



**ENFORCEMENT AND COMPOUNDING
COMMITTEE REPORT
June 7, 2018**

Allen Schaad, Licensee Member, Chair
Amy Gutierrez, PharmD, Licensee Member, Vice Chair
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Valerie Muñoz, Public Member

- 1. Call to Order, Establishment of Quorum, and General Announcements**
- 2. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings**

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

- 3. Discussion and Consideration of Possible Board Policy Relating to Transparency Involving the Issuance of Citations and Fines**

Attachment 1

Background

During the April 2018 Enforcement Committee meeting, the committee requested that board staff survey all DCA healing arts boards to determine how each of the boards handles general transparency related to the issuance of citations and fines.

Committee Discussion and Consideration

All DCA healing arts boards were surveyed to determine whether each board posted citations and fines issued to licensees on their websites.

The survey showed that fifteen of the eighteen DCA healing art boards post citations and fines on their website; however, the duration of the postings varies. It should be noted that most boards surveyed are actively using the BreEZe System, which may be programmed to upload citations and fines to their respective sites.

The chart below identifies the boards surveyed, whether the board posts citations and fines, the length of time citations and fines are posted, and whether or not the board participates in the BreEZe System.

Board	Citations & Fines are posted on website?	How long is the Citation & Fine posted?	BreZE System Participant?
Medical Board	Yes	3 years	Yes
Vocational Nursing & Psychiatric Technicians	Yes	Eternal	Yes
Behavioral Sciences	Yes	\$1500 or more = Eternal Less than \$1500 = 5 years	Yes
Dental Hygiene	Yes	Eternal	Yes
Naturopathic	No		Yes
Occupational Health	Yes	5 Years	Yes
Optometry	Yes	5 Years	Yes
Osteopathic Medical	Yes	3 Years	Yes
Physical Therapy	Yes	3 Years	Yes
Physician Assistant	Yes	Eternal	Yes
Podiatric Medicine	Yes	3 Years	Yes
Psychology	Yes	5 years	Yes
Registered Nursing	No		Yes
Respiratory Care	Yes	5 Years	Yes
Veterinary	Yes	5 Years	Yes
Acupuncture	No		No
Chiropractic	Yes	5 Years	No
Dental Hygiene	Yes	Eternal	Yes

Attachment 1 includes samples of citations and fines as provided on board other DCA websites.

4. Discussion and Consideration of Laws and Regulations Related to Petitions for Reduction of Penalty (Reinstatement, etc.) of Disciplined Licenses

Attachment 2

Relevant Law

Business and Professions Code section 4309 establishes the conditions under which an individual may petition the board for reinstatement of license that has been revoked or suspended. It also establishes the conditions under which a licensee may petition the board for a modification to a penalty, including modifications to probationary terms or early termination of probation. This section further specifies the time frames that must be satisfied before a petition can be considered including:

- (1) At least three years for reinstatement of a revoked license.
- (2) At least two years for early termination of probation of three years or more.
- (3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

This section also provides that a petition cannot be considered while the individual is under sentence for a criminal offense, including any period in which the individual is on court-imposed

probation or parole. In addition, a petition cannot be considered if there are additional accusations or a petition to revoke probation pending with the board.

Background Information

In recent years the board has considered such petitions at specially convened board meetings where the primary focus of the agenda is consideration of such petitions. Although the law allows for different adjudication processes, the board's policy in this area is to convene these petition matters as part of a board meeting whenever possible and to have the hearing presided over by an administrative law judge (ALJ). Following the hearings, board members meet in closed session with the ALJ to deliberate on the matters presented during open session hearing. Once the board makes its determination, the ALJ drafts the decision on behalf of the board.

In the event a quorum of the board cannot be achieved, the board's policy allows for petitions to be heard by a committee of the board. In such cases, the ALJ will draft a proposed decision for each petition and the decision will then be considered by all members as part of the mail vote process.

Under the law, a third option also exists where petitions are considered by an ALJ independent of the board. In such cases the ALJ renders a proposed decision, which is then considered by all members as part of the mail vote process. (This process is similar to administrative cases.)

In all three scenarios the respondent provides a packet of information and supporting materials intended to provide the board with information in advance of the hearing. Such information includes:

- Personal Information and license history information.
- Letters of recommendation from board licensees.
- Letters of recommendation from citizens.
- Continuing education.

The respondent is also afforded the opportunity to provide oral testimony under oath. In addition to the respondent's testimony, a representative of the Attorney General's Office is present and represents the people of California. The AG's Office is allowed to question the respondent as well as any witnesses. Although not done in all cases, the AG's Office may offer a recommendation to board on the outcome of the petition. Technically the board does not have representation in these petitions, and typically board staff does not offer testimony.

Since July 1, 2015, the board has considered 41 petitions including 26 petitions for early termination, two petitions for modification of penalty and 13 license reinstatements. Decisions are not final for all of the petitions heard, but of those where decisions have been rendered, 13 petitions have been approved and 17 petitions have been denied.

More specific details about these statistics as well as samples of the petitioner applications are included in **Attachment 2**.

For Committee Discussion

As provided in law, the board may consider factors including, but not limited to, the following:

1. All the activities of the petitioner since the disciplinary action was taken.
2. The offense for which the petitioner was disciplined.
3. The petitioner's activities during the time the license was in good standing.
4. The petitioner's documented rehabilitative efforts.
5. The petitioner's general reputation for truth and professional ability.

To assist in the collection of the relevant information and to provide guidance to potential petitioners, the board has developed petition packets that detail both required and supplemental materials sought from the petitioners and some FAQs about the process.

The criteria established in the law is very general. Staff is hopeful that the committee will provide policy guidance recommendations that ultimately can be considered by the full board when considering petitions. Such policy discussion will assist staff in ensuring the petition information collected is meaningful.

Some questions the committee may wish to consider include:

1. Is the current process for hearing petitions sufficient, or should the board consider reevaluating its policy?
2. Would it be helpful to have board staff testify regarding compliance with terms and conditions of probation, rehabilitative efforts demonstrated by the respondent, public protection concerns, etc?
3. Would it be helpful to request additional information in advance of the hearing from the petitioner to aid the board in making its decision?
4. Does the board wish to establish additional parameters a petitioner must satisfy prior to being eligible to petition the board?
5. Should a time frame be established that provides clarity on how long a petitioner has to satisfy the requirements set by the board for reinstatement (i.e., pass the NAPLEX, pass the CPJE, pay fines, etc.)?

Attachment 2 includes a copy of the BPC section and the sample petitioner packet.

5. **Discussion and Consideration of of Potential Statutory or Regulatory Amendments to Allow a Reverse Distributor to Accept Medications for Destruction in Limited Circumstances from a Previously Licensed Source**

Relevant Law

BPC section 4040.5 provides the definition of a reverse distributor as an entity that among other functions manages the disposition of outdated or nonsalable dangerous drugs or devices. (Note: A reverse distributor is licensed as a wholesaler and must comply with wholesaler requirements unless a specific exemption is provided in the law.)

BPC section 4163 specifies that a wholesaler can only acquire dangerous drugs and devices from a *licensed* source.

For Committee Discussion

Under current law, a reverse distributor is prohibited from acquiring dangerous drugs and devices from an entity unless the entity is licensed. This occasionally creates a barrier to the removal and destruction of such products when a pharmacy, wholesaler or other license is cancelled, surrendered or revoked.

Board staff is requesting that the committee consider pursuing a change in the law that would create a limited exception to allow for a reverse distributor to remove and arrange for the destruction of the drug products for a limited period of time after a license is cancelled, surrendered or terminated. Should the committee and board agree, staff will work with counsel to develop language.

6. Discussion and Consideration of Current Board Investigation Time Frames and Performance Measures

Attachment 3

Background

One of the committee's strategic goals is to implement processes to shorten the cycle times from the initial investigation to the resolution of cases. Below are benchmarks that are currently measured by board staff.

1. Assignment – Measures the time 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 reviewed 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.

In addition to the measures tracked by board staff, the department established enforcement performance measures as part of the *Consumer Protection Enforcement Initiative*. This data is typically reported on a quarterly basis for all programs within the DCA. The most recent report available is for the April – June 2017 reporting period; however, it is board staff's understanding that more recent data should be published in the coming months.

For Committee Discussion

Provided below are the average time frames for the benchmarks identified above for FY 2015/16 and FY 2016/17. The annual data for FY 2017/18 will be provided after the end of the fiscal year.

Pending Field Investigations as of 6/1/18			
Pending Case Status	# of Cases	Avg. Days at this Status	Avg. Case Age
Team Review for Assignment	131	31	50
Under Investigation	1,009	172	216
Report Review	190	42	298
2nd Level Report Review	10	14	482
Enforcement for Discipline	324	22	434
Grand Total	1,664	116	256

Pending Desk Investigations as of 6/1/18 (Includes CCU, Complaint, and Enforcement Units)			
Pending Case Status	# of Cases	Avg Days at this Status	Avg Case Age
Under Investigation	344	77	132
Report Review	18	100	256
2nd Level Report Review	7	24	162
Enforcement for Discipline	10	102	292
Grand Total	379	78	143

Also, **Attachment 3** includes DCA’s Enforcement Performance Measures 4th Quarter Report FY 2016/17 which includes information on case volume and cycle times. Note: The department’s benchmark for assignment is referred to as “Intake.” Further, the DCA time frames aggregate investigation, review time and closure time into a single measurement referred to as “Investigation.”

As the report indicates, the board’s target average for “Intake” is 20 days, and the actual average for the reporting period was 17 days. Further, the board’s target average for “Investigation” is 210 days, and the actual average for the reporting period was 320 days.

As part of its discussion the committee may wish to provide staff with guidance on what information regarding investigation time frames would be helpful to receive at future meetings.

7. Discussion and Presentation of the Administrative Case Process and Case Resolution Times for Matters Referred to the Office of the Attorney General

Attachment 4

Background

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

Pursuant to legislation in 2015, the Office of the Attorney General is now required to annually publish data on disciplinary matters including both case volume and average days for various benchmarks. The first report was published in January 2018.

For Committee Discussion

During the meeting, the committee will receive a brief presentation by Supervising Deputy Attorney General (SDAG) Joshua Room on the disciplinary process. As part of the presentation SDAG Room will also provide insight into some of the challenges that may impede more swift resolution of disciplinary matters and will provide a brief overview of the data provided in the report.

As part of its discussion the committee may wish to provide staff with guidance on what information regarding disciplinary time frames would be helpful to receive at future meetings.

Attachment 4 includes the executive summary and board specific data as published in the AG Office's Report as well as the volume and cycle time as reported by the DCA for 4th Quarter Report FY 2016/17.

8. Discussion and Consideration of Implementation Strategy for Anticipated Statutory Changes to Incorporate USP Compounding Chapters

Attachment 5

Background

During its May 2018 board meeting, members voted to pursue a statutory proposal to incorporate USP Compounding Chapters into the board's requirements for compounding drug preparations. As part of its discussion, the board noted that two of the compounding chapters, <795> and <797>, are in the revision process by USP and USP <800> has been finalized but is not yet in effect.

Chapter 795

The proposed revisions for USP <795> were released in March 2018 and an open microphone session was held on April 20, 2018. In addition, on May 1, 2018, Chapter 795 was formally published in *Pharmacopeial Forum* for review and public comment. The public comment period will close on July 31, 2018, and USP indicates that its intended publication date is June 1, 2019 with an anticipated official implementation date of December 1, 2019.

Chapter 797

The proposed revisions to USP <797> will be pre-posted by USP on July 27, 2018 and will be formally published on September 4, 2018. An open microphone session will be held on September 5, 2018 and the public comment period will closed on November 20, 2018. The intended publication date for this chapter is June 1, 2019 with an anticipated official implementation date of December 1, 2019.

Chapter 800

This chapter is in its final form, with an expected official implementation date of December 1, 2019 (to coincide with the anticipate official dates for Chapters 795 and 797).

For Committee Discussion

As the revisions for the respective chapters are finalized, it is anticipated that staff will complete a comprehensive review of the new requirements and provide recommendations to the board about necessary changes to the board's regulations. Further, the board's current regulation requirements related to hazardous drug compounding will also need to be reassessed to determine what if any action is necessary.

The committee may wish to provide further guidance to staff about the proposed implementation as well as direct staff to identify implementation challenges that could have a negative impact on consumers' access to compounded medications. As an example, the board's current regulations allow for a delay in implementation of some requirements that require physical construction to a facility to fully comply. More specifically, upon enactment of the statutory change discussed above, the statute requiring USP <800> (effective December 1, 2019) would supercede the board's current waiver process established in regulation. As staff is aware of some delays in the delivery of equipment used in compounding and possible shortages of experts (architects, engineers, etc.), implementation strategies may be necessary to mitigate further delays and/or possible access issues to compounded preparations.

Attachment 5 includes an excerpt from the draft May board meeting minutes detailing the board's discussion of the statutory proposal.

9. Discussion and Consideration of Enforcement Committee Strategic Goals for Fiscal Year 2018/19 and Thereafter

Attachment 6

In 2016 the board finalized its current strategic plan. It is recommended that the committee discuss its strategic goals for the coming fiscal year as well as the remainder of the plan.

Provided below are the goals currently included in the board's strategic plan along with a brief status.

2.1 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.

Status: During this meeting the committee will begin its discussion on investigation times.

2.2 Strengthen patient consultation outcomes for Californians and increase medication safety.

Status: The board is seeking to strengthen patient consultation requirements for mail order pharmacies. In addition, the board has received general information about board investigations involving patient consultation violations and efforts taken by district attorneys reaching settlements as a way to gain better compliance.

2.3 Collect data and report to board members about enforcement trends that are presented at case closures so the board can better educate licensees about board priorities.

Status: Multi-year enforcement statistics are provided on an annual basis during the July board meeting. Also, in addition to posting disciplinary information on line, the board's newsletter includes summaries of the violations leading to disciplinary action. In addition, during this meeting the committee will consider posting citations.

2.4 Evaluate industry technology trends to develop future regulatory infrastructures that promote patient safety.

Status: The board convened a technology summit on the use of automated drug delivery systems, evaluated the findings of a pilot project to expanding the use of ADDS and is currently sponsoring legislation to establish a regulatory framework for ADDS, as well as expand the conditions when such a device can be used.

2.5 Evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.

Status: During this meeting the committee will hear a presentation on the disciplinary process as well as performance statistics provided by the Office of the Attorney General.

2.6 Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery.

Status: No work has been done on this strategic goal.

2.7 Investigate options on the interoperability with a National Prescription Drug Monitoring Program.

Status: The board is the originator of legislation that will enable the CURES system to include interoperability with other PDMPs.

Attachment 6 includes the relevant portion of the board's strategic plan.

10. Discussion and Consideration of the Board's Enforcement Statistics

Attachment 7 includes the enforcement statistics for the first 10 months of the fiscal year. In addition to reviewing the statistics, the committee may wish to provide staff with feedback on the current format and data elements provided as well as suggested changes.

11. Future Committee Meeting Dates

Enforcement Committee dates for 2018:

- September 8, 2018
- December 13, 2018

A summary of the April 3, 2018, committee meeting will be provided at the meeting.

Attachment 1



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BOARD OF CHIROPRACTIC EXAMINERS

Licensee Name:	EGAN MONICA BROOKE
License Type:	Chiropractor
License Number:	31715
License Status:	VALID Definition
Expiration Date:	October 31, 2018
Issue Date:	June 29, 2010
Address:	250 BEL MARIN KEYS BLVD STE D-1
City:	NOVATO
State:	CA
Zip:	94949
County:	MARIN
Actions:	Yes

Related Licenses/Registrations/Permits

No records returned

Disciplinary Actions

No information available from this agency

Public Record Action(s)

CITATIONS

May 16, 2018:	Citation Paid In Full
CCR	303. FAILURE TO FILE CUR ADDRESS
CCR	308. FAIL TO DISPLAY LICENSE
CCR	312. UNLICEN INDIV-ILLEGAL PRACTICE
May 17, 2018:	Compliance obtained from licensee, citation closed
CCR	303. FAILURE TO FILE CUR ADDRESS
CCR	308. FAIL TO DISPLAY LICENSE
CCR	312. UNLICEN INDIV-ILLEGAL PRACTICE
May 30, 2018:	Citation Issued
CCR	303. FAILURE TO FILE CUR ADDRESS
CCR	308. FAIL TO DISPLAY LICENSE
CCR	312. UNLICEN INDIV-ILLEGAL PRACTICE

Disclaimer for Disciplinary Action Summary

The reports contained as part of this web site represent summaries of those formal disciplinary orders issued by the Department of Consumer Affairs (DCA) and its participating programs, boards, committees, and commissions, imposing suspension, revocation or other discipline. Disciplinary proceedings which are resolved by dismissal of the accusation or otherwise result in no actual discipline of a license are not reported at this web site. The lack of a summary for a particular licensed person does not mean that the licensee has never been the subject of an accusation or administrative discipline.

Summary information on recent orders is prepared approximately ninety (90) days after the final decision date of a disciplinary case. Therefore, although this web site may presently lack any such report, some licensees will actually be named in accusations, or be subject to disciplinary orders.

The brief summaries offered at this web site are not intended as substitutes for the actual decisions and orders issued by the Department of Consumer Affairs. Copies of those decisions and orders are available at no cost by writing to the designated address for each program or board.

Also, the actions reported here may not be final and may not reflect any judicial action to stay or modify the administrative order. You should not take any action based on information contained in these summaries without verifying the information and determining whether the administrative order has been stayed or modified by a court.

As used in this summary, the term "accusation" is a formal document that notifies a licensee of the agency's charges against the licensee, and that requests a disciplinary order. The licensee is entitled to contest the charges in a formal hearing before an administrative law judge. An accusation is usually resolved by an agency decision following such a hearing or by an agency decision pursuant to a

settlement agreement. Often there is a considerable period of time between the date of filing an accusation and the resolution of the accusation.

The term "suspended" means that the licensee's right to practice has been suspended for a period of time, usually for a specified number of days or months. A suspended licensee may not practice during the period of suspension. A suspension will usually be imposed in conjunction with a lengthy period of probation of two or more years.

The term "revoked" means that the licensee's right to practice has been completely taken away. Revocation is not necessarily permanent, however. A person whose license is revoked has the right, one year or more after the revocation, to apply for reinstatement. Some applications are successful. The applicant for reinstatement must, however, demonstrate to the BOARD OF CHIROPRACTIC EXAMINERS that the applicant is rehabilitated and is fit to resume practice.

For more information regarding these actions, please write to the BOARD OF CHIROPRACTIC EXAMINERS at the following address:

901 P Street, Suite 142A
Sacramento, CA 95814
Attn: Enforcement Unit

This information is updated Monday through Friday - Last updated: MAY-30-2018

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Attachment 2

Business and Professions Code section 4309

(a) A person whose license has been revoked or suspended or who has been placed on probation may petition the board for reinstatement or modification of penalty, including modification or termination of probation, after not less than the following minimum periods have elapsed from the effective date of the decision ordering disciplinary action:

(1) At least three years for reinstatement of a revoked license.

(2) At least two years for early termination of probation of three years or more.

(3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

(b) The petition shall state any facts required by the board, and the petition shall be accompanied by two or more verified recommendations from holders of licenses issued by the board to which the petition is addressed, and two or more recommendations from citizens, each having personal knowledge of the disciplinary penalty imposed by the board and the activities of the petitioner since the disciplinary penalty was imposed.

(c) The petition may be heard by the board sitting with an administrative law judge, or a committee of the board sitting with an administrative law judge, or the board may assign the petition to an administrative law judge. Where the petition is heard by a committee of the board sitting with an administrative law judge or by an administrative law judge sitting alone, the decision shall be subject to review by the board pursuant to Section 11517 of the Government Code.

(d) In considering reinstatement or modification of penalty, the board, committee of the board, or the administrative law judge hearing the petition may consider factors including, but not limited to, all of the following:

(1) All the activities of the petitioner since the disciplinary action was taken.

(2) The offense for which the petitioner was disciplined.

(3) The petitioner's activities during the time the license was in good standing.

(4) The petitioner's documented rehabilitative efforts.

(5) The petitioner's general reputation for truth and professional ability.

(e) The hearing may be continued from time to time as the board, committee of the board, or the administrative law judge designated in [Section 11371 of the Government Code](#) finds necessary.

(f) The board, committee of the board, or administrative law judge may impose necessary terms and conditions on the licensee in reinstating the license.

(g) No petition under this section shall be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole. No petition shall be considered while there is an accusation or petition to revoke probation pending against the person. The board may deny without a hearing or argument any petition filed pursuant to this section within a period of two years from the effective date of the prior decision following a hearing under this section.

(h) Nothing in this section shall be deemed to amend or otherwise change the effect or application of [Sections 822](#) and [823](#) .

(i) The board may investigate any and all matters pertaining to the petition and documents submitted with or in connection with the application.

PETITIONS HEARD				
FY	Petition Type	Early Termination	Modification of Penalty	Reinstatement
15/16	Pharmacist	4		2
	Pharmacy Technician	3		2
	Intern Pharmacist			
	Pharmacy	1		
	Total	8	0	4
16/17	Pharmacist	1	2	1
	Pharmacy Technician	1		2
	Intern Pharmacist	1		
	Pharmacy	1		
	Total	4	2	3
17/18	Pharmacist	13		6
	Pharmacy Technician			
	Intern Pharmacist			
	Pharmacy	1		
	Total	14	0	6

PETITION OUTCOMES							
FY	Petition Type	Early Termination		Modification of Penalty Granted		Reinstatement Granted	
		Granted	Denied	Granted	Denied	Granted	Denied
15/16	Pharmacist	2	2	1	1		2
	Pharmacy Technician	1	2			1	1
	Intern Pharmacist						
	Pharmacy		1				
	Total	3	5	1	1	1	3
16/17	Pharmacist	1		1	1		1
	Pharmacy Technician	1				1	1
	Intern Pharmacist	1					
	Pharmacy		1				
	Total	3	1	1	1	1	2
17/18*	Pharmacist	2	1			1	3
	Pharmacy Technician						
	Intern Pharmacist						
	Pharmacy						
	Total	2	1			1	3

*For FY 17/18 includes all petitions heard through December 12, 2017.



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

PETITION FOR EARLY TERMINATION OF PROBATION

Section 4309 of the Business and Professions Code states that a licensee may petition the Board of Pharmacy for early termination of probation of his or her license if they meet the following requirements:

1. Two years of a three year or more probationary period has elapsed from the effective date of the decision ordering disciplinary action or one year has elapsed for termination of probation of less than three years; or
2. Two years has elapsed since a petition was previously filed pursuant to section 4309 of the Business and Professions Code and the petitioner was afforded a hearing; or
3. A petitioner is not currently under sentence or on court-imposed probation or parole for any criminal offense. **IF YOU ARE NO LONGER ON CRIMINAL PROBATION, YOU MUST SUBMIT PROOF OF TERMINATION OF PROBATION;** and
4. There is currently no accusation or petition to revoke probation pending against the petitioner with the board.

If you meet the above requirements, you may petition the board for the early termination of your probation by completing and submitting the attached petition form. When completing your petition, please refer to the attached "Guidelines for Petitions for Reinstatement, Reduction of Penalty, and Early Termination of Probation." These guidelines outline the rehabilitation criteria the board has determined a petitioner should meet when petitioning for license reinstatement, reduction of disciplinary penalty, or early termination of probation. In addition, early termination of probation may not be considered unless the petitioner has been in compliance at all times with the terms and conditions of his or her probation.

The petition form **must** be accompanied by two or more verifiable letters of recommendations addressed to the board from holders of licenses issued by the Board of Pharmacy, and by two or more letters of recommendations from citizens. The letters must be within the last year from the date you are submitting your petition. Each author must indicate in their letter that they have personal knowledge of the disciplinary penalty imposed by the board and your activities since the disciplinary penalty was imposed. The board suggests that letters of recommendation include facts that demonstrate an author's personal knowledge of the subject's penalty and the petitioner's activities. Examples of activities may include employment, community service, volunteer work, etc. A board representative may contact you or anyone who has submitted a letter on your behalf.

Also, required is documentation of **30 hours of Board approved continuing education** (acquired within the last two years from the date of your application is received by the board). Photocopies of the certificates of completion should be sent and the original certificates retained for your records.

Submit the petition with the required documents to the address above, to the attention of the enforcement unit. The petition will be processed and evaluated for scheduling at the next available board meeting. Please be advised that you should allow 90 days for the processing of your petition, and the petition set for hearing. Below is a schedule of board meeting dates with the cut-off date for submission of a petition.

You will be notified in writing of the hearing date. At the hearing, you will be afforded the opportunity to present both oral and written evidence of your rehabilitation; and you may, but need not be, represented by counsel. In deciding the case, the board will take into consideration the petition, all recommendations, and any oral or written evidence. The board will be represented by the Attorney General's Office and an administrative law judge will preside over the hearing.

BOARD MEETING DATES	CUT-OFF DATES	LOCATION
February 6-7, 2018	December 6, 2017	Sacramento
March 27, 2018	January 27, 2018	TBD
May 2-3, 2018	March 2, 2018	TBD
June 6, 2018	April 6, 2018	TBD
July 24-25, 2018	May 24, 2018	TBD
September 6, 2018	July 6, 2018	TBD
October 23-24, 2018	August 23, 2018	TBD
December 12, 2018	October 12, 2018	TBD

17R10 (Rev. 1/2018)



GUIDELINES FOR PETITIONS FOR REINSTATEMENT, REDUCTION OF PENALTY OR EARLY TERMINATION OF PROBATION

In petitioning for reinstatement and early termination of probation under Business and Professions Code section 4309 or reduction of penalty under Government Code section 11522, the petitioner has the burden of demonstrating any rehabilitative or corrective measures he or she has taken since the revocation action and, that he or she has the necessary and current qualifications and skills to safely engage in the practice of pharmacy within the scope of current law, and accepted standards of practice. In reaching its determination the board considers various factors including the following:

- (a) The original violation(s) for which action was taken against the petitioner's license including:
 - 1. The type, severity, number, and length of violations.
 - 2. Whether the violation involved intentional, negligent or other unprofessional conduct.
 - 3. Actual or potential harm to the public, patients, or others.
 - 4. The length of time since the violation(s) was committed.

- (b) Prior disciplinary and criminal actions also taken against the petitioner by the board, and state, local or federal agency or court including:
 - 1. The petitioner's compliance with all terms of probation, parole, previous discipline or other lawfully imposed sanctions including any order of restitution.
 - 2. Whether the petitioner is currently on or has been terminated from probation or other lawfully imposed sanction.
 - 3. The petitioner's legal and regulatory history to and since the violation(s).

- (c) The petitioner's attitude toward his or her commission of the original violation(s) and his or her attitude in regard to compliance with legal sanctions and rehabilitative efforts.

- (d) The petitioner's documented rehabilitative efforts including:
1. Efforts to maintain and/or upgrade professional skills and knowledge through continuing education or other methods.
 2. Efforts to establish safeguards to prevent repetition of the original violation(s) including changes or modifications in policies, structure, systems, or methods of behavior applicable to the petitioner's pharmacy practice.
 3. Service to community or charitable groups.
 4. Voluntary restitution to those affected by the original violation(s).
 5. Use of appropriate professional medical or psychotherapeutic treatment.
 6. Participation in appropriate self-help and/or rehabilitation groups.
 7. Use of appropriate peer review mechanisms.
 8. Participation in professional pharmacy organizations or associations.
- (e) Assessment of petitioner's rehabilitative and corrective efforts including:
1. Whether the efforts relate to the original violation(s).
 2. The date rehabilitative efforts were initiated.
 3. The length, time, and expense associated with rehabilitative efforts or corrective actions.
 4. The assessment and recommendations of qualified professionals directly involved in the petitioner's rehabilitative efforts or acting at the request of the board, including their description of the petitioner's progress and their prognosis of the petitioner's current ability to practice pharmacy.
 5. The petitioner's reputation for truth, professional ability and good character since the commission of the original violation(s).
 6. The nature and status of ongoing and continuing rehabilitative efforts.

In addition, the board may consider other appropriate and relevant matters not listed in the above guidelines.

Please note that all statements to be introduced at hearing must be made in person or pursuant to Government Code section 11514 (evidence by affidavit). All other statements not made in person or pursuant to Government Code section 11514 must be under oath and will be considered only as administrative hearsay.



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STATE AND CONSUMER SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

PETITION FOR EARLY TERMINATION OF PROBATION

No petition for early release from probation will be entertained until one year after the effective date of the Board's disciplinary action. The decision will be made by the full board in accordance with section 4309 of the Business and Professions Code.

Early release from probation will be provided only in exceptional circumstances, such as when the board determines that the probationary terms imposed have been excessive, considering both the violation of law charged and the supporting evidence, or when there is sustantive evidence that there is no more need for probationary supervision. As a rule, no early termination will be granted unless the probationer has at all times been in compliance with the terms of probation.

Please print or type

1. Name	2. Date of Birth	3. California License Number
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4. Residence Address	Street and Number	City	State	Zip Code
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5. Telephone Number Hm () _____ Wk () _____	6. Are you licensed in any other state? yes <input type="checkbox"/> no <input type="checkbox"/>		
	State	Date of Issuance	Status of License

7. University, College or School of Pharmacy you attended.

Name of School	Dates Attended	Graduation Date	Degree
	From To		

8. List years, location, and type of practice for 5 years prior to the revocation of your California License.

Dates		Location	Type of Practice
From	To		

9. If your license is restored, what type of pharmacy do you intend to practice?

10. Are you or have you ever been addicted to the use of narcotics or hypnotics? Yes No
11. Are you or have you ever been habitually intemperate in the use of alcohol or other drugs? Yes No
12. Have you ever been or are you currently under observation or treatment for mental disorders, alcoholism, narcotic or hypnotic drug addiction? Yes No
13. Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state or a local ordinance? You must include all misdemeanor and felony convictions, regardless of the age of the offense, including those which have been set aside under Penal Code section 1203.4 (which includes diversion programs). Yes No
14. Are you now on probation or parole for any criminal or administrative violations in this state or any other state? (Attach certified copies of all disciplinary or court documents.) Yes No
15. Have you ever had disciplinary action taken against your pharmacist license in this state or any other state? Yes No

If the answer to any questions, 10 through 15, is yes you must attach a statement of explanation giving full details.

ON AN ATTACHED SHEET OF PAPER ANSWER THE FOLLOWING QUESTIONS

16. List the date of revocation of your license and explain fully the cause of the disciplinary action.
17. Explain fully why you feel your license should be restored.
18. Describe fully your activities and occupation since the date of the revocation of your license; include dates, employers, and locations.
19. Describe any rehabilitative or corrective measures you have taken since your license revocation to prepare yourself for reinstatement. List dates, nature of programs, and current status. You may include any community service or volunteer work.
20. List all post-graduate or refresher courses, with dates, location and type of course, you have taken since your license was revoked.
21. List all pharmaceutical literature you have studied during the last year.
22. List all continuing education courses you have completed since your license was revoked. Attach copies of the certificates.
23. List names, addresses, and telephone numbers of persons submitting the letters of recommendation accompanying this petition.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

DATE _____ Signature _____

NOTICE

Pursuant to Business and Professions Code section 4309(b) et seq., all items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the petition being rejected as incomplete. The information will be used to determine qualifications for reinstatement under the California Pharmacy Law. The official responsible for information maintenance is the Executive Officer, telephone (916) 445-5014, 400 R Street, Sacramento, California 95814-6237. The information may be transferred to another governmental agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are



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DEPARTMENT OF CONSUMER AFFAIRS

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INSTRUCTIONS FOR FILING A PETITION

These instructions should be followed when filing a petition with the Board of Pharmacy to reinstate your pharmacist license after it has been revoked or to reduce a Board-imposed penalty.

The burden of proof is on you to establish clear and convincing evidence that you are entitled to have your petition granted under California law. **It is your responsibility**, as the petitioner, to provide the Board with sufficient evidence to establish that it will be safe for consumers if your petition is granted. You must show that you are sufficiently rehabilitated and competent to safely practice pharmacy.

PROCESS FOR FILING A PETITION

Q. How do I file a petition with the Board of Pharmacy?

A. Filing a petition with the Board of Pharmacy is a two-step process:

1. Submit the following items to the Board.
 - The attached petition form completed and signed.
 - Documents to support your current competence and rehabilitation.
2. Appear at the hearing before the Board to present evidence of your rehabilitation and competency.

EVIDENCE

Evidence is the information that you submit to substantiate your request, including documentation and testimony.

Q. How can I support that my evidence is authentic and valid?

A. You should submit original, dated signed evidence if at all possible. Documents should be on official letterhead whenever appropriate, such as letters from employers, health care professionals and other official sources. Any letters or statements should contain the following "Penalty of Perjury" statement at the end: "I declare, under penalty of perjury, under the laws of the State of California, that the foregoing is true and correct." The statement should be signed and dated by the writer.

Q. What kinds of evidence are appropriate to present?

A. The following documents are examples of appropriate evidence, which may be helpful in demonstrating your rehabilitative efforts and competency. Documents should be recent and dated. The list is not intended to be comprehensive, and you are not limited to these examples. You should submit evidence that is relevant to the violation that led to the discipline of your license and your subsequent rehabilitation.

- Written statements from employers and persons in positions of authority who have on-the-job knowledge of your work performance. For probationers and out-of-state licensees who have practiced pharmacy subsequent to their disciplinary action, the statements should report on your current competency. (Include Penalty of Perjury statement.)
- Performance evaluation(s) from your current and recent employers.
- Letters from counselors regarding your participation in rehabilitation or recovery program, where appropriate. These should include a description of the program, frequency of sessions, diagnosis and prognosis in relation to safety to practice, current state of rehabilitation (or improvement), the counselor's basis for determining improvement, and credentials of counselor, and any other relevant information he or she can provide.
- Letters describing your participation in support groups, e.g. Alcoholics Anonymous, Narcotics Anonymous, Pharmacist Support Groups, etc... Where appropriate. Letters should include dates and frequency of attendance and documentation of attendance such as sign in-sheets. (Include Penalty of Perjury statement.)
- Laboratory analyses or drug screen reports, where appropriate.
- Physical and/or mental examination or assessment report by a licensed physician, psychiatrist, or psychologist related to your rehabilitation and safety to practice. If your license was revoked as a result of impairment due to mental or physical illness, the law requires competent evidence of the absence or control of the condition, which caused the action taken by the board.
- Certificates of completion or transcripts of courses related to pharmacy, which you may have completed since your license was disciplined.
- Letters or proof of community and volunteer work or other activities, which may be appropriate or relevant to demonstrating rehabilitation from the acts which, led to discipline. (Include Penalty of Perjury statement.)

- Q. Must these documents be original documents?
- A. Yes, original documents should be submitted as evidence with the petition packet. (Always keep a copy of these originals for your records.) All documents that are submitted with the petition packet must be clear and readable.
- Q. Will the board contact people who submit documents on my behalf?
- A. Yes, the board reserves the right to contact individuals who submit documents on your behalf to verify the information. A list of names, addresses, and phone numbers for everyone submitting documents on you behalf must be included with your petition packet.

HEARING

The Board hears the petitioner in a formal administrative hearing that resembles a court proceeding. At your hearing you have an opportunity to present evidence of your rehabilitation and competency.

- Q. How is the hearing conducted?
- A. An Administrative Law Judge will preside over the hearing proceedings. The Members of the Board of Pharmacy will hear and rule on your petition. You will sit at a table in front of the Board Members and the Administrative Law Judge. A Deputy Attorney General (DAG) from the Office of the California Attorney General will represent the State. The DAG will make a preliminary statement outlining all disciplinary actions, which have been taken against your license, and describe the documents you have submitted into evidence. The DAG may ask you questions about your violation and discipline, and efforts you have undertaken to rehabilitate yourself.
- Q. What will I be expected to do?
- A. You will be sworn under oath by the judge who will ask you to state in your own words what you have done to rehabilitate yourself and to maintain current pharmacy knowledge and skills. **Be prepared to make an oral presentation at this point, which includes such a statement.** The Board Members, the Administrative Law Judge and the Deputy Attorney General may ask questions to clarify your statement or elicit additional information regarding your rehabilitation and current competency.

- Q. May I be represented by an attorney at the hearing?
- A. Yes, but it is not required. You may represent yourself or an attorney may represent you.
- Q. May I have persons come to speak on my behalf?
- A. Yes, However, their testimony and yours should be directed specifically toward your pharmacy competence and/or rehabilitation. You may choose to bring family members or friends for support even if they do not testify.
- Q. May I submit documents at the time of the hearing?
- A. It is preferable and to your advantage to make every effort to submit all relevant documents with your petition 90 days prior to your hearing. This gives the Board Members a reasonable amount of time to review and study them beforehand. If you do submit something at the hearing, you must bring dated original documents. Please be aware that submitting documents at the last minute often causes delays in the processing and may result in a continuance in order to provide the Board Members with an opportunity to fully evaluate your documentation.
- Q. How is the date and place for my hearing decided?
- A. Enclosed is a schedule of Board meetings, dates and final filing dates for petitions. Petitions are scheduled during the closed session portion of each Board meeting. If the docket for petitions is not already filled, you will be scheduled for the Board meeting that you request.
- Q. When will I know the exact date, time, and location for the hearings?
- A. Approximately ten days prior to the Board meeting you will receive a formal "NOTICE OF PETITION HEARING" stating the date, time, and place at which you are to appear. Several cases may be scheduled on the hearing docket and it is not possible to know how long each case will last. Therefore, you need to be prepared to remain throughout the day depending on the number and length of cases and in which order they are scheduled.

THE BOARD'S DECISION

- Q. When will I be notified of the Board's decision regarding my petition?
- A. The Board's decision to grant or deny your petition will be mailed to you within approximately six weeks. The decision is not final until this legal document is mailed to you.
- Q. If the Board does not grant my petition, may I petition again?
- A. Yes. You may petition again one year after the effective date of the Board's decision to deny your petition. However, if you apply after one year has elapsed, it is at the board's discretion whether a hearing will be held.



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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

PETITION FOR REDUCTION OF PENALTY

Section 11522 of the Government Code states that a licensee may petition the Board of Pharmacy for a reduction of penalty if he or she meets the following requirements:

1. One year has elapsed from the effective date of the decision ordering disciplinary action; or
2. One year has elapsed from the denial of similar petition was filed;

In addition, Section 4309 of the Business and Professions code states that a licensee may petition the board for a modification of his penalty if he or she meets the following requirements:

3. **If you have been on probation or parole for any criminal offense, you must submit certified documentation of your release from probation or parole;** and
4. There is currently no accusation or petition to revoke probation against the petitioner with the board.

Petition the board for a modification of the terms and conditions of your probation by completing and submitting the attached petition form. When completing your petition, please refer to the attached "Guidelines for Petitions for Reinstatement, Reduction of Penalty, and Early Termination of Probation." These guidelines outline the rehabilitation criteria the board has determined a petitioner should meet when petitioning for license reinstatement, reduction of disciplinary penalty, or early termination of probation. In addition, modification of a disciplinary penalty or reduction or penalty may not be considered unless the petitioner has met all the requirements.

The petition form **must** be accompanied by **two** or more verifiable letters of recommendations addressed to the board from holders of licenses issued by the Board of Pharmacy, and by **two** or more letters of recommendations from citizens. The letters must be within the last year from the date you are submitting your petition. Each author must indicate in their letter that they have personal knowledge of the disciplinary penalty imposed by the board and your activities since the disciplinary penalty was imposed. The board suggests that letters of recommendation include facts that demonstrate an author's personal knowledge of the subject's penalty and the petitioner's activities. Examples of activities may include employment, community service, volunteer work, etc. A board representative may contact you or anyone who has submitted a letter on your behalf.

Also, required is documentation of **30 hours of Board approved continuing education** (acquired within the last two years from the date your application is received by the board). Photocopies of the certificates of completion should be sent and the original certificates retained for your records.

Submit the petition with the required documents to the address above, to the attention of the enforcement unit. The petition will be processed and evaluated for scheduling at the next available board meeting. Please be advised that you should allow **90** days for the processing of your petition, and the petition set for hearing. Below is a schedule of board meeting dates with the cut-off date for submission of a petition.

You will be notified in writing of the hearing date. At the hearing, you will be afforded the opportunity to present both oral and written evidence of your rehabilitation; and you may, but need not be, represented by counsel. In deciding the case, the board will take into consideration the petition, all recommendations, and any oral or written evidence. The board will be represented by the Attorney General's Office and an administrative law judge will preside over the hearing.

BOARD MEETING DATES	CUT-OFF DATES	LOCATION
February 6-7, 2018	December 6, 2017	Sacramento
March 27, 2018	January 27, 2018	TBD
May 2-3, 2018	March 2, 2018	TBD
June 6, 2018	April 6, 2018	TBD
July 24-25, 2018	May 24, 2018	TBD
September 6, 2018	July 6, 2018	TBD
October 23-24, 2018	August 23, 2018	TBD
December 12, 2018	October 12, 2018	TBD

17R12 (1/2018)



GUIDELINES FOR PETITIONS FOR REINSTATEMENT, REDUCTION OF PENALTY OR EARLY TERMINATION OF PROBATION

In petitioning for reinstatement and early termination of probation under Business and Professions Code section 4309 or reduction of penalty under Government Code section 11522, the petitioner has the burden of demonstrating any rehabilitative or corrective measures he or she has taken since the revocation action and, that he or she has the necessary and current qualifications and skills to safely engage in the practice of pharmacy within the scope of current law, and accepted standards of practice. In reaching its determination the board considers various factors including the following:

- (a) The original violation(s) for which action was taken against the petitioner's license including:
 1. The type, severity, number, and length of violations.
 2. Whether the violation involved intentional, negligent or other unprofessional conduct.
 3. Actual or potential harm to the public, patients, or others.
 4. The length of time since the violation(s) was committed.

- (b) Prior disciplinary and criminal actions also taken against the petitioner by the board, and state, local or federal agency or court including:
 1. The petitioner's compliance with all terms of probation, parole, previous discipline or other lawfully imposed sanctions including any order of restitution.
 2. Whether the petitioner is currently on or has been terminated from probation or other lawfully imposed sanction.
 3. The petitioner's legal and regulatory history to and since the violation(s).

- (c) The petitioner's attitude toward his or her commission of the original violation(s) and his or her attitude in regard to compliance with legal sanctions and rehabilitative efforts.

- (d) The petitioner's documented rehabilitative efforts including:
1. Efforts to maintain and/or upgrade professional skills and knowledge through continuing education or other methods.
 2. Efforts to establish safeguards to prevent repetition of the original violation(s) including changes or modifications in policies, structure, systems, or methods of behavior applicable to the petitioner's pharmacy practice.
 3. Service to community or charitable groups.
 4. Voluntary restitution to those affected by the original violation(s).
 5. Use of appropriate professional medical or psychotherapeutic treatment.
 6. Participation in appropriate self-help and/or rehabilitation groups.
 7. Use of appropriate peer review mechanisms.
 8. Participation in professional pharmacy organizations or associations.
- (e) Assessment of petitioner's rehabilitative and corrective efforts including:
1. Whether the efforts relate to the original violation(s).
 2. The date rehabilitative efforts were initiated.
 3. The length, time, and expense associated with rehabilitative efforts or corrective actions.
 4. The assessment and recommendations of qualified professionals directly involved in the petitioner's rehabilitative efforts or acting at the request of the board, including their description of the petitioner's progress and their prognosis of the petitioner's current ability to practice pharmacy.
 5. The petitioner's reputation for truth, professional ability and good character since the commission of the original violation(s).
 6. The nature and status of ongoing and continuing rehabilitative efforts.

In addition, the board may consider other appropriate and relevant matters not listed in the above guidelines.

Please note that all statements to be introduced at hearing must be made in person or pursuant to Government Code section 11514 (evidence by affidavit). All other statements not made in person or pursuant to Government Code section 11514 must be under oath and will be considered only as administrative hearsay.



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STATE AND CONSUMER SERVICES AGENCY
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 GOVERNOR EDMUND G. BROWN JR.

PETITION FOR REDUCTION OF PENALTY

No petition to modify the terms of probation will be entertained until one year after the effective date of the Board's disciplinary action. The decision on the petition will be made by the full Board and in accordance with Government Code section 11522.

Modification of the terms of probation will be provided only in exceptional circumstances, such as when the board determines that the penalty imposed has been excessive, considering both the violation of the law charged and the supporting evidence, or when there is substantive evidence that there is no more need for the degree of probationary supervision as set forth in the original terms and conditions. As a rule, no reduction of penalty will be granted unless the probationer has at all times been in compliance with the terms of probation.

Please print or type

1. Name		2. Date of Birth		3. California License Number	
4. Residence Address		Street and Number		City	State Zip Code
5. Telephone Number		6. Are you licensed in any other state? yes <input type="checkbox"/> no <input type="checkbox"/>			
Hm () _____		State		Date of Issuance	
Wk () _____				Status of License	
7. University, College or School of Pharmacy you attended.					
Name of School		Dates Attended		Graduation Date Degree	
		From	To		
8. List years, location, and type of practice for 5 years prior to the revocation of your California License.					
Dates		Location		Type of Practice	
From	To				
9. How should the penalty be reduced/modified?					

10. Are you or have you ever been addicted to the use of narcotics or hypnotics? Yes ____ No ____
11. Are you or have you ever been habitually intemperate in the use of alcohol or other drugs? Yes ____ No ____
12. Have you ever been or are you currently under observation or treatment for mental disorders, alcoholism, narcotic or hypontic drug addiction? Yes ____ No ____
13. Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state or a local ordinance? You must include all misdemeanor and felony convictions, regardless of the age of the offense, including those which have been set aside under Penal Code section 1203.4 (which includes diversion programs). Yes ____ No ____
14. Are you now on probation or parole for any criminal or administrative violations in this state or any other state? (Attach certified copies of all disciplinary or court documents.) Yes ____ No ____
15. Have you ever had disciplinary action taken against your pharmacist license in this state or any other state? Yes ____ No ____

If the answer to questions 10 through 15 is yes, you must attach a statement of explanation giving full details.

ON AN ATTACHED SHEET OF PAPER ANSWER THE FOLLOWING QUESTIONS

16. List the date of disciplinary action taken against your license and explain fully the cause of the disciplinary action.
17. Explain fully why you feel your license should be restored, or the disciplinary penatly reduced.
18. Describe fully your activites and occupation since the date of the disciplinary action; include dates, employers, and locations.
19. Describe any rehabilitative or corrective measures you have taken since your license was disciplined to support your petition. List dates, nature of programs, and current status. You may include any community service or volunteer work.
20. List all post-graduate or refresher courses, with dates, location and type of course, you have taken since your license was disciplined.
21. List all pharmaceutical literature you have studied during the last year.
22. List all continuing education courses you have completed since your license was disciplined. Attach copies of the certificates.
23. List names, addresses, and telephone numbers of persons submitting the letters of recommendation accompanying this petition.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

DATE _____

SIGNATURE _____

NOTICE

This information is requested pursuant to the provisions of Business and Professions Code section 4309(b). All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the petition being rejected as incomplete. The information will be used to determine qualifications for reinstatement under the California Pharmacy Law. The official responsible for information maintenance is the executive officer, telephone (916) 445-5014, 400 R Street, Sacramento, California 95814-6237. The information may be transferred to another governmental agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are indentified as confidential information and exempted by section 1798.3 of the Civil Code.



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DEPARTMENT OF CONSUMER AFFAIRS

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- A. Approximately ten days prior to the Board meeting you will receive a formal "NOTICE OF PETITION HEARING" stating the date, time, and place at which you are to appear. Several cases may be scheduled on the hearing docket and it is not possible to know how long each case will last. Therefore, you need to be prepared to remain throughout the day depending on the number and length of cases and in which order they are scheduled.

THE BOARD'S DECISION

- Q. When will I be notified of the Board's decision regarding my petition?
- A. The Board's decision to grant or deny your petition will be mailed to you within approximately six weeks. The decision is not final until this legal document is mailed to you.
- Q. If the Board does not grant my petition, may I petition again?
- A. Yes. You may petition again one year after the effective date of the Board's decision to deny your petition. However, if you apply after one year has elapsed, it is at the board's discretion whether a hearing will be held.

Attachment 3

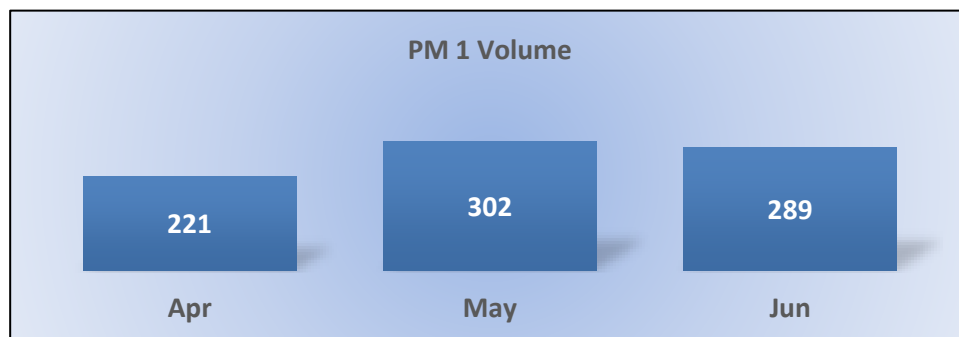
Enforcement Performance Measures

Q4 Report (April - June 2017)

To ensure stakeholders can review the Board's progress toward meeting its enforcement goals and targets, we have developed a transparent system of performance measurement. These measures will be posted publicly on a quarterly basis.

PM1 | Volume

Number of complaints and convictions received.

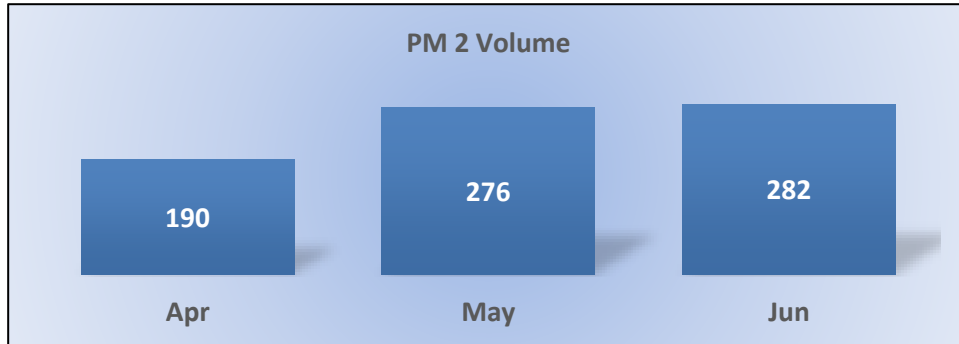


Total Received: 812 | Monthly Average: 271

Complaints: 546 | Convictions: 266

PM2 | Intake – Volume

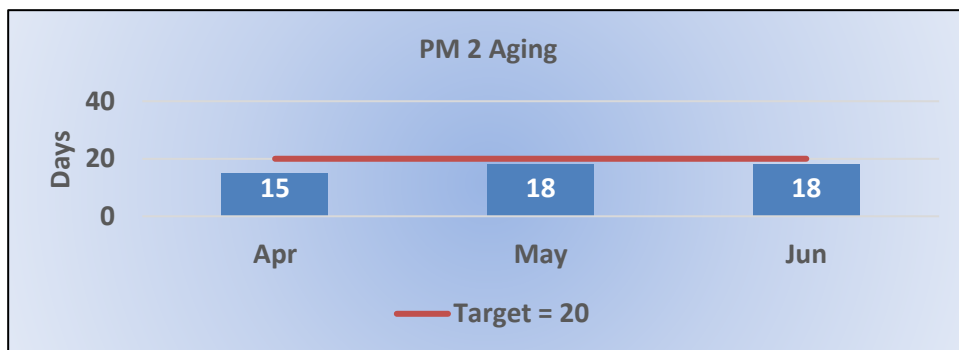
Number of complaints closed or assigned to an investigator.



Total: 748 | Monthly Average: 249

PM2 | Intake – Cycle Time

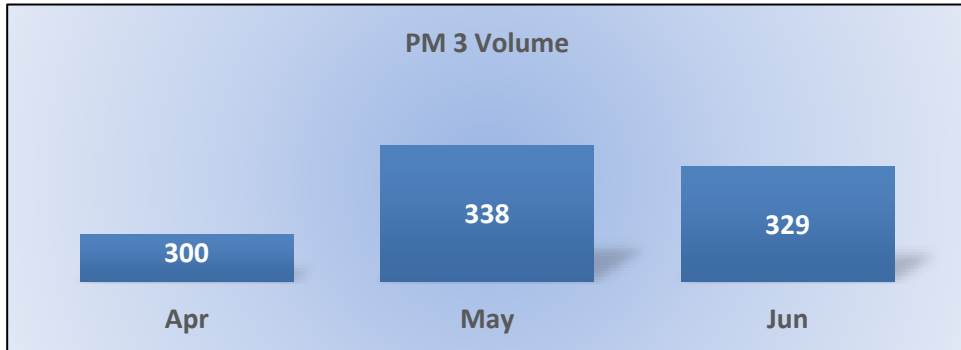
Average number of days from complaint receipt, to the date the complaint was closed or assigned to an investigator.



Target Average: 20 Days | Actual Average: 17 Days

PM3 | Investigations – Volume

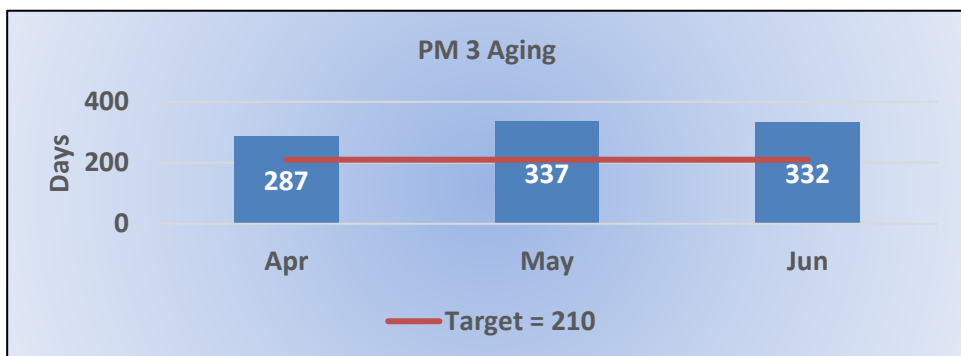
Number of investigations closed (not including cases transmitted to the Attorney General).



Total: 967 | Monthly Average: 322

PM3 | Investigations – Cycle Time

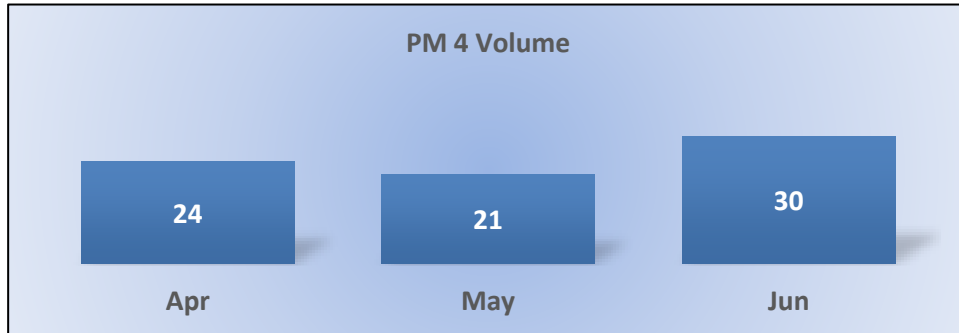
Average number of days to complete the entire enforcement process for cases not transmitted to the Attorney General.
(Includes intake and investigation.)



Target Average: 210 Days | Actual Average: 320 Days

PM4 | Formal Discipline – Volume

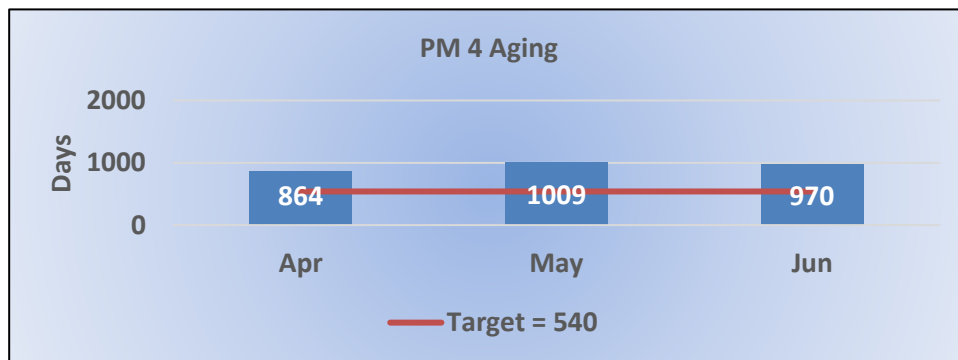
Cases closed after transmission to the Attorney General for formal disciplinary action. This includes formal discipline, and closures without formal discipline (e.g., withdrawals, dismissals, etc.).



Total: 75 | Monthly Average: 25

PM4 | Formal Discipline – Cycle Time

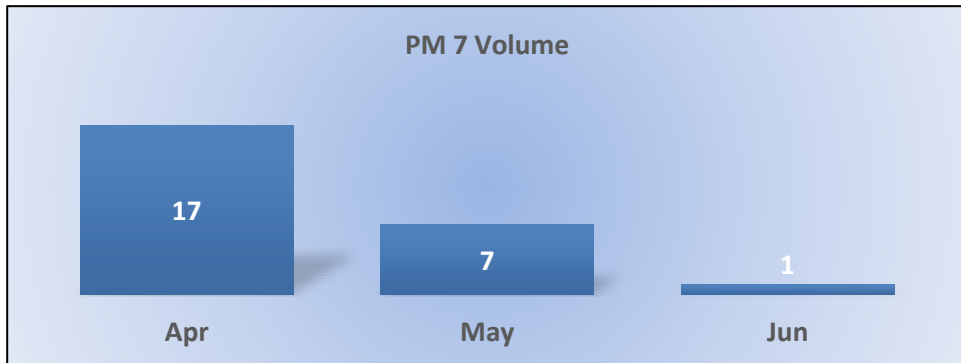
Average number of days to complete the entire enforcement process for cases transmitted to the Attorney General. (Includes intake, investigation, and case outcome.)



Target Average: 540 Days | Actual Average: 947 Days

PM7 | Probation Intake – Volume

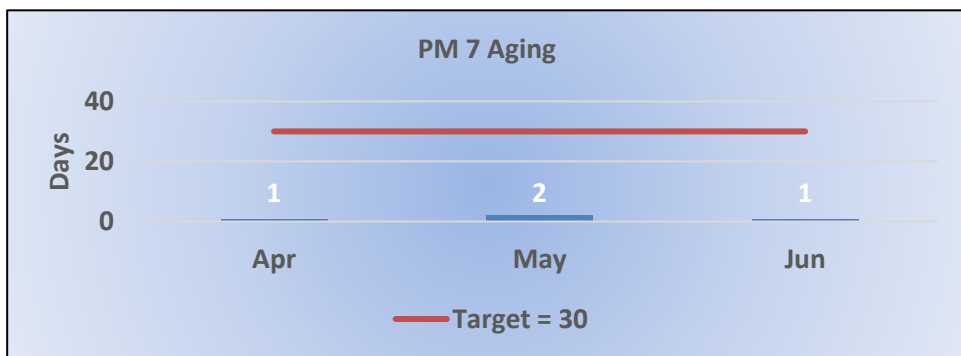
Number of new probation cases.



Total: 25

PM7 | Probation Intake – Cycle Time

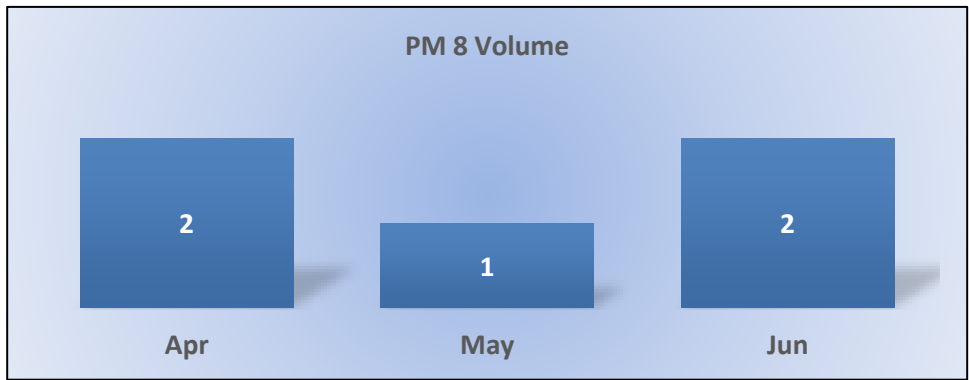
Average number of days from monitor assignment, to the date the monitor makes first contact with the probationer.



Target Average: 30 Days | Actual Average: 1 Day

PM8 | Probation Violation Response – Volume

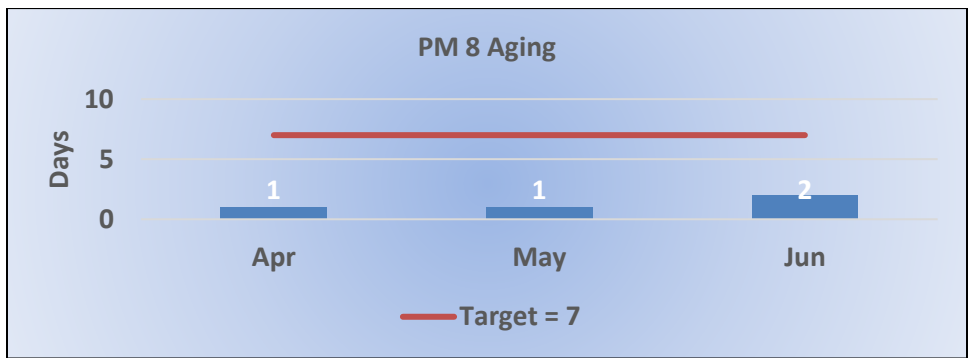
Number of probation violation cases.



Total: 5

PM8 | Probation Violation Response – Cycle Time

Average number of days from the date a violation of probation is reported, to the date the assigned monitor initiates appropriate action.



Target Average: 7 Days | Actual Average: 1 Day

Attachment 4



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

Business and Professions Code Section 312.2

January 1, 2018

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

January 1, 2018

EXECUTIVE SUMMARY

This is the first annual report by the Office of the Attorney General required under Business and Professions Code section 312.2, which became effective on January 1, 2016, and requires the first report to be filed by January 1, 2018. The report is based on information from Fiscal Year 2016-17. It provides a baseline concerning accusation referrals received and adjudicated accusations for each Department of Consumer Affairs client agency of the Licensing Section and Health Quality Enforcement Section of the Attorney General's Office.

Each client agency is unique and not comparable to each other, yet some general observations can be made from the data collected to compile this report. In Fiscal Year 2016-17, approximately 40 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, 3,097 accusation referrals were received from our Department of Consumer Affairs client agencies. Less than 2.7 percent of accusation referrals to the Attorney General's Office were rejected, and 10 percent of accusation referrals required further investigation.

The Office of the Attorney General adjudicated 3,384 accusations during the year. The matters adjudicated were transmitted to this office in Fiscal Year 2016-17 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 initial adjudication. Close to 60 percent of the total adjudications were by stipulated settlement, approximately 25 percent by default, and 12 percent by administrative hearing.

We have provided individual reports of the information requested in Business and Professions Code section 312.2 for each Department of Consumer Affairs client agency represented by the Licensing Section and Health Quality Enforcement Section of the Attorney General's Office.

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 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. Liaison deputies also regularly consult with agency clients and advise them on jurisdictional, legal, and programmatic issues. Deputy Attorneys General also frequently train Division of Investigation and agency investigators, agency staff, and expert witnesses.

Both sections prosecute licensing matters, including accusations (license discipline), which comprise about forty percent of their combined caseload. The balance of prosecution matters consist of statements of issues (appeal hearing when a license application has been denied), interim suspension

petitions (hearing 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 hearing 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 statistics 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 and Health Quality Enforcement Sections each have different licensing programs and processes unique to their practice areas. A few agencies issue only one type of license, but most issue multiple license types. Agencies also differ in how they refer accusation matters to the Attorney General's Office; some referring one matter for each licensee, while others refer multiple licensees involved in the same or related acts for which discipline is sought as a single matter to be included in one accusation. They may also refer additional investigations to the Attorney General's Office while an initial accusation matter is pending. Depending on the circumstances, subsequent investigations may or may not be counted as additional *accusation referrals* in this report. Some agencies have higher default rates than others, perhaps because some licensees have invested less time and money to obtain their license than others, just as the respondents for some agencies are almost always represented by counsel, while others have a mix of represented respondents and those who represent themselves. Client agencies also differ in their applicable burdens of evidentiary proof, and some are not subject to a statute of limitations. Most agencies are entitled to recover their costs of investigation and prosecution from respondents. The statistics 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. They generally assign investigation of their cases in four ways with an aim to balance quality and efficiency, and avoid insufficiency of evidence, which causes delay while further investigation is done to gather supplemental evidence. 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 and instead, since 2006, their cases have been investigated under a third model known as Vertical Enforcement and Prosecution, pursuant to Government Code section 12529.6. The Vertical Enforcement model requires a deputy attorney general, who will be responsible for prosecuting the case if the investigation results in the filing of an accusation, to be jointly assigned to the investigation with a Division of Investigation investigator from the Health Quality Investigation Unit. Some agencies represented by the Health Quality Enforcement Section of the Office of the Attorney General opt to

have some or all of their cases investigated under the Vertical Enforcement model. Lastly, all Division of Investigation investigators, agency investigators, and agency staff have the option of consulting with a liaison deputy assigned to each client agency by the Office of the Attorney General to provide counsel with respect to any investigation.

Administrative Adjudication Process

If the investigation reveals evidence that a licensee of an agency 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, the assigned 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. In such cases, in the Licensing Section, the file remains open pending receipt of supplemental investigation, and the file is documented to indicate the further investigation request. In the Health Quality Enforcement Section, the file will be returned to the client agency and will be rereferred to the Office of the Attorney General if further evidence is developed. 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 upon sufficient evidentiary support, the Attorney General's Office 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.) A deputy attorney general is assigned to prosecute the case and bring it to hearing. 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, issues a proposed decision, and sends it to the agency for its ultimate decision. Of course, settlement can occur at any time and is the most common method of adjudication of accusation matters.

Each licensing agency 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 call for the transcript. After review of the transcript, it can then adopt the proposed decision or issue its own decision. Most cases are resolved when the agency accepts a 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. The 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 the 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.

Business and Professions Code section 312.2, subdivision (a)(7), and subdivision (b)(1) – (6) request the number of matters adjudicated by the Office of the Attorney General, and average number of days for various components of the adjudication process. *Adjudication* means the work of the Office of the Attorney General is complete to bring the matter back before the agency for issuance of its decision. Adjudication occurs in four different ways:

1. Default. If a respondent does not timely submit a Notice of Defense, or fails to appear at a duly noticed hearing on the accusation, a default is provided to the agency for its ultimate decision, or the deputy attorney general conducts the hearing without the presence of the respondent.
2. Settlement. The complainant may authorize settlement of an accusation on terms that are sufficient to protect the public, which will be presented to the agency for its ultimate decision.
3. Hearing Submitted. Upon completion of the adjudicative hearing, the matter is submitted to the administrative law judge, who prepares a proposed decision and sends it to the agency for its ultimate decision.
4. Withdrawal of Accusation. Under certain conditions, an accusation that has been filed may be withdrawn by the complainant of the agency as recommended by the Office of the Attorney General, and the matter is closed.

Multiple adjudications may be reported in a single accusation matter in one or more fiscal years because more than one licensee is included in one matter, each with different adjudication dates and types, or a client agency exercises its discretion to reject a proposed settlement, non-adopt a proposed decision, or grant a petition for reconsideration.

MEASURES REPORTED

The following measures are reported, as required by Business and Professions Code section 312.2, which states:

- (a) The Attorney General shall submit a report to the department, the Governor, and the appropriate policy committees of the Legislature on or before January 1, 2018, and on or before January 1 of each subsequent year that includes, at a minimum, all of the following for the previous fiscal year for each constituent entity within the department represented by the Licensing Section and Health Quality Enforcement Section of the Office of the Attorney General:
 - (1) The number of accusation matters referred to the Attorney General.
 - (2) The number of accusation matters rejected for filing by the Attorney General.
 - (3) The number of accusation matters for which further investigation was requested by the Attorney General.

- (4) The number of accusation matters for which further investigation was received by the Attorney General.
 - (5) The number of accusations filed by each constituent entity.
 - (6) The number of accusations a constituent entity withdraws.
 - (7) The number of accusation matters adjudicated by the Attorney General.
- (b) The Attorney General shall also report all of the following for accusation matters adjudicated within the previous fiscal year for each constituent entity of the department represented by the Licensing Section and Health Quality Enforcement Section:
- (1) The average number of days from the Attorney General receiving an accusation referral to when an accusation is filed by the constituent entity.
 - (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.
 - (3) The average number of days from an agency filing an accusation to the Attorney General transmitting a stipulated settlement to the constituent entity.
 - (4) The average number of days from an agency filing an accusation to the Attorney General transmitting a default decision to the constituent entity.
 - (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.
 - (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.

METHODOLOGY

Case Management System

This report is based on data entered by legal professionals into the case management system of the Office of the Attorney General. Each matter received by the Licensing and Health Quality Enforcement Sections 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 dictate 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 undertaken 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 integrates them into its business routines and operations.

Data Presentation

The statistical information required 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 and Health Quality Enforcement Sections 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 Fiscal Year 2015-16 Sunset Review Reports of individual boards or the 2016 Annual Report of the California Department of Consumer Affairs, containing data from Fiscal Year 2015-16. This report can be found on line at: http://www.dca.ca.gov/publications/2016_annrpt.pdf. Further information concerning Department of Consumer Affairs agencies can be found through the links at: http://www.dca.ca.gov/about_dca/entities.shtml.

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)). 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 section 312.2, subdivision (a)(7). The word *average* in subdivision (b), is a general word that expresses the central or typical value in a set of data, which is most commonly thought of as the arithmetic mean. The mean is the result obtained by adding together several values, and then dividing this total by the number of values. 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 standard deviation indicates that the data points tend to be close to the mean (also called the expected value) of the set, while a high standard deviation indicates that the data points are spread out over a wider range of values. In Table 2, we have included the mean, median, and standard deviation, along with the number of values in the data set from which the averages were determined. The averages reported in Table 2 for section 312.2, subdivision (b)(2), were calculated from the date matters were received at the Office of the Attorney General until pleadings were sent to the agency, and include the time during which matters were reinvestigated and rereferred by the client back to the Office of the Attorney General. The pleadings filed reported in subdivision (b)(1) include the matters reported in subdivision (b)(2), that required further investigation before pleadings were sent to the agency for filing.

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

The balance of this page has intentionally been left blank.

California State Board of Pharmacy

The Board of Pharmacy regulated 138,444 licenses in Fiscal Year 2015-16 with 20 different 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, or referred to the Department of Consumer Affairs Division of Investigation, Investigations and Enforcement Unit, when appropriate. There were multiple respondents in about 26 percent of the Board's accusation matters adjudicated by the Attorney General, reported in subdivisions (a)(7) and (b), below. The tables below show data for Fiscal Year 2016-17.

Table 1 – Business and Professions Code Section 312.2, Subdivision (a)	
Number of –	Count
(1) accusation matters referred to the Attorney General.	258
(2) accusation matters rejected for filing by the Attorney General.	2
(3) accusation matters for which further investigation was requested by the Attorney General.	36
(4) accusation matters for which further investigation was received by the Attorney General.	23
(5) accusations filed.	238
(6) accusations withdrawn.	5
(7) accusation matters adjudicated by the Attorney General.	302

The statistics reported in Table 2 are 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	178	224	254
(2) to prepare an accusation for a case that is rereferred to the Attorney General after further investigation is received.	457	408	319	14
(3) from the filing of an accusation to when a stipulated settlement is sent to the agency.	308	249	227	143
(4) from the filing of an accusation to when a default decision is sent to the agency.	120	74	136	97
(5) from the filing of an accusation to the Attorney General requesting a hearing date.	127	118	103	85
(6) from the Attorney General's receipt of a hearing date to the commencement of a hearing.	167	143	112	44

Attachment 5

Excerpt from the May 2-3, 2018 Board Meeting Minutes

c. Matters Related to United States Pharmacopeia Chapter (USP) 797, USP 800, and Other USP Chapters Relating to Compounding

1. Anticipated Release of Updates and Impact on the Board's Regulation of Pharmacy

Chairperson Schaad explained that the proposed revisions for USP Chapter 795 were released in March 2018 and an open microphone session was held on April 20, 2018. On May 1, 2018, Chapter 795 will be formally published in *Pharmacopeial Forum* for review and public comment. He noted that the public comment period on USP 795 will close on July 31, 2018.

Chairperson Schaad reported that USP Chapter 797 will be formally published in the *Pharmacopeial Forum* for review and public comment on September 4, 2018. An open microphone session on Chapter 797 is scheduled for September 5, 2018. Chairperson Schaad added that the public comment period for Chapter 797 will close on November 30, 2018.

Chairperson Schaad stated that as part of a larger discussion, the Enforcement Committee was advised of the proposed changes to USP Chapters 795 and 797.

Chairperson Schaad reported that during the meeting the committee briefly reviewed the proposed changes to Chapter 795 and noted that further modifications would be made to the chapter. The committee asked staff to draft a summary of the proposed changes to be discussed at a future committee meeting.

Chairperson Schaad stated that following the committee meeting board staff participated in the open microphone session on April 20, 2018, and note that it appears that Chapter 795 may establish practice guidance, but may not be strictly enforced.

Chairperson Schaad explained that it is anticipated that the final versions of chapters 795 and 797 will be available June 1, 2019. Board staff will continue to monitor developments and will keep the committee apprised of such efforts. He added that as the chapters become finalized staff will provide the committee with summary documents highlighting the changes and any staff recommendations for consideration.

2. Discussion and Consideration of Statutory Proposal to Require USP Compliance in Pharmacy Law

Chairperson Schaad reported that for several years the Enforcement Committee and the board have discussed the regulation of sterile and nonsterile compounding and most recently hazardous compounding. The results of these discussions were comprehensive regulations promulgated to ensure compounded drug preparations are safe. He

explained that although not totally consistent, relevant USP chapters covering compounding served as part of the framework for these regulations.

Chairperson Schaad reported that during the February 2018 board meeting, counsel was directed to research the feasibility of incorporation USP standards into the board's regulation of compounding practice rather than creating its own requirements.

Chairperson Schaad stated that at the Enforcement Committee meeting the members discussed the following:

- Whether the board could adopt USP 797.
- Whether USP 795, 797 and 800 could all be included.
- Whether, following adoption, regulations would be used to identify higher California standards.

Chairperson Schaad noted that the committee heard comments from the public that not all chapters of USP are relevant to compounding of drug preparations and that it may be unclear which sections of USP would require compliance.

Mr. Schaad reported that after discussion the committee directed staff to draft a statutory proposal to incorporate USP into the board's requirements for compounding of drug preparations and bring the language to the board meeting for discussion and approval.

Mr. Schaad stated that as directed board staff and counsel drafted the following proposed statutory language for consideration by the board.

Add Section BPC 4122.5 as follows:

The compounding of drug preparations for furnishing, distribution, or use in California must be done consistent with standards established in the latest edition of the United States Pharmacopeia-National Formulary chapters on pharmacy compounding, including all relevant testing, and quality assurance. This does not, however, prevent the board from adopting regulations requiring additional standards for compounding drug preparations.

Daniel Martinez stated that CPhA supports the committee's recommendation to pursue a statutory change to incorporate USP Chapters. He added that CPhA would recommend adding the language to BPC 4108 and amending the language to specifically list USP chapters 797, 795 and 800.

Mr. Martinez added that CPhA member have also requested that if the board does adopt additional standards that they do so using scientific evidence. Board member Weisser expressed his disappointment that stakeholders believe that the regulations were not based on scientific evidence he added that board staff is careful to create regulations based on facts. President

Gutierrez added that there are some controversial and often conflicting scientific studies regarding sterile compounding.

A pharmacist from University Compounding Pharmacy spoke in support of adopting USP chapters and requested that the board specifically list USP chapters 795, 797 and 800. He added that California's regulations often conflict with USP and other states have already adopted USP. President Gutierrez explained that the reason the board is considering adopting USP is to eliminate conflicts.

Ms. Sodergren explained that staff used federal law as a reference when drafting the language and the federal law does not list specific chapters. She added that if the board chooses to list specific chapters the law would need to be updated any time an addition was made. The board agreed with the staff's recommendation to not specifically list chapters.

Pharmacist Virginia Partridge spoke in support of adopting USP chapters.

Ms. Herold stated that once the board approved a statutory amendment board staff will move forward to try to find a vehicle to implement the change during this legislative cycle.

Motion: Approve the statutory language as provided below.

Add Section BPC 4122.5 as follows:

The compounding of drug preparations for furnishing, distribution, or use in California must be done consistent with standards established in the latest edition of the United States Pharmacopeia-National Formulary chapters on pharmacy compounding, including all relevant testing, and quality assurance. This does not, however, prevent the board from adopting regulations requiring additional standards for compounding drug preparations.

M/S: Gutierrez/Munoz

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Khan				X
Law	X			
Lippe	X			
Munoz	X			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

Attachment 6



GOAL

2

ENFORCEMENT

The board protects consumers by effectively enforcing laws, codes, and standards when violations occur.

- 2.1** 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.
- 2.2** Strengthen patient consultation outcomes for Californians and increase medication safety.
- 2.3** Collect data and report to board members about enforcement trends that are presented at case closures so the board can better educate licensees about board priorities.
- 2.4** Evaluate industry technology trends to develop future regulatory infrastructures that promote patient safety.
- 2.5** Evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.
- 2.6** Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery.
- 2.7** Investigate options on the interoperability with a National Prescription Drug Monitoring Program.

Attachment 7

Board of Pharmacy Enforcement Statistics Fiscal Year 2017/2018

Workload Statistics July-Sept Oct-Dec Jan-Mar Apr-June Total 17/18

Complaints/Investigations

Received	676	630	749	235	2290
Closed	676	783	783	316	2558
4301 letters	6	5	8	2	21
Pending (at the end of quarter)	2283	2028	2023	1992	2023

Cases Assigned & Pending (by Team) at end of quarter*

Compliance / Routine Team	992	952	987	825	987
Drug Diversion/Fraud	370	307	321	385	321
RX Abuse	185	132	94	87	94
Compounding	130	86	78	104	78
Outsourcing	43	29	16	61	16
Probation/PRP	63	49	69	66	69
Mediation/Enforcement **	190	143	139	155	139
Criminal Conviction	320	330	319	309	319

Application Investigations

Received	228	96	100	34	458
Closed					
Approved	92	125	73	18	308
Denied	17	20	16	5	58
Total ***	126	177	112	24	439
Pending (at the end of quarter)	192	153	90	106	106

Letter of Admonishment (LOA) / Citation & Fine

LOAs Issued	30	73	63	7	173
Citations Issued	425	610	555	183	1773
Total Fines Collected ****	\$535,944	\$501,038	\$636,545	\$134,733	\$1,808,260

* This figure includes reports submitted to the supervisor and cases with SI awaiting assignment.

** This figure include reports submitted to the citation and fine unit, AG referral, as well as cases assigned to enf. Staff

*** This figure includes withdrawn applications.

****Fines collected (through 4/30/2018 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics

Fiscal Year 2017/2018

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 17/18**

Administrative Cases (by effective date of decision)

Referred to AG's Office*	83	102	68	36	289
Accusations Filed	78	43	84	32	237
Statement of Issues Filed	10	7	11	5	33
Petitions to Revoke Filed	2	0	4	2	8
Pending					
Pre-accusation	204	200	191	181	191
Post Accusation	245	237	246	269	246
Total*	471	516	484	503	484

Closed

Revocation					
Pharmacist	7	2	7	1	17
Intern Pharmacist	1	0	1	0	2
Pharmacy Technician	22	17	20	7	66
Designated Representative	0	0	0	0	0
Wholesaler	0	1	1	0	2
Sterile Compounding	1	0	0	0	1
Pharmacy	2	1	2	1	6

Revocation, stayed; suspension/probation					
Pharmacist	2	3	2	0	7
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Pharmacy	1	0	2	0	3

Revocation, stayed; probation					
Pharmacist	9	13	17	3	42
Intern Pharmacist	1	0	1	0	2
Pharmacy Technician	0	1	2	3	6
Designated Representative	1	2	0	0	3
Wholesaler	0	1	1	0	2
Sterile Compounding	3	0	0	0	3
Pharmacy	9	12	6	0	27

Surrender/Voluntary Surrender					
Pharmacist	2	3	8	3	16
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	4	3	8	1	16
Designated Representative	0	2	0	0	2
Wholesaler	1	0	0	0	1
Sterile Compounding	2	2	2	1	7
Pharmacy	6	3	9	3	21

Board of Pharmacy Enforcement Statistics Fiscal Year 2017/2018

Workload Statistics July-Sept Oct-Dec Jan-Mar Apr-June Total 17/18

Public Repraisal/Reprimand

Pharmacist	5	3	4	0	12
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	2	3	0	5
Designated Representative	0	0	1	0	1
Wholesaler	0	0	0	0	0
Sterile Compounding	1	0	0	0	1
Pharmacy	3	2	3	1	9

Licenses Granted

Pharmacist	1	1	0	0	2
Intern Pharmacist	1	3	2	0	6
Pharmacy Technician	1	2	3	1	7
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Pharmacy	0	0	0	0	0

Licenses Denied

Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	4	1	0	5
Designated Representative	0	0	1	0	1
Wholesaler	0	0	0	0	0
Sterile Compounding	1	0	1	0	2
Pharmacy	0	0	0	0	0

Cost Recovery Requested**	\$357,388	\$439,458	\$440,473	\$76,228	\$1,313,546.59
Cost Recovery Collected**	\$238,133	\$189,505	\$146,584	\$52,176	\$626,398.07

* This figure includes Citation Appeals

** This figure includes administrative penalties

Immediate Public Protection Sanctions

Interim Suspension Order	0	3	4	0	7
Automatic Suspension / Based on Conviction	2	0	2	0	4
Penal Code 23 Restriction	3	3	2	0	8
Cease & Desist - Sterile Compounding	1	0	0	0	1

Board of Pharmacy Enforcement Statistics Fiscal Year 2017/2018

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 17/18**

Probation Statistics

Licenses on Probation

Pharmacist	194	211	219	224	218
Intern Pharmacist	5	8	10	9	9
Pharmacy Technician	32	29	31	30	29
Designated Representative	1	3	2	2	2
Pharmacy	68	75	74	77	73
Sterile Compounding	15	16	15	15	16
Wholesaler	3	4	5	5	5
Probation Office Conferences	27	36	28	18	109
Probation Site Inspections	145	165	156	110	576
Successful Completion	6	7	9	7	29
Probationers Referred to AG for non-compliance	1	5	2	0	8

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences.

These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset,

2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

As of April 30, 2018.