of public comment, members of the public expressed concern regarding the expenditure of Cite and Fine monies. In relation, a member of the public asked why the board was not just part of the State General Fund. Supervising Deputy Attorney General (SDAG) Joshua Room provided the following clarification: the board is a Special Fund Agency and does not receive General Funds. Fines collected by the board are not the board's to spend, as special authorization is required to spend those funds, therefore, there is no financial incentive to collect additional fines because the board has no idea whether it will be allowed to spend those funds.

Ms. Sodergren recommended that further discussion regarding these budgetary issues could be discussed as an agenda item at the Organizational Committee. Vice President Lippe agreed to the recommendation.

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

Chairperson Schaad informed the committee that Goal 2.1, of the board's Strategic Plan seeks to implement processes to shorten the cycle times from investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection.

Chairperson Schaad stated that for several meetings the committee has been discussing investigation closure times and receiving updates on current data. Included in the chair report for review are pending investigation case historical and current data as well as case closure data.

Chairperson Schaad informed the committee that in the review of the Age of Pending Field Investigations , he noted a significant decrease in the number of pending investigations over 1 year, which shows progress. Additionally, a review of the Age of Field Cases Closed also reflects improvement in overall investigation time for cases that are closed. He recommended that the committee continue to monitor this progress.

President Law thanked staff for reducing investigation time. He noted that cases sent to board members by mail vote are also more current.

Chairperson Schaad thanked the staff for responding to direction by the committee. He stated that the board has heard the professions concern with efficiency and increased transparency in the discipline program.

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

Chairperson Schaad stated that Goal 2.5 of the board's Strategic Plan is to evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.

As required by law, the Office of the Attorney General (AG) is required to publish data annually on certain disciplinary matters. Chairperson Schaad invited SDAG Joshua Room to provide a brief presentation on the AG's Report.

SDAG Room informed the committee that this is the second reporting year for the Annual Report. This is an effort by the legislature to collect data on how quickly cases are progressing. SDAG Room reported that numbers are improving overall. He explained that Board of Pharmacy cases do not move as quickly due to complexity, number of respondents in each case, which slows down the progress. SDAG Room stated right now it is taking about six months for a case to go from receipt of the case at the AG's office to the filing of the Accusation with the goal being to get that time down to three months. The overall goal is to get Board of Pharmacy in and out of the AG's office within one year.

President Law inquired about the suspension of a license when a licensee is subject to a criminal case. SDAG Room confirmed that the process to suspend in such a case would be initiated pursuant to Penal Code section 23 (PC23). SDAG Room confirmed that the board has pursued PC 23 suspensions, whenever possible.

Ms. Sodergren stated the board attempts to obtain an Interim Suspension Order (ISO) when the PC 23 is not an option.

No public comment.

12. 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
a. Consideration of Possible Regulations
b. Consideration of Possible Statutory Changes

Chairperson Schaad informed the committee that AB 2138 places restrictions on the acts and convictions the board can consider when reviewing an applicant's criminal history, and had been previously discussed.

DCA Counsel Laura Freedman provided a brief overview of the bill. She stated that AB 2138 primarily changes the board's ability to deny an application. The bill contains two different provisions related to substantial relationships and rehabilitation.

Ms. Sodergren stated that AB 2138 reduces the opportunity for the board to consider some of the criminal activities that people engage in as a cause for discipline or denial of a license. The trigger in the statute is no longer necessarily substantial relationship, there is a hard deadline on when we can no longer consider the criminal activity. Ms. Sodergren informed the committee that the discussion today is whether AB 2138 is consistent with the board's mandate. Although the policy was decided and the bill was enacted, this committee previously discussed this legislation and directed staff to see if there are opportunities to request changes to the statute. Also, Ms. Sodergren added, as part of the statute, the board is required to make changes to the board's substantial relationship regulations and make updates to the pharmacy technician application form to conform with the law.

Chairperson Schaad stated that based on the draft language recommendations, statutory changes would allow the following:

1. Consideration of convictions of felony financial crimes;

2. Consideration of acts that would be grounds for denial of a federal registration to distribute controlled substances;
3. Consideration of acts that involve fraud in violation of state or federal law related to healthcare.
4. Consideration of convictions related to identify theft;
5. Consideration of convictions related to the sale of counterfeit products.

SDAG Room clarified that as of July 1, 2020, the conviction or the end of incarceration would have to have occurred within seven years of the application date, in order for the conviction to be considered for denial or discipline. There are certain exceptions which are not subject to the seven-year period such as serious felonies and sex crimes. Additionally, there are various other types of crimes, for specific agencies, that are not subject to the seven-year limitation, for example, financial crimes for the Fiduciaries Board. SDAG Room explained that a proposed amendment would put the Board of Pharmacy among the boards with the financial crime exception. Additionally, this proposed amendment would carve out a special set of crimes just for the pharmacy board, which would allow the board to continue to use in the consideration of denials and discipline.

Ms. Sodergren suggested drafting language to also allow the board to consider an applicant's criminal history, if they have something within the allowable seven years and history previous to that.

SDAG Room clarified, if someone has a lengthy criminal history, for example, 12 convictions leading up to eight years ago, then they have a period of legality, then they have one more conviction from three years ago; for purposes of their application, under the current law we would only be allowed to consider three years ago.

SDAG Room recommended the committee consider all amendments presented and after deciding which amendment to pursue, staff should seek an author for the amendments agreed upon by the board.

Motion: Committee recommended the board seek an author to make the statutory amendments, as included in the meeting materials, and include language specific to criminal history.

M/S: Lippe/Weisser

Support: 6 Oppose: 0 Abstain: 0

As part of the committee discussion, DCA Counsel Laura Freedman reviewed proposed draft language and options for regulatory amendments that would conform to AB 2138.

Motion: Approve draft regulations to include Section 1 with optional language, subdivision (c) and for Section 2, include Option A, without the variation. Make any non-substantive changes consistent with policy.

M/S: Lippe/Weisser

Support: 6 Oppose: 0 Abstain: 0

As part of public comment, concerns were raised regarding the consideration of crimes committed in other states, and whether the National Practitioner Data Bank (NPDB) could still be reviewed in the consideration of applications SDAG Room clarified that this regulation will have no effect on the process, just the criteria used consider an applicant for disciplinary action or denial.

Holly Strom of Strom & Assoc. asked if the applicant would need to disclose a conviction on the application. SDAG Room clarified the applicant would no longer be required to disclose, although the applicant could voluntary disclose and show rehabilitation.

13. <u>Presentation and Discussion on Disciplinary Guidelines</u>

Chairperson Schaad, informed the committee that as required by CCR section 1760, the board uses its Disciplinary Guidelines when considering disciplinary action. He stated that it is his intent to dedicate time at the next several meetings to discuss the current guidelines and determine what, if any, changes should be recommended to the full board for consideration.

Chairperson Schaad invited SDAG Room to provide a summary on the Disciplinary Guidelines.

The Disciplinary Guidelines are adopted and are therefore mandatory. They must provide guidance to the board in the decision of disciplinary actions. SDAG Room reviewed the various sections and categories in the Disciplinary Guidelines and informed the committee of the Uniform Standards.

Ms. Freedman clarified that the Uniform Standards speak only to substance-using licensees and the specific criteria were created by a specific organization of executive officers for healthcare.

Ms. Sodergren stated that when the board was considering the Disciplinary Guidelines at the policy level, the committee identified which of those standards should be included in the Disciplinary Guidelines. There were different types of directions within the Standards: directions to the board itself, directions to board staff on testing frequency recommendations, directions to respondents on what their requirements would be and directions for those boards who have a recovery program. As policy makers, the committee included in the guidelines those that were incumbent upon the respondent to satisfy.

Ms. Freedman informed the committee that DCA was the head of the organization that created the Uniform Standards.

President Law stated that the current process consists of an inspector completing a report and forwarding the file to a supervising inspector with a recommendation for cite and fine or referral to the AG's Office. President Law stated that previous discussions have recommended that the board should have a process to screen cases before they are issued a cite and fine or referral to the Attorney General's Office. President Law stated that only cases of the most serious nature should be referred to the AG's office.

Ms. Strom and Jenny Partridge expressed support of a more thorough review process.

The committee paused for lunch break at 1:05p.m. The committee returned and called the meeting back to order at 1:38p.m.

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

Chairperson Schaad introduced Danny Martinez, Government Relations and External Affairs for the California Pharmacists Association (CPhA). Mr. Martinez introduced Veronica Bandy, CPhA President.

Mr. Martinez presented "Proposal for a Pharmacy Advisory Committee". Mr. Martinez's presentation included a review of the Board of Pharmacy's Enforcement Process, CPhA's proposed changes to the Enforcement Process, and the proposal of a Pharmacy Advisory Committee.

As part of the presentation, Mr. Martinez's proposed that prior to initiation of the formal disciplinary process (referral to the AG's office), the board should permit licensees to go before a consortium of their practicing peers in order to help the board prioritize serious issues from less significant issues. Mr. Greg Lippe informed the presenter that the charge of the board is the protection of consumers and to recommend a consortium of only pharmacists is in opposition to the whole idea behind the board.

Mr. Martinez shared a proposed flowchart of the intake, investigation and outcomes process. Ms. Sodergren and SDAG Room expressed concern that the flowchart provided did not match the process suggested in the proposal. Mr. Martinez stated that the flowchart would need to be corrected in order to match his proposal and he informed the committee that his proposal is open to changes and suggestions.

Mr. Martinez stated that the Medical Board of California (Medical Board) has a process similar to the CPhA proposal, where a practicing licensee conducts a review of the investigation and provides a recommendation on whether they should proceed. If the evidence is not clear, it is sent to a second expert reviewer. SDAG Room provided clarification to the presenter that the Medical Board uses internal staff experts, as well as external experts; internal experts are employees of the Medical Board. Additionally, SDAG Room stated some agencies like the Dental Board, Medical Board and Veterinary Board employ in-house consultants to determine standards of care issues because they do not have subject matter experts on staff like the Board of Pharmacy. SDAG Room further stated that in-house consultants' sole mission is to determine whether there is enough of a possibility of a deviation from the standard of care that it should be sent out for an expert review; they are not making recommendations on whether a board or staff should pursue a case. Mr. Martinez stated that the information he was providing today was confirmed on the Medical Board website.

Mr. Martinez stated that the proposal is a hybrid of the Medical Board process as well as the process used by the Maryland Pharmacy Board.

Mr. Martinez stated to the committee that CPhA would like to recommend that board staff work with CPhA to modify this process to something to which the committee is comfortable.

President Law inquired, regarding the Maryland Pharmacy Board, where their review committee sits in the CPhA proposed model. Mr. Martinez stated that the committee, mandated by statute, sits at the beginning when the accusation is filed.

As part of the committee discussion, members expressed various areas of concern. Firstly, the charge of the board is the protection of consumers; to recommend a consortium of only pharmacists is in opposition to that concept. In addition, the membership criteria for CPhA's proposed advisory committee would exclude retired licensees who are still active members in the pharmacy profession. Mr. Weisser expressed his disappointment in the model proposed by CPhA.

SDAG Room presented a few possible legal objections to the CPhA proposal:

1) Committee members would have access to confidential information generally only shared with board staff who are subject to criminal and civil penalties for the potential release or abuse of private information.
2) The proposal could be considered a violation of statute or an unconstitutional delegation of this body's authority to another body. Creating the committee would require a statutory amendment.
3) By what process is a board of thirteen members going to appoint a subcommittee of five members?
4) The board has been previously briefed on anti-trust possibilities of treading to close to the line of having licensees exclusively policing other licensees under the North Carolina Dental Board case. If the board, which has been consciously constituted of professional and public members, were to delegate some portion of its authority to a subcommittee made up exclusively of members of the profession, who might have competitive interests involved in any case, the risks of liability, under the North Carolina case, would increase significantly. Other possible requirements like insisting on the president or executive officers be pharmacists, would put the members of the board in greater jeopardy for a trust violation.

SDAG Room stated he disagreed with Mr. Martinez's implication that the investigations performed by inspectors were somehow inferior due to an assumption incompetence, bias or inability to act as a jury of peers for their peers. SDAG Room stated most inspectors are dragged reluctantly to the conclusion that a member of their profession has failed the standards. Mr. Martinez stated that the proposal was not indicative of any feeling of biased or lack of confidence in the inspectors. He stated the intent of the proposal was to allow for discussion.

President Law stated that the proposal presented by CPhA was a concept that could be further developed. President Law explained that as the pharmacy profession progresses, there are different areas of specialization such as long-term care and Advanced Practice

Pharmacists (APH). Many cases come to an inspector's attention, he stated that the board cannot possibly have inspectors who are experts in all fields. President Law provided an example of an inspector who may have expert-level experience at a hospital pharmacy but may not have experience in a retail pharmacy. President Law stated there might be a place for the use of peer expertise in these particular areas to advise the board in decision making. President Law stated that he hopes to see in the future that as more difficult case come before the board, a way that the board can use different areas of expertise for Long-Term Care or APH. For example, if there is something wrong with an APH he hoped that there would be an APH expert to determine exactly if a practice is safe or just a simple mistake that may have just due to a lack of education. He stated looking forward it may not be a bad idea to explore this concept and expedite the process. President Law clarified that the proposal is a screening process and the final vote would still come to this board for consideration.

Ms. Freedman informed the committee that as an option the board has the authority pursuant to the BPC to hire subject-matter experts to assist and when they encounter a situation where the staff does not have the necessary expertise.

Mr. Weisser voiced his confidence in the level of diversity among the and backgrounds of inspectors as well as with the diversity of their training received at the board.

Dr. Wong stated that based on the possible breach of confidentiality, he proposed a committee of inspectors to review and approve recommendations, as opposed to a committee of persons outside of the board.

A member of the public stated that the proposed process would allow a licensee an opportunity to explain their side of the story to committee members before being sanctioned. Additionally, he informed the committee that the states of Iowa, Texas and Florida all allow licensees the opportunity to be heard. Another member of the public emphasized the specific need to seek pharmacists who are experts in the area of collaborative drug therapy pharmacy, to consult and guide the process; he suggested there are more areas in which investigators and board members need guidance, due to lack of in-house experience.

Ms. Sodergren stated that this year, the board has referred about 150 cases to the AG's office.

DCA Counsel Kelsey Pruden, provided the committee members with an overview of the review process for the State of Texas. SDAG Room stated that other than the inclusion of a board member, the Texas process is the same as California. SDAG Room explained that every administrative case offers the licensee the opportunity to seek settlement by communication with the AG's office to arrange a settlement conference with Office of Administrative Hearings.

President Law asked if the board could pay for per diem experts. SDAG Room confirmed that the board could hire experts and has already done so in the past

The committee heard comment from Lauren Walmsey of Walgreens who serves on the Arizona Pharmacy Board. She informed the board that in Arizona all disciplinary matters start at a sub-committee level discussion, made up of a public member, a pharmacy technician and two practicing pharmacists who are all board members appointed by the Governor. The committee makes a recommendation on the discipline and the full board decides how to move forward. An investigator conducts an investigation, an investigation summary is written, the summary is reviewed by the committee, and then a recommendation is made by the committee. The committee may recommend dismissing the case, formal discipline, or suggest continuing education. SDAG Room clarified that in AZ there is no requirement for a pleading to be filed prior to discipline. Ms. Walmsey responded that each state has a variety of ways to handle disciplinary cases, pursuant to each state's statutes.

As part of the public discussion, a community pharmacist, stated that if a licensee was afforded the right to present testimony prior to disciplinary action, it would allow for a learning opportunity to identify barriers and discuss what tools or assistance are available to correct the violation as well as open lines of communication between the board and licensees. Another member of the public called attention to the inconsistency of disciplinary actions for similar violations; she supported the idea of using expert consultants before determining formal disciplinary action.

President Law acknowledged that board members are not always provided the opportunity to hear the licensees side of the case. He stated the committee is trying to determine a process which helps the profession and protects the consumer.

Mr. Weisser stated that when presented with the opportunity to vote on a case he reviews all materials provided and he is given the option to agree, disagree and/or comment. Mr. Lippe stated that the board policy is that if two members object then the case is brought back to the board.

Ms. Freedman confirmed with committee members that the committee requests a future discussion on how the enforcement program is structured.

The committee directed board staff to work with the chair of the committee to explore alternative solutions.

DCA Counsel suggested that the committee request a future discussion on how the enforcement program is structured. President Law agreed and directed board staff to research other state enforcement models and continue the discussion on disciplinary matters

15. **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)**

Ms. Sodergren informed the committee that the study will end in June 2019 and the board should expect to receive a final report in Fall 2019.

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

Chairperson Schaad informed the committee that CCR section 1715 establishes the requirements for completion of the pharmacy and hospital pharmacist self-assessment forms. CCR section 1784 establishes a similar requirement for completion of a wholesaler self-assessment. In all cases, the self-assessment is a compilation of relevant laws that are intended to allow for the entity to self-evaluate compliance with various provisions of law. Because the various forms are incorporated by reference in the respective regulation sections, a regulation change is necessary whenever the forms require update. The proposed revisions incorporate recent changes to pharmacy law.

Motion: Recommend to the board approval of the draft self -assessment forms.

M/S: Weisser/Sanchez

Support: 6 Oppose: 0 Abstain: 0

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

Chairperson Schaad stated that as part of the committee's discussion on the development of its inventory reconciliation requirements, the requirement to report drug losses was discussed. He explained an owner is required to report any loss of a controlled substance, including the amount and strength. This report must be made to the board within 30 days.

Previous discussions noted the difference between California Law and DEA reporting requirements. Included in the chair report was data for both types of loss reports for several fiscal years and the first six months of FY 2018/19. Also included was a breakdown of the number of reports received based upon the loss in dosage units. Ninety-one percent of loss reports indicated a loss of less than 100 dosage units.

President Law acknowledged that the number of drug losses has reduced significantly but noted concern over the 17 cases identified with over losses over 10,000.

As part of public comment, Dr. Gray stated he has been asked about the new regulation regarding inventory and reconciliation every quarter and for every controlled substance. He stated the implication is that on all the other controlled substances, Schedules III, IV and V, there also must be a reconciliation. If they have to report every missing tablet, it means each time they do a reconciliation on that many products, they would have something missing. If there is no ability to say if a loss is significant then pharmacies would rather wait once every two years to inventory Schedules III, IV and V. He requested that the committee revisit the process of reporting drug losses to do what DEA does and establish criteria for reporting a loss, which varies depending on the schedule of the controlled substance. Paige Talley of CCAP, encouraged the committee to determine a definition of "significant loss" in numbers.

Ms. Freedman advised the committee that the board would have to describe what significant means to the board and create standards.

Ms. Sodergren suggested, and the board agreed, that staff would survey a couple other states for their drug loss reporting requirements and research the types of drugs that are in that 1 to 100 dosage units threshold.

Dr. Wong asked if a drug loss could be submitted electronically. Ms. Sodergren stated that the board is working on an interface to submit losses electronically.

Mr. Weisser left the meeting at 3:24 p.m.

18. **Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board's Ask An Inspector Program**

This item was moved to the next committee meeting.

19. **Discussion and Consideration of Board's Enforcement Statistics**

Chairperson Schaad informed the committee that they have been provided a copy of the enforcement statistics reflecting data from July 1, 2018, through February 28, 2019.

The committee agreed to review the data, and if they have any questions, they would be addressed at the next committee meeting.

20. **Future Meeting Dates**

Chairperson Schaad stated that the next meetings are scheduled for July 2, 2019 and September 25, 2019.

The meeting adjourned at 3:31 p.m.