California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Amy Gutierrez, PharmD, Board President
Debbie Veale, RPh, Board Vice-President

a. Budget Update/Report

1. Budget Report FY 2015/16

Attachment 1

The new budget year began July 1, 2015. The board's spending authorization for the year is $19,770,000 which is a 3 percent increase from the prior year.

As of March 31, 2016, the board has expended $15,119,992 and taken in $15,742,900 in revenue. Budget charts detailing revenue and expenditure information for the first quarter of the fiscal year are provided in **Attachment 1**.

As it has for the past few years, budget projections for the remainder of the fiscal year indicate that the board will again need to seek a midyear augmentation to its budget to secure the necessary funding to cover the enforcement related costs incurred by services provided by the Attorney General's Office as well as the Office of Administrative Hearings. This augment is necessary to ensure continuing services from both offices through the fiscal year. As enforcement activities are the core of the board's consumer protection mandate, it is essential that this be pursued. We do not anticipate a decrease in these enforcement related costs in future years. The midyear augment will serve as a temporary fix until a more permanent solution is achieved.

2. Fund Condition Report

Attachment 2

Attachment 2 includes the fund condition report prepared by the Department. The information below reflects the estimated fund condition with the additional revenue from the approved fee increase:

2014/15	$11,742,000	6.5
2015/16	$ 6,219,000	3.6
2016/17	$ 1,821,000	1.0
2017/18	-$ 2,882,000	-1.6

Note: This fund condition does include the midyear augmentation request referenced in the prior item.

As our fund condition reflects, the board will need to pursue a fee increase to sustain operations. As a precursor to making such a determination, a fee analysis was conducted. During the November 2015 board meeting, the board was provided with

information about the analysis, methodology, etc. and subsequently was provided with a copy of the final analysis on December 1, 2015, as part of the Sunset Report. Additional information on this issue is provided later in this report.

3. Governor's Proposed Budget for FY 2016/2017

On January 7, 2016, the governor released his proposed budget for FY 2016/17. Included in this proposal was funding to make several limited term positions permanent. Provided below is a list of the positions.

Cures – Combating RX Drug Abuse	AGPA (1.0); Research Program Specialist (1.0); Inspector (5.0); Sup. Inspector (1.0)
SB 294 – Sterile Compounding	AGPA (1.0); SSA (0.5); Inspector (4.0)
Total Positions	**12.5 positions**

Ms. Herold has been providing testimony on the need for permanent funding for these positions when the board's budget and requests are discussed during legislative hearings.

b. National Association of Boards of Pharmacy 2016 Annual Meeting in San Diego

As previously discussed, The National Association of Boards of Pharmacy is holding its annual meeting in San Diego May 14 -17. This annual meeting is attended typically by the California's Board of Pharmacy's counterparts in the USA. California is thus designated as the host state for this meeting where more than 500 typically attend.

c. Board Member Reimbursement

Board members may seek reimbursement for expenses and per diem payments. These are hours and expenses claimed by board members during the indicated periods are reported during each quarterly board meeting. Board members are paid for each day of a board meeting, but in accordance with board policy, may also submit hours for work performed doing additional board business. It is important to note that these figures only represent hours where reimbursement was sought. It is not uncommon for board members to waive their per diem payments. The most current reimbursement information will be provided at the board meeting.

d. Personnel Update

Board Member Updates

The board currently has one position vacant. This position was formerly held by Rosalyn Hackworth. This position is designed for a public member that will be appointed by the Speaker of the Assembly.

Staff Update

Recent Hires/Transfers/Promotions

- Connie Tang joined the board on 4/13/16 as an Inspector on the Prescription Drug Abuse Team.
- Veronica Wojec joined the board on 4/18/16 as a Staff Services Manager II over Enforcement, CCU, and the Complaint Units.

Recruitments

- One PIO responsible for development of brochures/notices, communication and public education outreach support activities, and liaison with Board Communication and Public Education Committee and DCA Office of Public Affairs.
- One Seasonal Clerk for the Licensing unit.
- Three Inspectors for the Compliance / Routine Inspection teams.
- One Inspector for the Drug Diversion & Fraud team.
- One CEA to serve as Chief of Enforcement over three Compliance Investigation / Routine Inspection teams and one Sterile Compounding team.
- One CEA to serve as Chief of Enforcement over two Drug Diversion and Fraud teams, the Prescription Drug Abuse team, and the Probation / Drug Diversion for Self-Use team.

The following recruitment is for a limited term position.

- One Inspector for the Sterile Compounding Team.

e. <u>Future Board Meeting Dates</u>

1. Remaining Dates Established for 2016

- June 7 & 8, 2016, Location to be determined.
- July 27 & 28, 2016, DCA Headquarters, First Floor Hearing Room, 1625 N. Market Blvd., Sacramento, CA 95834
- October 26 & 27, 2016, Location to be determined.

2. Proposed Dates for 2017

- January 24 & 25, 2017
- May 3 & 4, 2017
- July 25 & 26, 2017
- November 7 & 8, 2017

The locations for the above dates have yet to be determined. Additionally, the dates for the one-day board meetings designated for the purpose of the board to hear petitions have not yet been established. These dates will be provided at the July Board Meeting.

f. <u>Discussion and Consideration of Sunset Review Process and Actions</u>

Attachment 3

1. Board Written Responded Provided in Response to Sunset Issued Identify by the Joint Committee

As part of the Sunset Review process, the Joint Oversight Committee (comprised of members of the Senate Business, Professions, and Economic Develop and members of the Assembly Business and Professions Committee) identified issues that it would like the board to respond. These issues are identified in a committee background paper. Members were provided with a copy of this paper on March 15, 2016.

Board staff worked with the board president and vice-president to provide written responses to each of these issues. **Attachment 3** includes a copy of the final response.

2. Legislative Proposals Resulting from Sunset Review

As part of the Sunset Review process, the board has the opportunity to identify legislative proposals. Provided below are proposals for the board to consider. Staff has worked on these proposals with this committee.

- Technical Changes to Statutes

  Attachment 4

  Several changes were identified that are technical in nature. These proposals include the following:
  - Amendment to Health and Safety Code Section 11164.5 removing an outdated provision that is no longer necessary given the requirements of e-prescribing.
  - Amendment to Health and Safety Code Section 1261.6 restoring a provision that was sunsetted to allow for the use of a security camera as part of the automated delivery system.
  - Amendment to Business and Professions Code Section 4110 and 4127.8 to expand the conditions when the board may issue a temporary license to a pharmacy to mirror the provisions of other license types. Under current law the board can only issue a temporary license to a pharmacy if a change of location or ownership has occurred.
  - Amendment to Sections 4107, 4127, 4127.3, 4127.7, 4127.9, 4128.6 & 4161 to remove strike the word "injectable" or references to requirements prior to SB 294. These amendments are necessary to make conforming changes based on SB 294 (Emmerson, Statutes of 2014) that improved the board's oversight of specialty pharmacies that compound sterile products. Section 4127 also includes amendment to remove the routes of administration for the compounded product as well as the effective date of the statute.

- Proposal to Add Section 4105.5 to the Business and Professions Code Relating to the Registration of Automated Delivery Systems

  Attachment 5

  During the February 2016 board meeting, the board considered a draft proposal

to establish a registration requirement for pharmacies that use automated delivery systems. Subsequent to that meeting, staff has been working with the board president and vice-president to refine the language. **Attachment 5** includes the revised proposal.

- Proposal to Add Section 4083 to the Business and Professions Code Relating to Recall Notices for Compounded Drug Products

Attachment 6

Recently board staff was alerted to a pharmacy that was performing general compounding in an unsafe fashion. In this case, two MedWatch reports were submitted and ultimately the FDA required the pharmacy to recalls the compounded product. When staff evaluated the scenario, it was determined that the board should receive notification of MedWatch reports as well as recall notices for compounded drug products. **Attachment 6** includes a draft proposal that could be used to facilitate such notification requirements. If the board votes to pursue the draft proposal, board staff will request that the provisions be included in the board's sunset extension bill.

3. Next Step in Sunset Review

Attachment 7

The board's sunset extension provisions are contained in Senate Bill 1193. This measure passed out of Senate Business, Professions and Economic Development Committee on April 18, 2016 and was referred to Senate Appropriations.

The board's fee proposal, which is contained in Senate Bill 1039, passed out of committee as well and was referred to Senate Appropriations.

The board may wish to discuss the next steps in the sunset review process.

g. Discussion of Implementation of Assembly Bill 15 (Chapter 1, Statutes of 2015-16 Extraordinary Session) End of Life Option Act

Attachment 8

On October 5, 2015, Governor Brown signed the End of Life Option Act (Act). The provisions take effect June 9, 2016. This new law may impact pharmacists who may be asked to assist patients in this process in a very prescribed manner.

This law allows a Californian with a terminal illness and who complies with specified criteria to end his or her life through the voluntary self-administration of lethal medications, expressly prescribed by a physician for that purpose. The law is very specific and contains procedures that physicians, pharmacies and patients need to follow. There are no exceptions to the requirements specified in the law.

Very generally, to qualify for a prescription for medication under the End of Life Option Act, a patient must be:

- A resident of California (specific qualifying criteria are provided in the law);
- 18 years of age or older;
- Mentally competent, i.e., capable of making and communicating your health care decisions; and
- Diagnosed with a terminal illness that will, within reasonable medical judgment, lead to death within six months.

The patient must be able to self-administer and ingest the prescribed medication. Two physicians must determine whether all these criteria have been met.

The attending physician, if he or she possesses specified criteria and with the consent of the qualified individual (the patient), may contact a pharmacist, informing the pharmacist of the prescriptions and delivering to the pharmacist the written prescriptions personally, by mail or electronically. The pharmacist may dispense the drug to the qualified individual, the attending physician or a person expressly designated by the qualified individual and with the designation delivered to the pharmacist in writing or verbally.

The law requires that a specified request form for an aid-in-dying drug include, among other things, the following statement:

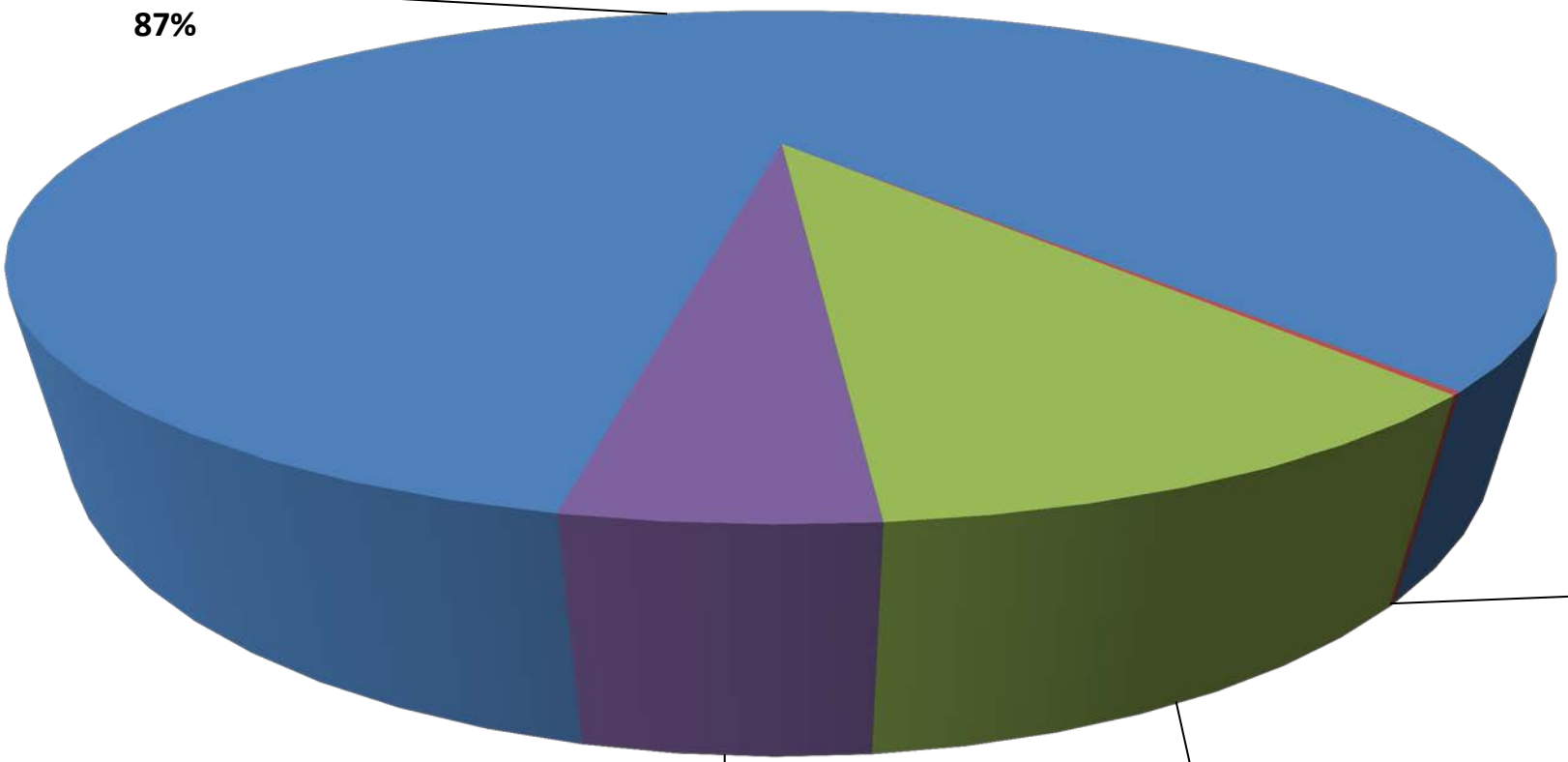
> *I request that my attending physician prescribe an aid-in-dying drug that will end my life in a humane and dignified manner if I choose to take it, and I authorize my attending physician to contact any pharmacist about my request.*

The law also requires that a person who has custody or control of any unused aid-in-dying drugs prescribed pursuant to the Act after the death of the patient shall personally deliver the unused aid-in-dying drugs for disposal by delivering it to the nearest qualified facility that properly disposes of controlled substances, or – if none is available – the person shall dispose of it by lawful means in accordance with guidelines promulgated by the California State Board of Pharmacy or a federal Drug Enforcement Administration approved take-back program.

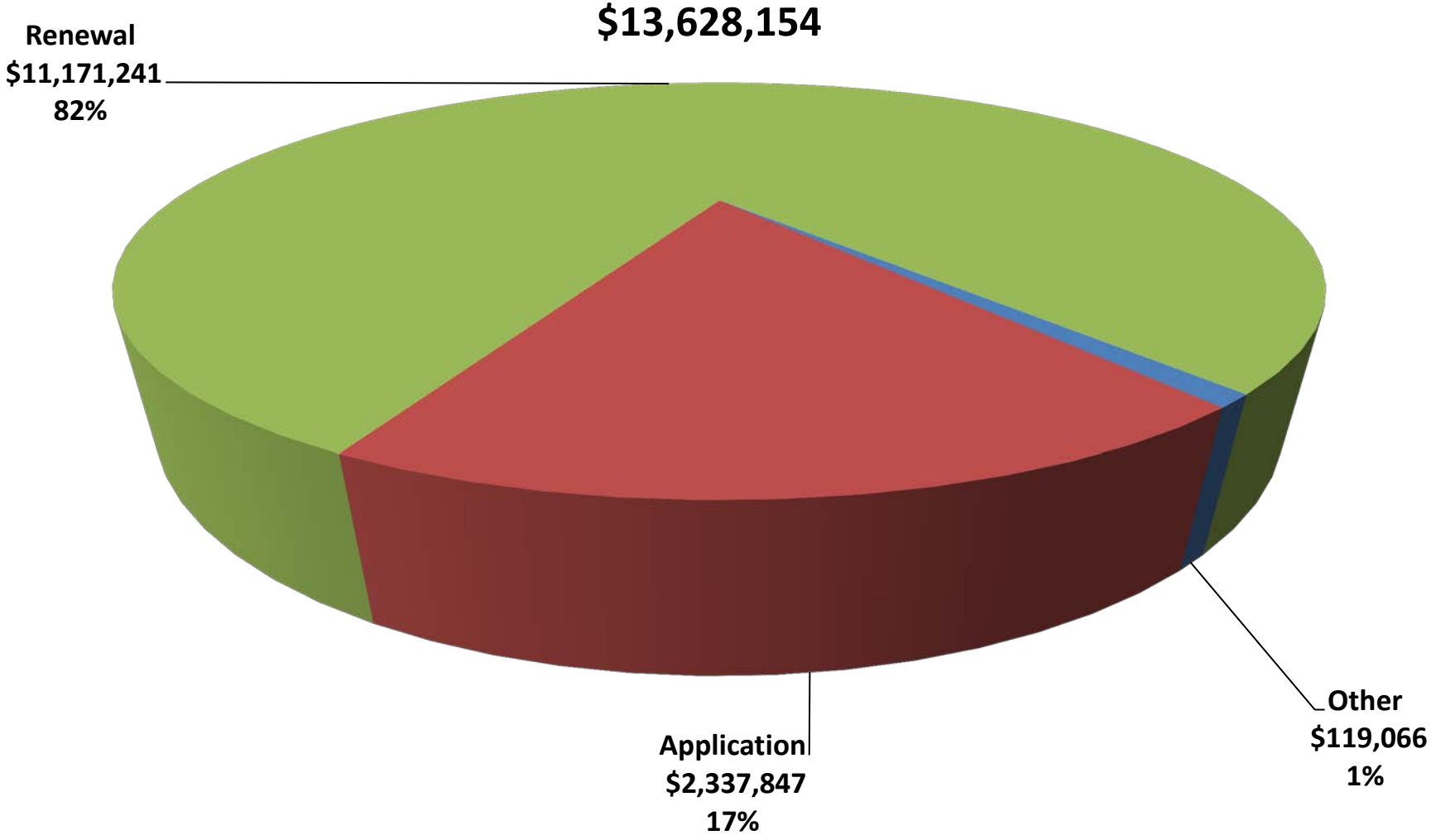
A copy of End of Life Options Act, which was enacted as Chapter 1, Statutes of 2015-16 Second Extraordinary Session, is provided in **Attachment 8** along with a draft of a newsletter article discussing the provisions.

Attachment 1

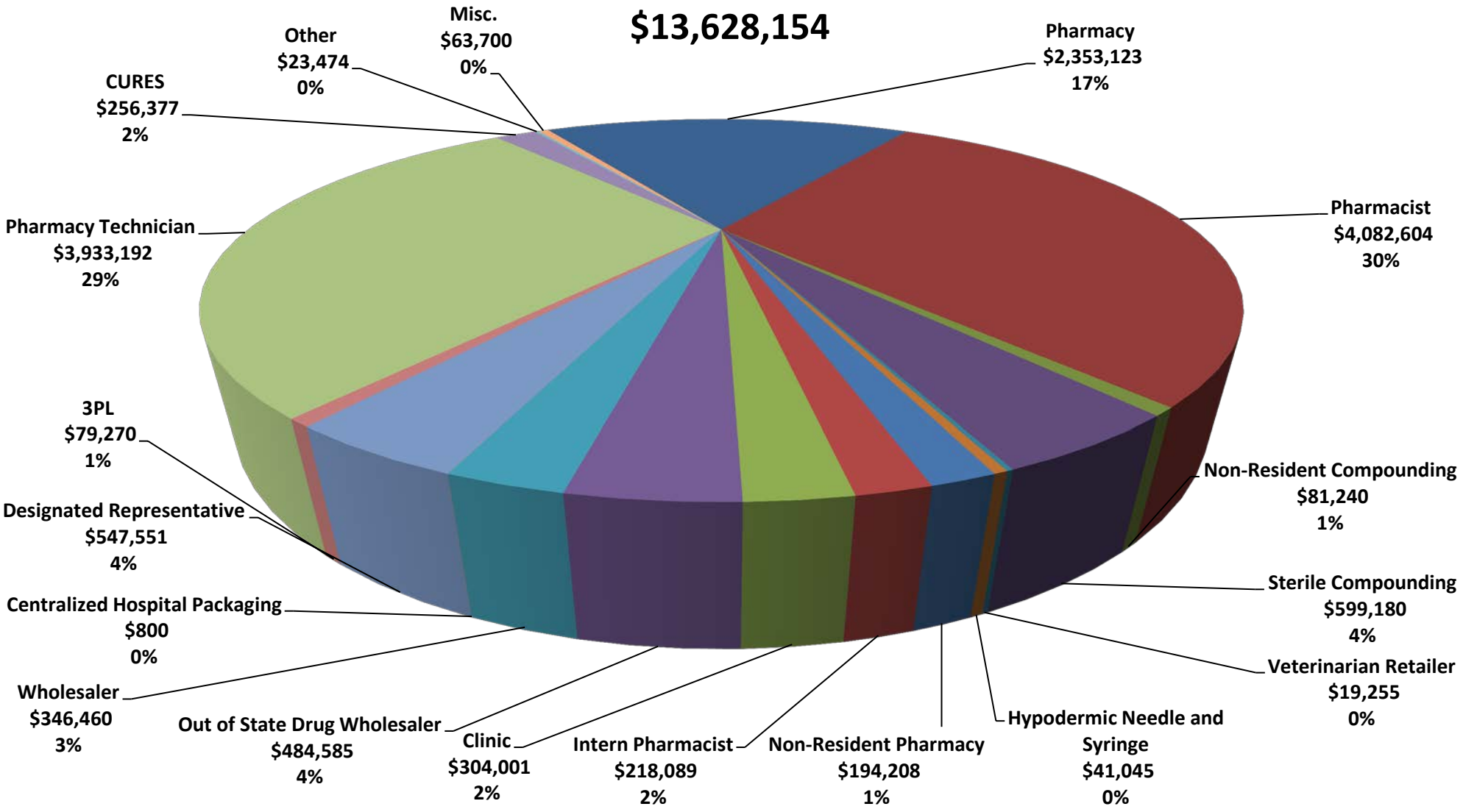
Origin of Revenue
FY 2015/2016
FM 9
$15,742,900



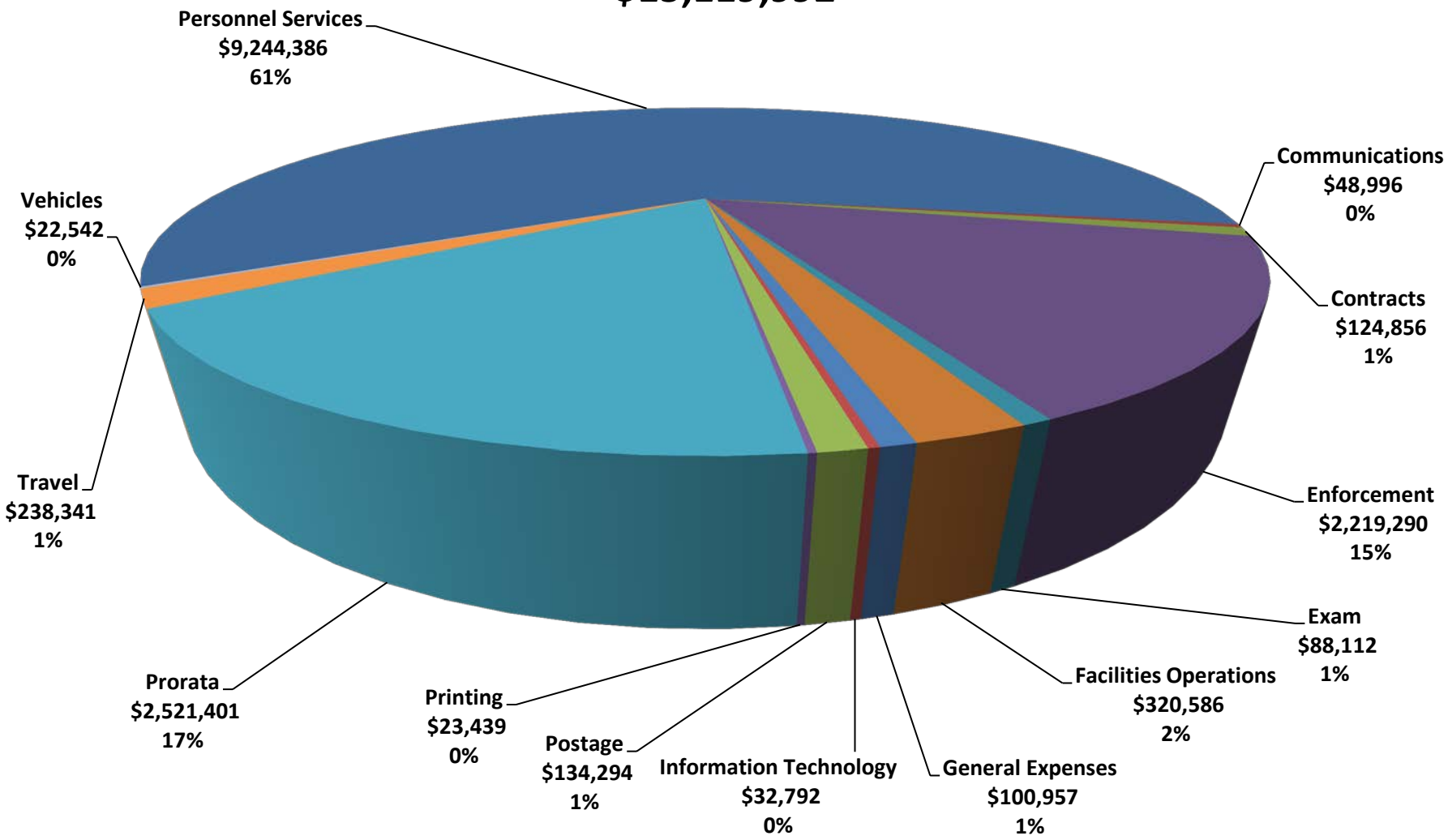
Application vs. Renewal
FY 2015/2016
FM 9
$13,628,154



Revenue by Program
FY 2015/2016
FM 9
$13,628,154



Expenditures
FY 2015/2016
FM 9
$15,119,992



Attachment 2

0767 - State Board of Pharmacy
Analysis of Fund Condition

4/11/2016

(Dollars in Thousands)

2016-17 Governor's Budget w/ Proposed AG Augmentation

		ACTUAL 2014-15	CY 2015-16	BY 2016-17	BY +1 2017-18
BEGINNING BALANCE		$ 12,770	$ 11,742	$ 6,219	$ 1,821
Prior Year Adjustment		$ 108	$ -	$ -	$ -
Adjusted Beginning Balance		$ 12,878	$ 11,742	$ 6,219	$ 1,821
REVENUES AND TRANSFERS					
Revenues:					
125600	Other regulatory fees	$ 2,074	$ 864	$ 864	$ 864
125700	Other regulatory licenses and permits	$ 3,865	$ 3,508	$ 3,508	$ 3,508
125800	Renewal fees	$ 11,774	$ 11,723	$ 11,723	$ 11,723
125900	Delinquent fees	$ 184	$ 172	$ 172	$ 172
131700	Misc. revenue from local agencies	$ 262	$ -	$ -	$ -
141200	Sales of documents	$ -	$ -	$ -	$ -
142500	Miscellaneous services to the public	$ 1	$ -	$ -	$ -
150300	Income from surplus money investments	$ 33	$ 25	$ 13	$ -
160100	Settlements and Judgements - Anti Trust Actions	$ 4	$ -	$ -	$ -
150500	Interest Income From Interfund Loans	$ -	$ -	$ -	$ -
160400	Sale of fixed assets	$ -	$ -	$ -	$ -
161000	Escheat of unclaimed checks and warrants	$ 21	$ -	$ -	$ -
161400	Miscellaneous revenues	$ 9	$ -	$ -	$ -
Totals, Revenues		$ 18,227	$ 16,292	$ 16,280	$ 16,267
Transfers from Other Funds:					
FO0001	GF loan repay per item 1110-011-0767, BA of 2008				
Transfers to Other Funds:					
Totals, Revenues and Transfers		$ 18,227	$ 16,292	$ 16,280	$ 16,267
Totals, Resources		$ 31,105	$ 28,034	$ 22,499	$ 18,088
EXPENDITURES					
Disbursements:					
0840 State Operations		$ -	$ -	$ -	$ -
1110 Program Expenditures (State Operations)		$ 19,350	$ 20,064	$ -	$ -
1111 Program Expenditures (State Operations)		$ -	$ -	$ 20,652	$ 20,970
Proposed AG Augmentation		**$ -**	**$ 1,716**	**$ -**	**$ -**
8880 FISC (State Operations)		$ 13	$ 35	$ 26	$ -
Total Disbursements		$ 19,363	$ 21,815	$ 20,678	$ 20,970
FUND BALANCE					
Reserve for economic uncertainties		$ 11,742	$ 6,219	$ 1,821	$ -2,882
Months in Reserve		6.5	3.6	1.0	-1.6

Attachment 3

BACKGROUND PAPER FOR
The Board of Pharmacy

(Joint Oversight Hearing, March 14, 2016, Senate Committee on Business, Professions and Economic Development and the Assembly Committee on Business and Professions)

IDENTIFIED ISSUES, BACKGROUND AND RECOMMENDATIONS REGARDING THE BOARD OF PHARMACY

CURRENT SUNSET REVIEW ISSUES

The following are unresolved issues pertaining to the Board of Pharmacy, or areas of concern for the Committees to consider, along with background information concerning the issue of oversight for private postsecondary institutions. There are also recommendations Committee staff have made regarding particular issues or problem areas which need to be addressed. The Board and other interested parties have been provided with this Background Paper and the Board will respond to the issues presented and the recommendations of staff.

BOARD ADMINISTRATION ISSUES

ISSUE #1: (BreEZe.) The Board was originally slated to be a part of the DCA's second release of a new information technology (IT) system but is now included in a third release, which has been cancelled from the current project, and the plans for which are unclear. What is the Board doing in the meantime to address IT needs? Does the Board have systems in place to track key data necessary to identify performance measures and to track important information about its licensees?

Background: The DCA has been working since 2009 on replacing multiple antiquated standalone IT systems with one fully integrated system. In September 2011, the DCA awarded Accenture LLC (Accenture) with a contract to develop and implement a commercial off-the- shelf customized IT system, which it calls BreEZe. BreEZe is intended to provide applicant tracking, licensing, renewals, enforcement, monitoring, cashiering, and data management capabilities. In addition, BreEZe is web-enabled and designed to allow licensees to complete and submit applications, renewals, and the necessary fees through the internet. The public also will be able to file complaints, access complaint status, and check licensee information if/when the program is fully operational.

The project plan called for BreEZe to be implemented in three releases. The first release was scheduled for July 2012. The Board was originally scheduled for inclusion in Release 2 of the project. As the Board began the steps towards transition to the new system, two board staff were assigned to assist in the development of components that could meet the Board's needs. According to the Board, these staff spent a considerable amount of time working on the preliminary configuration for the Board's conversion into the new system. However, as the configuration progressed, Board staff identified key functionality absent from the system that was critically needed by the Board.

The Board has now been pushed back to Release 3 of BreEZe, but under Special Project Report 3.1 that outlined the changing scope and cost of the BreEZe project, Release 3 was removed from the project entirely. DCA currently has no formal plan to expand BreEZe to the 19 boards in Release 3. Instead, DCA first intends to conduct a cost-benefit analysis for Release 3 boards after Release 2 is completed in 2016 and then make a decision about whether boards previously slated for Release 3 of the project will come onto BreEZe and if so, how that will be implemented. It is not clear whether the system has been evaluated to meet the needs of Release 3 entities like the Board, many of which are facing significant operational challenges due to their lack of dynamic IT capacity. To date the Board has contributed $1.5 million towards this upgraded system.

It would be helpful for the Committees to understand what the plan is moving forward for the Board and any IT upgrades. It would also be helpful to understand, particularly given the Board's fiscal issues as discussed later, what future costs are anticipated.

Staff Recommendation: ***The Board should provide the Committees an update on the status of Release 3 of BreEZe, as they have been advised by the DCA, and should provide the Committees a breakdown of charges the DCA has told the Board they will be paying for BreEZe in FY 2016/17 and ongoing. The Board should report whether it is currently using any workaround systems to meet data tracking needs.***

Board Response: The board has been advised by the DCA that consistent with the findings of the California State Auditor's *California Department of Consumer Affairs' BreEZe System* audit, the department will be conducting a thorough cost/benefit analysis of the BreEZe system before it moves forward with the remaining agencies. The timeframe for completion of this analysis is currently unclear. In the interim the board has asked the department to consider options that will allow the board to accept credit card payments for renewals as a stop gap measure to increase services to our licensees.

Further, as the outcome of the cost/benefit analysis is currently unknown, the board will consider pursuing the Stage-Gate process established by California's Office of Technology which is the process now required by the state to identify and procure new IT solutions.
To date the board has incurred the following BreEZe costs:

Pre 2011/12	$72,156
2011/12	$214,509
2012/13	$134,555
2013/14	$396,747
2014/15	$203,760
Sunset Review Years	$949,571
2015/16	$536,529
2016/17	$474,871
Total Forecast Costs	$1,011,400
Total BreEZe Costs	**$2,033,127**

The board has been advised that it could be added to Release 3 of BreEZe. Initial information provided to the board some time ago was that the transition would begin in December 2016.

The board has more than 20 workaround systems currently in place to track workload; hopefully many of these would no longer be needed if the board transitions to BreEZe.

ISSUE #2: (REGULATIONS.) The Board is tasked with implementing a number of pieces of recently enacted legislation through the promulgation of regulations. The Board also may initiate a rulemaking package to address other important issues. How are regulations prioritized? How are staff resources dedicated to the Board's many rulemaking packages?

Background: Since the prior sunset review, the Board has initiated and adopted 11 regulatory proposals, has initiated and withdrawn 4 regulatory proposals, had 1 regulatory proposal denied by the Office of Administrative Law and, as of November 5, 2015, has 14 regulatory proposals in progress. The scopes of these rulemaking packages is broad and include (but are not limited to) a range of topics from updating applications for pharmacy technicians to outlining procedures for the take back of prescription drug medication to establishing a state protocol to allow pharmacists to provide self-administered hormonal contraception. The Board maintains that it must "remain vigilant in evaluating regulations, working to remove outdated provisions while securing changes necessary to amend existing regulations to strengthen its role as a consumer protection agency or provide additional guidance and clarification to licensees on legal requirements".

Some regulatory packages take significantly longer than others and it would be helpful for the Committees to know how rulemaking needs are prioritized. It would be helpful to understand what leads to delays in rulemaking related to implementation of statute (for example, the drafting of a statewide protocol for pharmacists to provide hormonal contraceptives as discussed further in Issue #15).

It would also be helpful to understand what legal support the Board receives to swiftly draft regulations and when the Board proposes rulemaking in response to perceived attention or action by the Legislature. For example, the Board moved in Fall 2015 to initiate rulemaking related to the take back of drugs at pharmacies and by Board licensees, an issue that the Legislature has proposed and enacted legislation on since 2006. A number of local ordinances throughout the state *require* pharmacies to take back medication but the Board's proposed language asserts that pharmacies *may* take back medication according to certain standards and with certain safeguards in mind. The Board itself sought clarification on preemption and whether local ordinances would supersede the Board's rule or vice versa. Particularly as this remains an important national issue, it would be helpful for the Committees to understand the Board's efforts, rationale for regulatory efforts and impacts of Board rules on issues that continue to be debated by the Legislature.

Staff Recommendation: ***The Board should advise the Committees its regulation package prioritization and how the Board determines when to proceed with initiating a new rule or amending current rules. The Board should also report to the Committees on regulatory action necessary to implement recently enacted legislation. The Board should report to the Committees on whether it takes preemptive regulatory action when the Legislature is discussing statutory changes.***

Board Response: The board has regulations that are short and very specific as well others that are technical, complex and lengthy. For example, currently pending are regulations that substantially enhance regulation of compounding, establish protocol parameters for drug take-back programs in pharmacies, establish licensure requirements for advanced practice pharmacists, and require monthly or quarterly medication reconciliation by pharmacies to identify drug losses more quickly. These examples demonstrate the robust and complex regulatory scheme under the board's jurisdiction.

Most regulations undertaken by the board are major regulations. The board prioritizes rulemakings based on their impact to public health and safety. Regulations designed to improve efficiencies,

streamline processes, etc., many times are not a top priority given the importance of other pending issues and their direct impact on public health and safety.

The rulemaking process established in the APA is lengthy and requires the review of multiple agencies. The board currently has 15 regulations pending. Of those pending 12 are in response to enacted legislation. To provide greater transparency in the current status of each regulation, the board has expanded the information available on its website about rulemakings to include the current status.

The current status of the 12 regulations is:

Regulations Pending that Were Promulgated to Implement or Clarify Legislation

1. Patient-Centered Labels for Prescription Containers (updating existing regs): Awaiting board review of comments submitted which will occur at the April 27, 2016 Board Meeting

2. Travel Medications: Second 15-day comment period closed April 12, 2016. Awaiting board review of comments submitted which will occur at the April 27, 2016 Board Meeting

3. Drug Warning Labels: Awaiting board review of comments which will occur at the April 27, 2016 Board Meeting

4. Disciplinary Guidelines: Awaiting board review of comments submitted during the second 15-day comment period which will occur during the April 27, 2016 Board Meeting

5. Advanced Pharmacist Qualification Methods (sections 1730, 1730.1 1749): Board's work completed: rulemaking file undergoing review by DCA

6. Advanced Practice Pharmacist Qualification Methods (section 1730.2): Board's work completed: rulemaking file undergoing review by the DCA

7. Vaccinations: Board's work completed: rulemaking file undergoing review by DCA

8. Compounded Drug Preparations: rulemaking file undergoing review by DCA

9. Self-Assessment Form Revisions: rulemaking file undergoing review by the Office of Administrative Law

Other Regulations

1. Drug Take Back: 45-Day public comment period closed March 28, 2016. Public hearings held April 13, 2016. Board to review comments at board meeting on April 27, 2016.

2. Board Accredited Continuing Education: 45-Day public comment period closed December 28, 2015. Hearing held February 2, 2016. Board to review comments at board meeting on April 27, 2016

3. Reconciliation and Inventory Report: 45-Day public comment period closed. Hearing held February 2, 2016. Board to review comments at board meeting on April 27 2016

Generally legislation is enacted first, and regulations are developed to implement the legislation. Because of the uncertain nature of legislation, it is hard to forecast what components will be enacted and what, if any action may be necessary by the board. As such the board initiates rulemaking following enactment of legislation once the provisions are finalized.

BOARD BUDGET ISSUES

ISSUE #3: (FUND CONDITION AND STAFFING LEVELS.) The Board's staff continues to grow yet delays in certain application processing and workload continue. Is the Board appropriately directing staff resources to meet its needs? Does the Board focus too much on boosting enforcement staff? The Board is also facing a serious deficit and may need to raise fees to continue to do its job. However, fee caps were just raised through legislation in 2009. Is the Board's program growing beyond what fees can cover? Did the Board properly evaluate licensing fees for new categories like sterile compounding facilities located in other states that provide drug products to California?

Background: Since the prior review, the Board has experienced a 51 percent increase in authorized expenditures. Revenue has not kept pace with this level of spending and the Board is projected to have depleted its fund sometime in FY 2017/18 given the current structure. As the Board's program has grown, it has received authority for an increase in staff positions, specifically the approval of five BCPs since FY 2013/14. However, the Board is facing backlogs in processing applications and appears to focus primarily on enforcement rather than other program functions. The Board has also made significant budget adjustments, to the tune of over $1.5 million, for costs related to the BreEZe program which the Board now has no future plans to be a part of.

The Board is currently authorized in the Governor's 2016/17 budget for a total of 100.7 positions. The Board has also submitted two budget change proposals (BCPs) requesting to transition eight limited term positions that it was authorized in FY 2014/15 to permanent in order to focus on prescription drug abuse issues, and to transition to transition 5.5 limited term positions that it was authorized in FY 2014/15 to permanent in order to inspect, investigate, license and review enforcement needs for sterile injectable compounding facilities.

The Board attributes its action to raise fees to the statutory maximum in 2014 to three primary efforts: CPEI, the prescription drug abuse epidemic and the need for greater regulation over pharmacies that compound sterile products.

The national attention to prescription drug abuse, as well as documented impacts of this significant problem, is at an all-time high, with Board licensees directly in the middle of many of these conversations. Federal data for 2014 showed that abuse of prescription pain killers now ranks second, just behind marijuana, as the nation's most widespread illegal drug problem. Abuse can stem from the fact that prescription drugs are legal and potentially more easily accessible, as they can be found at home in a medicine cabinet. Data shows that individuals who misuse prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a health care professional and thus are safe to take under any circumstances. The Board has a RX Drug Abuse team within its enforcement unit and utilizes the AG's Controlled Substance Utilization Review and Evaluation System (CURES) prescription drug monitoring program more than any other regulatory

boards. Pharmacies are required to report the dispensing of controlled drugs to CURES by drug name, quantity, prescriber, patient, and pharmacy and the Board in turn conducts research and monitoring of this data. The Board's current BCP specifically notes that with additional position authority, dedicated staff will continue efforts to use CURES data in Board enforcement efforts.

The Board has also significantly expanded its oversight role of sterile compounding pharmacies. Compounding pharmacies make drugs, but they are limited to either producing small amounts in response to a specific patient's prescription, or to create a small supply for an identifiable patient population to ensure continuity of treatment. In October 2012, the New England Compounding Center (NECC), based in Massachusetts, shipped contaminated product throughout the country, including California, that resulted in the death of more than 40 people and illness in more than 450 patients from NECC's tainted steroid injections. The Board was concerned that it did not have the opportunity or authority to inspect NECC or prevent NECC from shipping products into California until patients in other states had already been harmed, and subsequently sponsored SB 294 (Emmerson, Chapter 565, Statutes of 2013) which requires an inspection by the Board prior to licensure for all compounding pharmacies that make or distribute compounded drugs in California, including those located within the state and those located in other states that ship products into California for use by California patients. The current fee for nonresident sterile compounding pharmacies is $780, which the Board now believes is substantially less than the true cost of regulating these entities.

The Board has provided a fee audit to the Committees and responded to a fee background questionnaire from the Committees, in which it proposes new statutory minimum and maximum fees.

Initial Fees

Fee Type	Current	Proposed	Proposed	Change from
Centralized Hospital Packaging	$800	$820	$1,150	3%
Designated Representative Certificate – Third Party Logistics Provider	$330	$150	$210	-55%
Designated Representative Certificate – Veterinary Food-Animal Drug Retailers	$330	$150	$210	-55%
Designated Representative Certificate – Wholesalers	$330	$150	$210	-55%
Hypodermic Needle and Syringe	$165	$170	$240	3%
Intern Pharmacist	$115	$165	$230	43%
Non-Resident Pharmacy	$520	$520	$570	0%
Non-Resident Sterile Compounding	$780	$2,380	$3,335	205%
Non-Resident Third Party Logistics Provider	$780	$780	$820	0%
Non-Resident Wholesaler	$780	$780	$820	0%
Pharmacist Initial License Fee	$195	$195	$215	0%
Pharmacist Licensure Exam	$260	$260	$285	0%
Pharmacy	$520	$520	$570	0%
Pharmacy Technician	$105	$140	$195	33%
Sterile Compounding	$780	$1,645	$2,305	111%
Third Party Logistics Provider	$780	$780	$820	0%
Veterinary Food-Animal Drug Retailer	$425	$435	$610	2%
Wholesale Drug	$780	$780	$820	0%

Renewal Fees

Fee Type	Current Fee	Proposed Statutory Minimum	Proposed Statutory Maximum	Change from
Designated Representative Certificate – Veterinary Food-Animal Drug Retailers Renewal	$195	$215	$300	10%
Designated Representative – Wholesalers Renewal	$195	$215	$300	10%
Hypodermic Needle and Syringe Renewal	$165	$200	$280	21%
Non-Resident Pharmacy Renewal	$325	$325	$360	0%
Non-Resident Sterile Compounding Renewal	$780	$2,270	$3,180	191%
Non-Resident Third Party Logistics Provider Renewal	$780	$780	$820	0%
Non-Resident Wholesaler Renewal	$780	$780	$820	0%
Pharmacist Renewal	$195	$360	$505	85%
Pharmacy Renewal	$325	$665	$930	105%
Pharmacy Technician Renewal	$130	$140	$195	8%
Sterile Compounding Renewal	$780	$1,325	$1,855	70%
Third Party Logistics Provider Renewal	$780	$780	$820	0%
Veterinary Food-Animal Drug Retailer Renewal	$325	$330	$460	2%
Wholesale Drug Renewal	$780	$780	$820	0%

There is no doubt that the Board is a key player in all of these important issues but it would be helpful for the Committees to better understand the Board's justification for prioritizing certain efforts and how cost estimates are made to ensure that regulatory fees pay for the Board's regulatory activities. It would also be helpful for the Committees to understand whether the Board believes it will require additional fee increases in coming years, what feedback it receives from licensees on fee increase efforts and what the Board can do to partner with agencies and existing resources to continue to do its important work without having to negotiate fee cap raises within a short period of time.

Staff Recommendation: ***The Board needs to provide information to the Committees outlining efforts to maintain a healthy fund condition, even as it works on important issues with national attention. The Committees may wish to require the Board to conduct workload analyses related to certain licensing categories to determine where certain processes can be streamlined for less complicated licenses. The Committees may wish to amend the Pharmacy Law to allow the Board to raise the statutory cap on fees.***

Board Response: The board believes it needs to be frugal but prudent in its budget. Since the last sunset review, the board pursued budget augmentations to address emerging public health issues such as prescription drug abuse, sterile compounding and the Consumer Protection Enforcement Initiative. As a result the board staffing and approved expenditure levels have increased.

The board has for several years recognized that it will need to increase fees to maintain its current operational structure and staffing. This subject is discussed at every board meeting via a budget report which details the board's expenditures and revenue.

Recognizing that a fee increase would be needed in the future and to ensure application and renewal fees are commensurate with the costs to deliver the service, the board undertook a fee analysis by the DCA. Based on the findings of the DCA, the board is seeking to modify its current fee structure contained in Business and Professions Code section 4400. The board's legislative solution includes immediate changes to 21 fees, including 18 that will be immediately increased upon implementation of the legislation and three fees will be immediately reduced. For all other fees where a proposed change is being sought, the current statutory maximum is becoming the new statutory minimum and a new maximum would be established.

The board also strives to become more efficient as a part of its normal operations. For example, the board has secured both legislative and regulation changes to streamline application processes. Senate Bill 590 (Stone, Chapter 147, Statutes of 2015) streamlines the application process for recent pharmacy school graduates seeking licensure as a pharmacist.

The board also has completed and submitted the Fee Background Information Questionnaire required by the Sunset Review Committee.

The board welcomes the opportunity to work with the committee on this issue.

LICENSING ISSUES

Background: The Board's failure to timely issue a license to an individual or entity prevents or at least delays that individual or business from working. For example, if the Board delays a licensing decision because it is investigating an applicant's criminal background, the job intended for that applicant may be given to another individual. As a result, the Board's delay in licensing, while often necessary, has a direct impact on consumers and practitioners.

The Board aims to issue a permit as quickly as possible once the applicant has been determined to be qualified for licensure. The Board notes that it works with applications from new businesses that must be licensed by the Board, and strives to ensure that they can open on the date they desire, even when they turn applications in very close to the desired opening date. According to the Board, this usually can be accomplished but there are a number of components that must be completed before an applicant can receive a new pharmacy or wholesaler license. The Board does have the ability to issue temporary licenses to pharmacies and wholesalers if a certain number of requirements are fulfilled, which in turn permits the new business to operate and the Board can then finalize review of the licensing documents over the course of 180 days.

Below are the Board's timelines for licensing for the past four FYs:

	FY 2011/12		***FY 2012/13***		***FY 2013/14***		***FY 2015/15***	
Application Type	*Rec'd*	*Days*	*Rec'd*	*Days*	*Rec'd*	*Days*	*Rec'd*	*Days*
Pharmacy Technician	9,491	110	8,741	70	8,211	89	7,151	93
Pharmacist Exam	2,467	35	1,805	32	2,682	38	3,122	46

The Board states that fluctuations in licensing are due to a number of factors including staff vacancies, new licensing programs which lead to staff resources being redirected, sudden surges in workload related to peak cycles times (graduation dates) and large buyouts of chain store pharmacies. The
Board states that it is currently focusing on timely processing of applications and recently reinstituted a quarterly review of all of its pending applications which is intended to serve as another opportunity for the Board to reach out to applicants and request necessary information before an application would otherwise be withdrawn. The Board projects, based on recent efforts in this area, that completing this review quarterly will result in deficiencies being remedied more quickly and licenses being issued faster. As of October 30, 2015, the Board had over 2,500 pending applications for initial licensure.

As a means of decreasing processing times, the Board highlights that it is working to secure additional resources as well as improving application instructions and educating applicants about the requirements for licensure. The Board is working to simplify and clarifying instructions and

applications as a means of reducing the number of deficiencies on initial applications, thereby reducing the overall application processing times. The Board has discussed application requirements during Board and committee meetings that are webcast, highlighting application requirements as well as common deficiencies and is working to develop videos that will also serve to assist applicants through the application process.

The Board may also benefit from a statutory clarification related to processing timelines for applications filed by clinics opening a new location, reporting a change to an existing location or updating certain information like changes to corporate officers. Similarly, a streamlined process for commonly-owned clinics to use just one application may speed up timelines and improvements may be realized if clinic corporations owning more than one Board-licensed clinic are authorized to renew all of their permits at one time.

Staff Recommendation: ***The Board should provide the status of its licensing backlog. The Committees may wish to amend the Pharmacy Law to require clinic applications to be processed within 30 days, to create a streamlined process for commonly-owned clinics to report organization-wide changes in corporate officers, consulting pharmacists and medical directors and to create one renewal date for all clinic permits, ensuring that commonly owned clinics could be renewed in a timely manner.***

Board Response: The board recognizes its role in helping individuals and businesses create jobs in California. The board strives to ensure its application processes are consistent, reliable and timely, and strives to remove unnecessary barriers to licensure.

The board does not believe it currently has a backlog of applications. The board did have delays in processing applications during mid-2014 through 2015 due to significant expansion of one licensing program and the creation of two others, coupled with staff vacancies.

The board believes it now has acceptable processing times, with initial processing times for all license types at or below 30 days following receipt. The board has also developed a system to ensure that deficient applications do not languish. The board has one staff member who reviews deficient files and works with applicants to complete the licensing process. Further the board has undertaken a modest education campaign to ensure applicants understand the application process and requirements. If the board is able to reduce the number of applications that are submitted with deficiencies, individuals and businesses will benefit by becoming licensed more readily and staff time currently spent resolving deficiencies can be redirected to initial processing.

By law, the board issues a license to a site, not a corporation. The board uses a headquarters system to manage large chain store ownership information centrally. The board's computer system is programmed to accommodate this structure. For smaller organizations the board creates a "masterfile" that retains centralized information for the various licensed locations.

The board has recently worked with a large California clinic system to establish a centralized file to track ownership and medical directors. The board is committed to continuing its efforts to address concerns of this organization and others, and streamline reporting of changes in personnel where possible. The board will explore options to facilitate use of a single expiration date for clinics under common ownership.

ISSUE #5: (OUTSOURCING FACILITIES). Should the Board license outsourcing facilities to align its regulatory system with the FDA and other states?

Background: The federal Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013. Prompted by the fatal fungal meningitis outbreak in 2012 linked to unsanitary conditions at a Massachusetts compounding pharmacy, as well as concerns regarding increases in counterfeit, falsified, substandard and dangerous prescription medications, DQSA contained two parts – the Compounding Quality Act and the Drug Supply Chain Security Act.

The Compounding Quality Act created a voluntary compliance regime in which large-scale compounding pharmacies may voluntarily register as "outsourcing facilities" and be subject to oversight by the Food and Drug Administration (FDA) in much of the same way that traditional pharmaceutical manufacturers are monitored. These facilities must adhere to more stringent current good manufacturing practices and are subject to a risk-based inspection schedule. The FDA has registered 59 outsourcing facilities, three of which are in California.

California law does not currently recognize outsourcing facilities because state law authorizes only limited anticipatory pharmacy compounding, either for prescriber office use or to meet customary demand. For a number of years, the Board and other federal and state regulatory agencies have grappled with establishing a tipping point at which a pharmacy compounds enough medications to become a manufacturer.

The Board currently licenses entities that would be considered outsourcing facilities as sterile compounding pharmacies – "resident" if they are located in California and "non-resident" if located out of state and ships into California. There is no distinction between large scale and small scale facilities.

However, this regulatory system is losing its viability as a solution for two reasons. First, it does not recognize the federal outsourcing requirements that permit large scale compounding. Second, it does not align with other states' systems; multiple states are moving to establish regulatory frameworks to license outsourcing facilities as separate entities and some prohibit licensure of these facilities as sterile compounding pharmacies, contrary to California's structure.

In 2015, the Board sponsored legislation (SB 619, Morrell) to license outsourcing facilities. The Board believes that licensing these entities both within and outside California will ensure that the state's hospitals and practitioners have access to high quality, carefully compounded sterile medication.

Staff Recommendation: ***The Committee suggests adding an outsourcing facility license to the Pharmacy Law and recommends that the Board conduct a careful calculation of costs associated with regulating these facilities to ensure that budget imbalances do not result (in the event that the workload and travel necessary for the scope of this work) exceed the revenue from fees.***

Board Response: The board believes that creating a separate license for outsourcing facilities (also known as 503B facilities) is necessary, given that these new entities require separate regulations from pharmacies that prepare patient-specific sterile compounds. The regulation of outsourcing facilities under this new license structure is necessary to ensure the quality of sterile compounded

medication made available to the state's hospitals, practitioners and patients. The board also believes that a separate set of regulations are necessary to ensure that these entities comply with the FDA's requirements. The board will carefully evaluate the necessary fees and costs associated with regulating the facilities based on its experience in regulating compounding pharmacies. It is also contacting other agencies that regulate similar types of entities to validate board workload and resource requirement estimates. The board welcomes the opportunity to work with the committee on this issue.

ISSUE #6: (AUTOMATED DELIVERY DEVICES). The Board has discussed instances where machines dispense and provide medication, focusing on the need for accountability for the inventory when emerging technologies are used for medication delivery. Should operators of Automated Delivery Devices be required to register use of these devices with the Board? What would registration mean for the Board's licensing backlogs and enforcement priorities?

Background: Current law authorizes the use of "automated drug delivery systems," which are a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system is required to collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. Under some circumstances the pharmacist must authorize the release of medication.

Pharmacies are able to operate automated delivery devices in various settings away from a licensed pharmacy or within a licensed facility. This includes in skilled nursing homes and other specified health care facilities, certain clinics, and hospitals for drug storage and access outside of the pharmacy.

The demand for additional use of these delivery devices is growing. A pilot study is currently underway that would allow patients to pick up medication from a delivery device that is not specifically located in a pharmacy so long as patient consultation is first provided.

The Board reports that it is not currently able to track how many of these delivery devices are in use, where they are in use, or which pharmacy is responsible for specific delivery devices. A registration would enable the Board to identify which pharmacies operate these delivery devices and where each is located.

Staff Recommendation: ***The Committees may wish to authorize the Board to establish a registration requirement that links automated delivery device systems to the pharmacy that owns and is responsible for the medications stored and released from the device. As part of the registration, the Committees may wish to require that the Board is provided with the policies and procedures that demonstrate appropriate security of the device and how patient consultation is being provided. Registration of these systems may also require a reporting function to ensure that the Board is made aware of drug losses from the machines, similar to the requirement for pharmacies to report drug loss information.***

Board Response: The board supports the staff's recommendation. The board has developed draft statutory provisions which it will refine during its April 27 & 28, 2016 meeting. The board welcomes the opportunity to work with the committee on this issue.

ISSUE #7: (PROFESSIONAL CORPORATIONS). Should pharmacists be included on the list of individuals who may be a shareholder, officer, or director of a medical corporation?

Background: Corporations Code 13401.5 authorizes the formation of various healing arts professional corporations and establishes which healing arts licensees who are not of the same license type as the corporation may be shareholders, officers, and directors of that corporation. Any person licensed under the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act may be employed by these professional corporations. Thus, the services of professional corporations are not limited to the named profession. For example, a nursing corporation may have a director who is a chiropractor, a shareholder who is an acupuncturist, and employ an accountant, podiatrist, and a marriage and family therapist, none of which would traditionally be seen as providing the professional services of nursing.

Current law authorizes a medical corporation to have the following licensees as officers, directors, and shareholders:

(1) Licensed doctors of podiatric medicine.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed physician assistants.

(8) Licensed chiropractors.

(9) Licensed acupuncturists.

(10) Naturopathic doctors.

(11) Licensed professional clinical counselors.

(12) Licensed physical therapists.

Stakeholders have requested that pharmacists be added to this list, given the recent expansion of the pharmacists' scope of practice by SB 493 (Hernandez, Chapter 469, Statutes of 2013).

Pharmacy corporations were authorized in 1996 in the Pharmacy Practice Act, rather than the Corporations Code. Current law allows a pharmacy corporation's officers, directors, and shareholders to be anyone who is a "licensed person" as defined in Section 13401 of the Corporations Code:

> "Licensed person" means any natural person who is duly licensed under the provisions of the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act to render the same professional services as are or will be rendered by the professional corporation or foreign professional corporation of which he or she is, or intends to become, an officer, director, shareholder, or employee.

Since the "same professional services" rendered by the corporation is an expansive concept, it can be argued that a physician can be an officer, director, or shareholder of a pharmacy corporation. It follows, then, that it would be equitable for a pharmacist to be an officer, director, or shareholder of a medical corporation.

Staff Recommendation: ***Pharmacists should be added to the list for medical corporations. In addition, the Board should examine the other professional corporations authorized by the Moscone-Knox Professional Corporation Act and determine whether there are others to which it makes sense for pharmacists to be added as officers, shareholders, or directors.***

Board Response: This policy issue is the subject of 2016 legislation. The board has not yet had an opportunity to discuss or review this policy issue but will do so during its April 27 & 28, 2016 meeting.

ENFORCEMENT ISSUES

ISSUE #8: (ENFORCEMENT PRIORITIZATION.) The Board has taken on a substantially expanded role in response to heightened attention to certain issues, and this attention is impacting its workload. There have been concerns that pharmacy inspectors may be looking for violations or responding to heightened attention on certain issues that are impacting pharmacy inspections. How does the Board prioritize enforcement efforts and outcomes?

Background: The Board's enforcement roles continue to evolve and grow. While the Board is a regulatory body with the ability to take administrative action against licensees, it participates in joint investigations with the Department of Health Care Services, Department of Public Health, FDA, FBI, Drug Enforcement Administration and other local, state and federal law enforcement agencies.

The Board reports that as part of all complaint investigation assignments, a case priority is established by a supervising inspector. The Board reports that it uses a case prioritization system tailored to meet the diversity of individual licensees and practice settings that the Board regulates, specifically:

> Priority 1 and 2 investigations are the most serious and pose the highest risk to the health and safety of the public. Examples of priority 1 and 2 investigations include reports of an impaired licensee on duty, prescription drug theft by a licensee, a pharmacy operating without a pharmacist on duty, large controlled substances losses, sterile compounding violations and unauthorized furnishing of prescription drugs and/or controlled drugs. Priority 1 and 2 complaints are those complaints that generally will be referred to the AG for formal disciplinary action. Accusations are filed in these serious cases and the Board states that it vigorously pursues the appropriate disciplinary penalty, either through the administrative hearing process or through a stipulated settlement.
>
> Priority 3 and 4 complaints are less serious and pose a lower risk to the health and safety of the general public but are still important. Examples of priority 3 and 4 investigations include reports of failure to provide patient consultation, prescription errors that do not result in patient harm, working on an expired license and general noncompliance issues. Priority 3 and 4

complaints typically result in the issuance of a citation, citation and fine or letter of admonishment. Priority 3 and 4 complaints, while lesser in priority, are nevertheless very important to the consumer who files the complaint.

The Board highlights the following violations investigated by the Board:

A pharmacy has numerous medication containers that are overfilled with medication, some of which contain pills other than those of the manufacturer indicated on the label. In this case the pharmacy had obtained medications from unauthorized sources. The Board secured an interim suspension order (ISO) against the licensees involved and ultimately the licenses were revoked.

A pharmacist unlawfully accessed the confidential health information of coworkers hundreds of times. The Board secured an ISO against this pharmacist and ultimately secured a disciplinary license surrender.

A pharmacy was dispensing pain medication to large numbers of patients, and neighbors of the pharmacy reported observing drug deals taking place in the parking lot. The pharmacy and pharmacist licenses were both revoked.

A pharmacy located out of state shipped contaminated eye medication to physicians in California and patients were seriously injured. The Board issued a cease and desist order to prevent the shipping of additional medication into the state and ultimately secured a disciplinary surrender of the license.

In August 2013, the Board of Pharmacy made a 2012 license revocation case a "precedential decision." In this case, the Board revoked the licenses of both a Huntington Beach pharmacy and its pharmacist because the pharmacist failed to comply with corresponding responsibility requirements in the distribution of opioid drugs. The Decision and Order concluded that a pharmacist must inquire whenever a pharmacist believes that a prescription may not have been written for a legitimate medical purpose and that the pharmacist must not fill the prescription when the results of a reasonable inquiry do not overcome concern about a prescription being written for a legitimate medical purpose. The facts in this case constituted clear violation of law and significant patient harm; however, it would be helpful for the Committees to understand how this precedential decision is being applied and how this case is shaping Board enforcement work.

The Board also has the final authority over the disposition of its cases and is able to take action that may differ from that recommended by an Administrative Law Judge (ALJ). It would be helpful for the Committees to understand how many times the Board has voted to take a different action than that recommended by an ALJ or when the Board continued to take action against a licensee when an ALJ decided in favor of the licensee.

Staff Recommendation: ***The Board should advise the Committees on its case and complaint priorities and how inspectors, licensees and the public are made aware of these. The Board should report to the Committees on other cases that may be adopted as a precedential decision and what this means for enforcement efforts. How does the Board maintain consistency in investigations and enforcement outcomes?***

Board Response: The above summary by the committee accurately conveys the board's priorities when investigating complaints. Staff is made aware of a case priority at the time of assignment.

Further, the board itself publicly discusses its priorities in meetings. Additionally the types of cases referred to any of the board's teams have a certain priority assigned by the type of allegations involved. For example, as stated above, complaints involving a medication error where there is no patient harm does not have the same priority as a pharmacist working under the influence. There are times when as part of an investigation, additional information is obtained that will change the priority of a case. In such a circumstance, the supervisor is consulted.

At time of assignment one of the board's supervising inspectors completes an investigation plan and assessment that ensures consistent factors will be investigated based on the nature of the complaint. Upon completion of the investigation report, the supervisor reviews the case and either approves it or sends it back for additional investigation. A second review is completed by one additional supervising inspector or senior staff member. The case then may be closed no further action, referred for a midlevel sanction (e.g., a citation) or referred for formal discipline. The board is recruiting for two chief of enforcement positions to review cases, adjudicate citation and fine appeals, evaluate trends to increase board consistency and reduce case closure time.

The board notes that while allegations may seem the same, each case is different which warrants separate and independent assessment.

The board is instituting post inspection surveys conducted by a supervising inspector after the board inspects a licensed premises. This information will used to improve board inspections and provide immediate followup to licensees who may have questions about items discovered or cussed during the inspection. The board's supervising inspectors are also going out on inspections at least once each quarter with each of their assigned inspectors. This will increase the consistency of the board's inspections.

The board has only one precedential case at this time. Should other decisions be adopted where broad public policy is involved that supports the board's mandate, the board will consider adopting the decision as an additional precedential decision. Any such decision must be made in a public meeting, with public comment.

As with the current precedential decision the board will educate its licensees through various avenues, as it has in the past. For example, the board developed educational materials that it disseminates at events, included information in its newsletter about the precedential decision, used its listserve to disseminate information and posted information on its website.

ISSUE #9: (CASE TIMELINES.) The Board is experiencing delays in enforcement. What efforts is the Board taking to ensure the timely processing of complaints and investigations? How are licensees and the public made aware of these timeframes?

Background: The Board is responsible for regulating the practice of pharmacy and also works to ensure the safety of drug products dispensed to patients in California. The Board regulates those who handle, store and ship drug products from the manufacturer, through the supply chain, to the pharmacy and ultimately to the patient. The Board's performance objectives for its investigation activities include completing all desk investigations within 90 days, completing all field investigations within 120 days and closing all investigations within 180 days. At the end of FY 2014/15, the Board

completed 43 percent of desk investigations within 90 days, completed 11 percent of field investigations within 120 days and closed 55 percent of investigations within 180 days.

In the three years prior to the last sunset review, the Board received 7,340 complaints. In the three years prior to this review, the Board received 10,399 complaints, a 42 percent increase. To respond to the growing workload, the Board has restructured its organization to include additional enforcement management to assist in coordinating investigation and enforcement activities, aiming to reduce case closure time and bring about more consistent work product and case resolutions. Between 2011/12 and 2014/15, the Board referred 20 percent more cases for investigation. The Board notes that reviewing allegations for the complaints the Board received does not show any significant increases or decreases, with the exception of unprofessional conduct that continues to increase as an allegation.

The Board cites a few reasons for enforcement delays. The Board is working to train new staff, given its 23 percent growth in the past two years in enforcement staff, primarily in the number of field staff. Coordination and consistency among the Board's inspectors and supervisors is an ongoing issue for the Board but the Board reports that it expects case closure times to improve as field staff become more experienced. The Board notes that it sometimes still does not receive data from licensees within the required timeframe, in part because in large corporate structures where a corporate office first has to review information before it is sent to the Board, but attempts to work with licensees to obtain data necessary for investigations. The Board also cites the complexity of the cases necessary for investigation has increased and notes that errant licensees and individuals seem to be more aggressively violating Pharmacy Law.

Staff Recommendation: ***The Board should update the Committees on the steps it is taking to increase efficiencies in enforcement.***

Board Response: Since late-2014, the board's efforts have been to hire and train new inspector staff. Concurrently, the board lost multiple long-term pharmacy inspectors due to retirement (six inspectors and supervising inspectors retired with more than 100 years of aggregate experience). New inspectors have been hired, but much training is needed for these employees to be able to perform all their duties at mastery levels.

On a monthly basis, supervising inspectors review pending cases with each of their assigned inspector team members to address investigative barriers and support the timely completion of work by establishing deadlines.

Additionally board supervising inspectors are specifically being directed to participate in inspections with their subordinate inspectors at least once each quarter to assist staff in the field to oversee inspector training in the field.

As training is completed, investigation times should continue to improve. As of December 31, 2015, 35 percent of field investigations are currently completed within 120 days and 49 percent of all investigations are closed within 180 days. We recognize that investigation times may be improved and we are in the process of improving data tracking to identify mechanisms for improvement.

ISSUE #10: (TIMELY RECEIPT OF INFORMATION.) Healing arts boards are required to take certain steps when they become aware that licensees have been convicted of a crime or entered into a settlement in a civil case. However, delays in receiving documents from other entities can delay investigations. Should other state agencies and courts be required to provide timely information to healing arts boards like the Board?

Background: While the Board is receiving mandatory reports about its licensees (under BPC Section 800) more regularly as outlined above, the Board continues to have challenges obtaining documentation from some law enforcement agencies and state and federal courts that are key to the Board investigating these cases. Historically, documentation like certified court and arrest records, confirmation of criminal probation status, and any outstanding arrest warrants were readily provided to the Board upon request. Now, according to the Board, many arresting agencies and courts now require a fee to release records which requires a state-issued requisition. In addition, the Board is concerned that some agencies take weeks and even months to respond to the Board's requests, regardless of whether they charge a fee. According to the Board, the fees and delays in receiving records hamper the Board's ability to complete investigations in a more timely manner. While the Board uses online court information when available, the information may not provide the necessary details or sufficient evidence.

This issue is not unique to the Board and is a problem faced by other healing arts programs under the DCA.

Staff Recommendation: ***To ensure timely receipt of important information to assist the Board in making determinations about violations of law by licensees, the Committees may wish to require state agencies, upon a written request from a healing arts board, to provide records relevant to a current investigation in a timely manner, ensuring that a board maintains the confidentiality of personal identifying information. The Committees may also wish to clarify that records can be produced prior to receiving payment from a healing arts board so that the procedures involved in receiving approval for, and subsequently submitting payment for, important documents are not the source of delay for a board to obtain information.***

Board Response: The board would support any efforts to assist it in securing necessary arrest and conviction documentation to decrease investigation times. We believe this recommendation from the committees would aid the board in securing this information in a more timely manner.

ISSUE #11: (CEASE AND DESIST FOR UNLICENSED ACTIVITY.) The Board continues to work to prevent unlicensed pharmacy practice. Should the Board be granted additional authority to support these efforts?

Background: As outlined above, the Board continues to focus on unlicensed activity and take swift action to prevent harm to California patients. One particular are of unlicensed activity that the Board has identified is the provision of services to Californians from a business or individual located out of state, that may be licensed to do business in that state, but is not licensed under the Board as a nonresident pharmacy or wholesaler. Sometimes the Board may come across pharmacy services being performed outside of a pharmacy but not licensed by the Board. Periodically, the Board identifies brokers who make prescription drug transactions without licensure; for example, a wholesaler broker offers to sell to a pharmacy prescription drugs, however the broker is not licensed in California as required.

The Board does not currently have the authority to issue a cease and desist order to businesses involved in unlicensed activity. Simply citing and fining an unlicensed business is often an insufficient consequence to stop unlicensed activity because the Board reports that frequently the business will continue to do the very action which violates the law.

Staff Recommendation: ***The Committees may wish to amend the Pharmacy Law to allow the Board to issue a cease and desist order for unlicensed activity.***

Board Response: The board thanks the committees for their consideration of this proposal to allow the board to issue a cease and desist order for unlicensed activity, and welcomes the opportunity to work with the committees on this issue.

ISSUE #12: (UNIFORM STANDARDS FOR SUBSTANCE ABUSE AND THE BOARD'S PHARMACIST RECOVERY PROGRAM.) The Board delayed implementing uniform standards for substance abusing licensees. What is the status of implementation of SB 1441? How does this impact the Board's diversion program?

Background: During the prior sunset review of the Board, the Committee was concerned about the effectiveness of the Board's Pharmacist Recovery Program (PRP) and what steps the Board was taking to adopt uniform standards for substance abusing licenses set forth in legislation.

In 1985, the Board sponsored legislation that required the Board to develop PRP. This program identifies and rehabilitates chemically dependent or mentally impaired pharmacists or interns. The general process requires evaluating the nature and severity of the chemical dependency and/ or mental illness, developing a treatment plan and contract, monitoring participation, and providing encouragement and support for the successful completion of the program, typically in three to five years. The Board sees the PRP as an important enforcement tool and believes it is critical, especially given the nature of pharmacies as a "candy story to a substance abuser who can readily divert drugs sometimes for considerable periods without detection." The Board requires pharmacies to report any admission of chemical, mental or physical impairment affecting an individual's ability to practice safely, any admission or evidence demonstrating such conditions and any termination of a licensee

based on theft, diversion or self-use, allowing the Board to be made aware about drug diversion as well as substance abuse involving Board licensees.

The PRP serves as a diversion program to which the Board may refer pharmacists and interns either in lieu of discipline or in addition to disciplinary action. The PRP is also a confidential source of treatment for pharmacists and interns who may enter the program on a voluntary basis and without the knowledge of the Board. Regardless of the type of referral into the program, all participants are afforded the same treatment opportunities in the PRP. The Board states that the PRP ensures that licensees afflicted with mental illness or chemical dependency receive the treatment and the rehabilitation and monitoring they need to return to normal and productive work. Board policy is to speed the entry into the PRP rather than wait until the completion of an investigation by informally referring pharmacists during the course of an investigation. However, the pharmacist or intern must voluntarily contact the program and undergo an intake evaluation and assessment. This early intervention assists the licensee in beginning his or her recovery, and results in the pharmacist or intern receiving treatment and being monitored while the case is being investigated.

Specially trained board inspectors also make periodic visits to PRP participants' worksites and meet to discuss pharmacy practice issues as well as sobriety. The Board uses this information to validate information provided by the PRP administrator as well as to evaluate the contractor's performance. Participants who are terminated from the program for failure to derive benefit or noncompliance are immediately referred to the Board's Enforcement Unit for investigation and referral to the AG for expedited formal discipline due to the imminent danger to the public of such individuals continuing to practice.

SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) created the Substance Abuse Coordination Committee within the DCA to formulate uniform standards for all healing arts boards to use in dealing with substance abusing licensees. DCA published the "Uniform Standards Regarding Substance-Abusing Healing Arts Licensees" (Uniform Standards) for adoption by all healing arts boards in April 2011.

An October 2011 Legislative Counsel opinion stated that all healing arts boards are required to fully implement the Uniform Standards, whether or not a board has a formal diversion program. The Board disagreed with this analysis and challenged the validity and applicability of the Standards in a 2013 opinion request from the AG. In April 2015, the AG determined that the Uniform Standards were valid, and though the Board is not required to adopt them as regulations in order to be effective, they "must use the uniform standards as written in all cases in which they are found to apply, but the boards retain discretion in applying the uniform standards to particular circumstances and in deciding individual cases." Thus, the Board must use the Uniform Standards generally, but may deviate when necessary.

The Board states that they have been working in a "thoughtful and deliberate manner" to implement the Uniform Standards since they were finalized. Beginning in 2011, the Board heard presentations on the Uniform Standards and initiated a rulemaking to incorporate them into the Disciplinary Guidelines. In FY 2011/12 the Board began publishing the statistics required pursuant to Standard 16 and later worked with DCA to secure the necessary contract changes to align the Board's PRP with the requirements outlined in the Uniform Standards.

Following receipt of the dispositive 2015 AG opinion, the Board reestablished its SB 1441 Uniform Standards Implementation Committee to resume efforts to update the Board's Disciplinary Guidelines. On September 4, 2015, the notice of proposed action along with the proposed text was published by

the Office of Administrative Law for the required 45-day comment period. The proposed regulations were modified following the comment period on October 22, and the new comment period extended to January 6, 2016.

Staff Recommendation: ***The Board should update the Committees on the status of the regulations to incorporate the Uniform Standards into the Disciplinary Guidelines. The Board should provide information for the next sunset review indicating how often it deviates from the Uniform Standards. The Board should provide an update on the audit of the PRP, as required by the Uniform Standards, and provide the Committees with a copy of the audit report upon completion.***

Board Response: As discussed in the board's sunset report, the board has implemented many of the uniform standards. Although the legal opinion provided by the Attorney General's Office concludes that the board does not need to adopt these standards to implement them, the board is currently moving to incorporate provisions of the SB 1441 standards into its *Disciplinary Guidelines*. The board's *Disciplinary Guidelines* already contain several provisions that allowed the board to effectuate the provisions of the uniform standards without a regulation change. For example, the board's current guidelines already allow for drug testing as well as the suspension from practice when an individual tests positive. Staff also uses the testing frequency established in SB 1441 standards when determining the frequency of testing.

The SB 1441 standards were amended into the contract with the vendor that administers the Pharmacist Recovery Program in 2013. Further, below is a chart that details the provisions of the 1441 standards and if the provisions are currently included in the Disciplinary Guidelines

Standard	Currently a term in the board's disciplinary guideline
Standard 1	Term 18 – Mental Health Examination Term 21 – Pharmacist Recovery Program
Standard 2	Term 18 – Optional Language Term 22 – Drug Testing Term 21 – Pharmacist Recovery Program
Standard 3	Term 6 – Notice to Employer Term 21 – Pharmacist Recovery Program
Standard 4	Term 22 – Drug Testing Term 21 – Pharmacist Recovery Program
Standard 5	Term 16 – Attend Substance Abuse Recovery Relapse Prevention and Support Groups Term 21 – Pharmacist Recovery Program
Standard 6	Term 18 – Mental Health Examination Term 21 – Pharmacist Recovery Program
Standard 7	Term 18 – Worksite Monitor (Pharmacy Technicians and Designated Representatives) Term 30 – Supervised Practice (Pharmacist and Interns) Term 21 – Pharmacist Recovery Program
Standard 8	Term 22 – Drug Testing Term 24 – Prescription Coordination and Monitoring of Prescription Drug Use Term 21 – Pharmacist Recovery Program
Standard 9	Term 22 – Drug Testing Term 21 – Pharmacist Recovery Program
Standard 10	Term 22 – Drug Testing Term 18 – Mental Health Examination

	Term 21 – Pharmacist Recovery Program
Standard 11	Term 22 – Drug Testing Term 18 – Mental Health Examination Term 21 – Pharmacist Recovery Program
Standard 12	Term 22 – Drug Testing Term 18 – Mental Health Examination Term 21 – Pharmacist Recovery Program
Standard 13	Contract Requirements for vendor. Not appropriate for Disciplinary Guidelines
Standard 14	Notice requirement. Not appropriate for Disciplinary Guidelines
Standard 15	Audit requirement for vendor. Not appropriate for Disciplinary Guidelines
Standard 16	Statistical reporting requirement. Not appropriate for Disciplinary Guidelines

An outside audit was completed in February 2016 of the current vendor that administers the Pharmacists Recovery Program. The board provided committees' staff with a copy of the audit. The overall conclusion of the audit includes the following:

> "Overall, this audit found Maximus is effectively and efficiently managing the various Board diversion programs and recommends the program be continued under the vendor. This audit identifies a variety of non-compliant instances and opportunities for improvement, but nothing of a systemic nature that materially affects program effectiveness and efficiency."

Should the committees wish for the board to provide a report on how often it deviates from the Uniform Standards, we will identify ways to ensure this data is collected so that it can be reported at the board's next sunset review.

PHARMACY RELATED STATUTORY IMPLEMENTATION EFFORTS

ISSUE #13: (PRESCRIPTION LABEL STANDARD). The source of a lengthy rulemaking process and subsequent legislative efforts following the initial enacting legislation, California's standardized prescription label appears to still be a topic of discussion and regulatory updates. What is the status of the standardized label? Does the Board anticipate additional changes to the label?

Background: California was the first state to require redesigned prescription container labels to emphasize information most important to consumers – offering an element of safety and consistency since prescription labels are the key source patients' reference for information when taking medications in their homes. Part of this requirement also ensures that oral interpreter services are available to limited English speaking patients in pharmacies, to ensure such patients have access to information about how to take their medications.

SB 472, The California Patient Medication Safety Act, (Corbett, Chapter 470, Statutes 2007) sought to deal with the lack of uniformity in prescription drug labels throughout the state and the resulting confusion and medication errors that may arise. Much of the conversation during the SB 472 debate

focused on the fact that individual pharmacies design and format their own labels, resulting in a lack of standards across all pharmacies, which adversely affects medication users who are elderly, suffer from poor vision, have difficulty reading and understanding instructions on labels or have limited English proficiency.

The Board completed its work on the first iteration of the patient-centered prescription container labels in June 2010, and the regulation took effect in January 2011. However, there were several contentious issues that the Board agreed to revisit. In January 2015, the Board changed the typeface requirement from 10- to 12-point font for all elements in the patient- centered portion of the label, and the Board has also proposed the following changes, presently pending in rulemaking:

Removing the manufacturer's name from the patient-centered area of the label to area outside this designated space; and

Requiring a label for generic drugs that indicate what the generic is replacing.

As part of the initial regulation, the Board required that all pharmacies be able to provide oral interpretation services in 12 languages. In 2015, the Board sponsored legislation to promote the use of translated standardized directions for use that had been vetted in five non-English speaking communities that were made available on the Board's website (Ting, AB 1073, Chapter 784).

These efforts have been a success; since 2011, the patient-centered requirements developed by the Board have been established as standards for prescription container labels by the US Pharmacopeia Board of Pharmacy, the Institute for Safe Medication Practices, and the National Association of Boards of Pharmacy.

Staff Recommendation: ***The Board should update the Committee when the regulations are finalized. Does the Board track decreases in medication errors stemming from the label standard?***

Board Response: The board initiated a rulemaking to update the patient-centered labeling requirements in October 2015. The board will consider comments submitted in response to this regulation during its April 2016 board meeting.

The board has no baseline for tracking medication errors. There is no requirement for a pharmacy to report medication errors to the board unless the error has resulted in a settlement of $3,000 or more. The intent of the patient-centered label requirement was aimed at improving patient understanding of how to appropriately utilize their medication, and to provide the ability for the consumer to be actively engaged in ensuring that his or her medication is administered in compliance with the provider's directions.

ISSUE #14: (IMPLEMENTATION OF RECENTLY ENACTED LEGISLATION.) The Board is tasked with implementing a number of pieces of recently enacted legislation, some significantly impacting the Board's licensing population and Board's work. SB 493, for example, tasked the Board with creating several protocols authorizing pharmacists to provide certain services and also created a new category of Advanced Practice Pharmacists with additional authorities. While the Board is focused on implementing these laws, some efforts may take longer than others and regulation packages are delayed.

Background: Since the Board's prior review, there have been a number of pieces of legislation (in

addition to those discussed previously) impacting the Board and Board licensees:

SB 1329 (Simitian, Chapter 709, Statutes of 2012) – made a number of changes to the way a surplus prescription drug collection and distribution program could be authorized and the entities eligible to donate medications under such a program. The bill authorized a county public health officer delegated by a county board of supervisors to implement a program, in addition current law which required a program to be implemented via a county ordinance. The bill also added several categories of licensed health care facilities that may donate medications and allowed both primary care clinic pharmacies and primary care clinics that have Board licensees, to administer and dispense medication, provided these Board licensees are in good standing with the Board.

SB 493 (Hernandez, Chapter 469, Statutes of 2013) – authorized pharmacists to perform additional functions according to specified requirements, including: administering physician prescribed injectable medications; furnishing immunizations for people ages three and up, if the pharmacist has completed training and follows specified procedures; furnishing self-administered hormonal contraceptives based on a state protocol developed jointly by the Board and Medical Board of California (MBC), pursuant to guidelines of the Centers for Disease Control (CDC); furnishing nicotine replacement products in accordance with a state treatment protocol developed jointly by the Board and MBC; and furnishing travel medications recommended by the CDC for individuals traveling outside of the United States. SB 493 also established "advanced practice pharmacist" (APP) recognition, allowing such pharmacists to write or issue a prescription in certain settings; perform patient assessments; order and interpret drug therapy-related tests; refer patients to other providers; initiate, adjust and discontinue drug therapy in specific circumstances, providing notification to the diagnosing prescriber; and participate in the evaluation and management of diseases and health conditions in collaboration with other providers. The Board established a subcommittee focusing on implementing SB 493 and is in the process of receiving final approval from OAL for regulations related to APP licensure and regulations and establishing the state protocols for: pharmacists dispensing self-administered hormonal contraceptives; pharmacists dispensing nicotine replacement products; pharmacists who administer and initiate vaccinations and; pharmacists who dispense travel medications.

SB 809 (De Saulnier, Chapter 400, Statutes of 2013) – established a funding mechanism to update and maintain CURES while also requiring all prescribing health care practitioners to apply to access CURES information.

SB 600 (Lieu, Chapter 492, Statutes of 2014) – repealed California's electronic pedigree (e-pedigree) law to conform California to the federal DQSA. The Board was in the process of promulgating regulations to establish requirements for e-pedigree and specifications for the unique serialized number of each saleable unit.

AB 467 (Stone, Chapter 10, Statutes of 2014) – established a new Board licensure category for a surplus medication collection and distribution intermediary for the purpose of facilitating the donation of medications to, or transfer of medications between, participating entities under a county's unused medication repository and distribution program. The Board now licenses one intermediary.

AB 1535 (Bloom, Chapter 326, Statutes of 2014) – authorizes pharmacists to furnish naloxone

hydrochloride, an opioid antidote that can reverse a drug overdose, in accordance with standardized procedures or protocols developed and approved by the Board and MBC, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association and other appropriate entities. The Board is in the process of establishing the permanent state protocol to allow pharmacists to furnish naloxone hydrochloride without a prescription from a physician, replacing the protocol the Board had previously adopted under emergency rulemaking provisions.

AB 1073 (Ting, Chapter 784, Statutes of 2015) – required a dispenser, upon the request of a patient or patient's representative, to provide translated directions for use and authorizes a dispenser to use translations made available by the Board. The bill also required a dispenser to be responsible for the accuracy of the English-language directions for use provided to a patient.

The Board also relies on the rulemaking process to further its priorities and work, including regulations that are currently pending related to compounding drug products. The Board has faced challenges in implementing legislation, as discussed during the prior review, such as those required for the development of a standardized label, and the Legislature has weighed in at various times to clarify Legislative intent as the Board is negotiating rules. It would be helpful for the Committees to understand why some regulation packages, like the rules necessary to implement SB 493, have been significantly delayed and what barriers the Board faces to implementing laws.

Staff Recommendation: ***The Board should provide an update on the status of the regulations for SB 493. Why has it taken so long?***

Board Response: Implementation of SB 493 required the board to promulgate several regulations in the following areas:

1. Nicotine Replacement Therapy – Regulation took effect January 25, 2016.
2. Hormonal Contraception – Regulation took effect April 8, 2016.
3. Advanced Practice Pharmacist – Two Regulations. Both have been adopted by the board. Both rulemakings have been compiled and are currently undergoing review by the DCA.
4. Immunizations – Adopted by the board and undergoing review by the DCA.
5. Travel Medications – The comment period is closed. The matter was discussed by the board during its March 28, 2016 teleconference meeting, and released for a 15-day comment period to clarify certificate from certification. The board will take action on the comments received during the comment period at its April 27, 2016 Board Meeting.

As the board was developing these regulations for SB 493, a provision in 2014-enacted legislation -- AB 1535 (Bloom) -- required the board to promulgate emergency regulations to develop a state protocol for Naloxone. This protocol first took effect April 10, 2015 with the permanent regulation taking effect January 27, 2016.

The board created a separate committee to develop regulations for SB 493 in 2014 and 2015, and secured funding from the California HealthCare Foundation to obtain an individual with legal expertise for nine months to assist the work of this committee. The board also increased its regular board meetings to accomplish its role in reviewing SB 493 regulations, doubling the number of board

meetings with a specific focus on SB 493 regulations.

It is important to note that some of the provisions of SB 493 are groundbreaking, as California is the first US state to implement such provisions. As a result, the board had the responsibility of being a pioneer in an area where no previous regulatory standards existed. Some of these provisions were controversial and necessitated input from a variety of stakeholders, with the rulemaking process requiring multiple opportunities for public engagement prior to adoption by the board.

Upon adoption, there also are multiple opportunities for review by designated control agencies. The board estimates that absent an emergency rulemaking process, it takes approximately 300 days from initiation of a rulemaking (the date the board approves the language to initiate the formal rulemaking process) through final filing by the Office of Administrative Law to the Secretary of State's Office.

TECHNICAL CHANGES

ISSUE #15: (TECHNICAL CHANGES MAY IMPROVE EFFECTIVENESS OF THE PHARMACY LAW AND BOARD OPERATIONS.) There are amendments to the Act that are technical in nature but may improve Board operations and the enforcement of the Pharmacy Law.

Background: There are instances in the Pharmacy Law where technical clarifications may improve the Board's operations and application of the statutes governing the Board's work.

Staff Recommendation: ***The Committees may wish to amend the Act to include technical clarifications.***

Board Response: The board would welcome to opportunity to discuss technical changes needed in pharmacy law.

1. Mandatory reporting of medication recalls by compounding pharmacies (general compounding) and reporting to MedWatch.
2. Remove from H&S code section 11164.5 subdivisions (a) and (b) related to outdated provisions for e-prescribing of controlled substances.
3. Expand the conditions for a temporary permit to a pharmacy to mirror the temporary provisions for wholesalers.
4. Amendment to Health and Safety Code Section 1261.6 restoring a provision that was sunsetted and thus to allow for the use of a security camera as part of the automated delivery system.
5. Remove in Article 7.5 Sterile Drug Products all references to "injectable" – sections 4127.3, 4127.7, 4127.8, 4127.9
6. Remove "injectable" from sections 4128.6 and 4161
7. Amend section 4110 and section 4127.8 to broaden when a temporary permit may be issued.

8. Remove “injectable” from 4107 and add nonresident sterile compounding pharmacies to locations that can hold two licenses from the board in the same location.

9. Remove “for injection, administration into the eye, or inhalation” from the definition of sterile compounding pharmacy in section 4127.

CONTINUED REGULATION OF PHARMACIES AND PHARMACISTS BY THE CALIFORNIA STATE BOARD OF PHARMACY

ISSUE #16: (CONTINUED REGULATION BY BOARD OF PHARMACY.) Should the licensing and regulation of pharmacies, pharmacists and key players in the drug supply chain be continued and be regulated by the current Board membership?

Background: The Board of Pharmacy has shown over the years a strong commitment to improve its overall efficiency and effectiveness and has worked cooperatively with the Legislature and this Committee to bring about necessary changes. The Board should be continued with a four-year extension of its sunset date so that the Committee may review once again if the issues and recommendations in this Background Paper and others of the Committee have been addressed.

Staff Recommendation: ***Recommend that the pharmacist profession, pharmacies and other licensees necessary in the delivery of medication to patients continue to be regulated by the current Board members in order to protect the interests of the public and be reviewed once again in four years.***

Board Response: The board thanks the committee for its recommendation to extend the sunset date of the board.

Attachment 4

Amendment to Health and Safety Code Section 11164.5

HEALTH AND SAFETY CODE - HSC

DIVISION 10. UNIFORM CONTROLLED SUBSTANCES ACT [11000 - 11651]

(Division 10 repealed and added by Stats. 1972, Ch. 1407.)

CHAPTER 4. Prescriptions [11150 - 11209]

(Chapter 4 added by Stats. 1972, Ch. 1407.)

ARTICLE 1. Requirements of Prescriptions [11150 - 11180]

(Article 1 added by Stats. 1972, Ch. 1407.)

11164.5.

~~(a) Notwithstanding Section 11164, with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration. The California State Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision.~~

~~(b) Notwithstanding Section 11164, if approved pursuant to subdivision (a), a pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance classified in Schedule II, III, IV, or V shall not be required to reduce that prescription or order to writing or to hard copy form, if for three years from the last day of dispensing that prescription, the pharmacy or hospital is able, upon request of the board or the Department of Justice, to immediately produce a hard copy report that includes for each date of dispensing of a controlled substance in Schedules II, III, IV, and V pursuant to the prescription all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040 of the Business and Professions Code and the name or identifier of the pharmacist who dispensed the controlled substance.~~

(~~c~~ a) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital

and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(~~d~~ b) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

Amendment to Health and Safety Code Section 1261.6

HEALTH AND SAFETY CODE - HSC
DIVISION 2. LICENSING PROVISIONS [1200 - 1796.63]

(Division 2 enacted by Stats. 1939, Ch. 60.)

CHAPTER 2. Health Facilities [1250 - 1339.59]

(Chapter 2 repealed and added by Stats. 1973, Ch. 1202.)

ARTICLE 1. General [1250 - 1264]

(Article 1 added by Stats. 1973, Ch. 1202.)

1261.6.

(a) (1) For purposes of this section and Section 1261.5, an “automated drug delivery system” means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, “facility” means a health facility licensed pursuant to subdivision (c), (d), or (k), of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, “pharmacy services” means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs

ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

~~(C) This paragraph shall remain in effect only until January 1, 2012, unless a later enacted statute is enacted on or before January 1, 2012, deletes or extends that date.~~

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets, cards, or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

Amendment to Business and Professions Code Sections 4110 and 4127.8

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4426]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 7. Pharmacies [4110 - 4126.5]

(Article 7 added by Stats. 1996, Ch. 890, Sec. 3.)

4110.

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, ~~when the ownership of a pharmacy is transferred from one person to another~~, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required in an amount established by the board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

(c) The board may allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged, the mobile pharmacy is necessary to protect the health and safety of the public, and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.

(2) The mobile pharmacy is under the control and management of the pharmacist-in-charge of the pharmacy that was destroyed or damaged.

(3) A licensed pharmacist is on the premises while drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction of, or damage to, the pharmacy and an expected restoration date.

(6) Within three calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration of the permanent pharmacy.

(7) The mobile pharmacy is not operated for more than 48 hours following the restoration of the permanent pharmacy.

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4426]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 7.5. Sterile Drug Products [4127 - 4127.9]

(Heading of Article 7.5 amended by Stats. 2013, Ch. 565, Sec. 1.)

4127.8.

The board may, at its discretion, issue a temporary license to compound ~~injectable~~ sterile drug products, ~~when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another,~~ upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (u) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested at the licenseholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

Amendment to Business and Professions Code Sections 4107, 4127, 4127.3, 4127.7, 4127.9, 4128.6 and 4161

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4426]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 6. General Requirements [4100 - 4107.5]

(Article 6 added by Stats. 1996, Ch. 890, Sec. 3.)

4107.

(a) The board may not issue more than one site license to a single premises except as follows:

(1) To issue a veterinary food-animal drug retailer license to a wholesaler pursuant to Section 4196.

(2) To issue a license to compound sterile ~~injectable~~ drugs to a pharmacy pursuant to Section 4127.1 or Section 4127.2.

(3) To issue a centralized hospital packaging license pursuant to Section 4128.

(b) For the purposes of this subdivision, “premises” means a location with its own address and an independent means of ingress and egress.

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4426]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 7.5. Sterile Drug Products [4127 - 4127.9]

(Heading of Article 7.5 amended by Stats. 2013, Ch. 565, Sec. 1.)

4127.

(a) A pharmacy that compounds sterile drug products ~~for injection, administration into the eye, or inhalation~~ shall possess a sterile compounding pharmacy license as provided in this article.

(b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(c) The board shall review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary for the regulations adopted by the board pursuant to subdivision (b).

~~(d) This section shall become operative on July 1, 2014.~~

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4426]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 7.5. Sterile Drug Products [4127 - 4127.9]

(Heading of Article 7.5 amended by Stats. 2013, Ch. 565, Sec. 1.)

4127.3.

(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding ~~injectable~~ sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding ~~injectable~~ sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4426]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 7.5. Sterile Drug Products [4127 - 4127.9]

(Heading of Article 7.5 amended by Stats. 2013, Ch. 565, Sec. 1.)

4127.7.

On and after July 1, 2005, a pharmacy shall compound sterile ~~injectable~~ products from one or more nonsterile ingredients in one of the following environments:

(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

(b) An ISO class 5 cleanroom.

(c) A barrier isolator that provides an ISO class 5 environment for compounding.

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4426]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 7.5. Sterile Drug Products [4127 - 4127.9]

(Heading of Article 7.5 amended by Stats. 2013, Ch. 565, Sec. 1.)

4127.9.

(a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2, ~~including a pharmacy that is exempt from licensure pursuant to subdivision (d) of Section 4127.1 and subdivision (c) of Section 4127.2,~~ that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4426]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 7.6. Centralized Hospital Packaging Pharmacies [4128 - 4128.7]

(Article 7.6 added by Stats. 2012, Ch. 687, Sec. 2.)

4128.6.

All compounding and packaging functions specified in Section 4128 shall be performed only in the licensed centralized hospital packaging pharmacy and that pharmacy shall comply with all applicable federal and state statutes and regulations, including, but not limited to, regulations regarding compounding and, when appropriate, sterile ~~injectable~~ compounding.

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4426]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 11. Wholesalers, Third-Party Logistics Providers, and Manufacturers [4160 - 4169]

(Heading of Article 11 amended by Stats. 2014, Ch. 507, Sec. 16.)

4161.

(a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

(c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

(2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound ~~injectable~~ sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the

temporary licenseholder be deemed to have a vested property right or interest in the license.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

Attachment 5

BUSINESS AND PROFESSIONS CODE - BPC

Proposal to Add Section 4105.5

(a) For purposes of this section, an automated drug delivery system includes a device as defined in Health and Safety Code Section 1261.6(a)(1).

(b) Every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall provide the board in writing with the location of each device within 30 days of installation of such a device, and on an annual basis as part of the license renewal. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.

(c) Every pharmacy that uses such a system may only do so if all of the following conditions are satisfied.

1. Use of the device is consistent with legal requirements.
2. Policies and procedures include appropriate security measures and monitoring of the inventory to prevent thefts and diversion. <u>The inventory shall be done at least quarterly.</u>
3. Drug losses from the device are reported to the board as required by law.
4. The pharmacy license is in good standing with the board.
5. <u>The device is located within a seventy-five mile radius of the pharmacy</u>.

(d) The board may prohibit a pharmacy from using a system if it determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal such a decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

<u>(e) A device used in a licensed hospital for doses administered in the hospital is exempt from subdivision (b).</u>

Attachment 6

Add Section 4083.1

(a) A pharmacy that issues a recall notice regarding a nonsterile compounded drug product shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

(c) In cases where patient harm has occurred resulting from use of the compounded product, the event shall be reported to MedWatch within 72 hours of the pharmacy being advised.

Attachment 7

AMENDED IN SENATE APRIL 13, 2016

SENATE BILL No. 1193

Introduced by Senator Hill
(Principal coauthor: Assembly Member Salas)

February 18, 2016

An act to amend Sections ~~4001 and 4003 of~~ *4001, 4003, 4119.1, and 4400 of, to add Sections 4034, 4203.5, and 4316 to, and to add Article 7.7 (commencing with Section 4129) to Chapter 9 of Division 2 of,* the Business and Professions Code, *and to amend Section 13401.5 of the Corporations Code,* relating to healing ~~arts.~~ *arts, and making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1193, as amended, Hill. ~~California State Board of Pharmacy: executive officer.~~ *Pharmacy: outsourcing facilities.*

The Pharmacy Law provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy, which is within the Department of Consumer Affairs, and authorizes the board to appoint, with the approval of the Director of Consumer Affairs, an executive officer, as specified. ~~Existing~~ *That* law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017. Under existing law, the board is subject to evaluation by the Joint Sunset Review Committee upon its repeal. *That law authorizes a pharmacy to provide pharmacy services to specified licensed health facilities through the use of an automated drug delivery system. That law also provides for the board to issue a license, after an investigation to determine whether the applicant and the premises qualify for a license, that authorizes specified clinics to purchase drugs at wholesale for administration or dispensing, under*

the direction of a physician and surgeon, to patients registered for care at the clinic. Existing law makes a violation of any provision of the Pharmacy Law punishable as an infraction if no other penalty is provided.

This bill would extend the operation of the board and the board's authorization to appoint an executive officer until January 1, 2021. *The bill would require a pharmacy to register use of an automated drug delivery system with the board, including the address and location of use. The bill would require the board, when a clinic applicant submits specified types of applications, to issue a license or incorporate changes to an existing license within 30 days of receipt of a completed application and payment of fees. The bill would not limit the board's authority to investigate to determine whether the applicant and the premises qualify for a license. By placing new requirements on a pharmacy, this bill would expand an existing crime and would, therefore, impose a state-mandated local program.*

The Pharmacy Law prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board and prohibits the board from issuing or renewing that license until the board has, among other things, reviewed a current copy of the pharmacy's procedures and policies for sterile compounding. Existing law provides that fees collected on behalf of the board are credited to the Pharmacy Board Contingent Fund, which continuously appropriates fees in the fund.

The bill would require the board to license an outsourcing facility, as defined, and would prohibit an outsourcing facility to be concurrently licensed with the board as a sterile compounding pharmacy at the same location. The bill would require an outsourcing facility to be licensed with the board before doing business within or into the state and would require an outsourcing facility to, among other things, notify the board of any disciplinary or other action taken by another state or the federal Food and Drug Administration within 10 days of the action. The bill would require the board to, among other things, inspect the location of an outsourcing facility to ensure that the outsourcing facility is in compliance with all laws and regulations before issuing or renewing an outsourcing facility's license. The bill would make a violation of any of these provisions or regulations adopted thereto punishable by a fine of up to $5,000 per occurrence. The bill would, on or after January 1, 2018, require the board to provide a report, as specified, to the Legislature regarding the regulation of nonresident outsourcing

facilities. The bill would also authorize the board to collect a fee of $780 for the issuance and renewal of an outsourcing license and a fee of $715 for a temporary license, as specified. By increasing the amount of money deposited into a continuously appropriated fund, the bill would make an appropriation.

Existing law authorizes specified healing arts licensees to be shareholders, officers, directors, or professional employees of a designated professional corporation, subject to certain limitations relating to ownership of shares.

This bill would additionally authorize licensed pharmacists to be shareholders, officers, directors, or professional employees of a designated professional corporation, subject to certain limitations relating to ownership of shares.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: ~~no~~ *yes*. Fiscal committee: yes. State-mandated local program: ~~no~~ *yes*.

The people of the State of California do enact as follows:

SECTION 1. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include

at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) This section shall remain in effect only until January 1, 2021, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 2. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 3. Section 4034 is added to the Business and Professions Code, to read:

4034. "Outsourcing facility" means a facility that meets all of the following:

(a) Is located within the United States of America at one address that is engaged in the compounding of sterile drugs and nonsterile drugs.

(b) Has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).

(c) Is doing business within or into California.

(d) Is licensed with the board as an outsourcing facility pursuant to Article 7.7 (commencing with Section 4129).

SEC. 4. Section 4119.1 of the Business and Professions Code is amended to read:

4119.1. (a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

(2) The pharmacy shall own and operate the automated drug delivery system.

(3) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system.

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) The pharmacy shall register use of an automated drug delivery system with the board, including the address and location of use.

~~(e) Nothing in this~~

(f) This section shall *not* be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

SEC. 5. Article 7.7 (commencing with Section 4129) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.7. Outsourcing Facilities

4129. (a) A facility licensed as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California.

(b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.

(c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after their release in order to determine whether

revisions are necessary for any regulations promulgated by the board.

(e) An outsourcing facility licensed by the board shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients.

4129.1. (a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

(1) Prior to inspection, reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the outsourcing facility's premises conducted in the prior 12 months.

(3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.

(3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.

4129.2. (a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) as an outsourcing facility and has an address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for distribution or use into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

(d) A license for a nonresident outsourcing facility shall not be issued or renewed until the board:

(1) Prior to inspection, reviews a current copy of the nonresident outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the nonresident outsourcing facility's premises conducted in the prior 12 months.

(3) Prior to inspection, receives a list of all sterile drug products and nonsterile drug products compounded by the pharmacy as reported to the FDA within the prior 12 months.

(e) A nonresident outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the nonresident outsourcing facility.

(3) A copy of any complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.

(4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to a nonresident outsourcing facility's products.

4129.3. (a) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident outsourcing facilities. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident outsourcing facilities.

(2) Whether fee revenue collected pursuant to subdivision (x) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of Section 4129.2 provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident outsourcing facilities.

(3) The status of proposed changes to federal law that are under serious consideration and that would govern outsourcing facilities and compounding pharmacies, including, but not limited to, legislation pending before Congress, administrative rules, regulations or orders under consideration by the FDA or other appropriate federal agency, and cases pending before the courts.

(4) If applicable, recommended modifications to the board's statutory duties related to nonresident outsourcing facilities as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(b) The requirement for submitting a report imposed under subdivision (a) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

4129.4. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease

and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections and any regulations.

(c) The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days after the date the request of the owner is received by the board. The president shall render a written decision within five days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

4129.5. Notwithstanding any other law, a violation of this article, or regulation adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to five thousand dollars ($5,000) per occurrence pursuant to a citation issued by the board.

4129.6. For purposes of this article, "sterile compounded products" means compounded preparations for injection, administration into the eye, or inhalation.

4129.8. The board, at its discretion, may issue a temporary license to an outsourcing facility when the ownership of the outsourcing facility is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required as specified in subdivision (w) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued

subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon the earlier of personal service of the notice of termination upon the licenseholder or service by certified mail with return receipt requested at the licenseholder's address of record with the board. The temporary licenseholder shall not be deemed to have a vested property right or interest in the license for purposes of retaining a temporary license or for purposes of any disciplinary or license denial proceeding before the board.

4129.9. (a) An outsourcing facility licensed pursuant to Section 4129.1 or 4129.2 that issues a recall notice for a sterile drug or nonsterile drug compounded by the outsourcing facility, in addition to any other duties, shall contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 24 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber and the prescriber shall ensure the patient is notified.

(2) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy and that pharmacy shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

SEC. 6. Section 4203.5 is added to the Business and Professions Code, to read:

4203.5. (a) Notwithstanding any other law, when a clinic applicant submits either type of application described in subdivision (b), the board shall issue a license or incorporate the reported changes, as appropriate, within 30 days of receipt of a completed application and payment of any prescribed fees.

(b) This section applies to the following types of applications:

(1) A new clinic license application filed under Section 4180.

(2) Applications to report changes to an existing site licensed under Section 4180, including, but not limited to, changes in professional director, clinic administrator, corporate officers, change of location, or change of address.

(c) This section shall not be construed to limit the board's authority to conduct an investigation to determine whether applicants and the premises for which an application is made qualify for a license.

SEC. 7. Section 4316 is added to the Business and Professions Code, to read:

4316. (a) The board is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

SEC. 8. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars ($400) and may be increased to five hundred

twenty dollars ($520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars ($200) and may be increased to two hundred sixty dollars ($260).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars ($125) and may be increased to one hundred sixty-five dollars ($165).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary

food-animal drug retailer pursuant to Section 4053 shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars ($80) and may be increased to one hundred five dollars ($105). The fee for renewal of a pharmacy technician license shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars ($405) and may be increased to four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars ($780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the

required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

~~(w) This section shall become operative on July 1, 2014.~~

(w) The fee for the issuance or renewal of an outsourcing facility license shall be seven hundred eighty dollars ($780). The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance or renewal of a nonresident outsourcing facility license shall be seven hundred eighty dollars ($780). In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

SEC. 9. Section 13401.5 of the Corporations Code is amended to read:

13401.5. Notwithstanding subdivision (d) of Section 13401 and any other provision of law, the following licensed persons may be shareholders, officers, directors, or professional employees of the professional corporations designated in this section so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the professional corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional corporation so designated herein does not exceed the number of persons licensed by the governmental agency regulating the designated professional corporation. This section does not limit

employment by a professional corporation designated in this section to only those licensed professionals listed under each subdivision. Any person duly licensed under Division 2 (commencing with Section 500) of the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act may be employed to render professional services by a professional corporation designated in this section.

(a) Medical corporation.

(1) Licensed doctors of podiatric medicine.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed physician assistants.

(8) Licensed chiropractors.

(9) Licensed acupuncturists.

(10) Naturopathic doctors.

(11) Licensed professional clinical counselors.

(12) Licensed physical therapists.

(13) Licensed pharmacists.

(b) Podiatric medical corporation.

(1) Licensed physicians and surgeons.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed chiropractors.

(6) Licensed acupuncturists.

(7) Naturopathic doctors.

(8) Licensed physical therapists.

(c) Psychological corporation.

(1) Licensed physicians and surgeons.

(2) Licensed doctors of podiatric medicine.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed chiropractors.

(8) Licensed acupuncturists.

(9) Naturopathic doctors.

(10) Licensed professional clinical counselors.
(d) Speech-language pathology corporation.
(1) Licensed audiologists.
(e) Audiology corporation.
(1) Licensed speech-language pathologists.
(f) Nursing corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(11) Licensed professional clinical counselors.
(g) Marriage and family therapist corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed clinical social workers.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(8) Licensed professional clinical counselors.
(h) Licensed clinical social worker corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed marriage and family therapists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(8) Licensed professional clinical counselors.
(i) Physician assistants corporation.
(1) Licensed physicians and surgeons.
(2) Registered nurses.
(3) Licensed acupuncturists.
(4) Naturopathic doctors.

(j) Optometric corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(k) Chiropractic corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(10) Licensed professional clinical counselors.
(*l*) Acupuncture corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed physician assistants.
(9) Licensed chiropractors.
(10) Naturopathic doctors.
(11) Licensed professional clinical counselors.
(m) Naturopathic doctor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed physician assistants.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Licensed physical therapists.
(8) Licensed doctors of podiatric medicine.

(9) Licensed marriage and family therapists.
(10) Licensed clinical social workers.
(11) Licensed optometrists.
(12) Licensed professional clinical counselors.
(n) Dental corporation.
(1) Licensed physicians and surgeons.
(2) Dental assistants.
(3) Registered dental assistants.
(4) Registered dental assistants in extended functions.
(5) Registered dental hygienists.
(6) Registered dental hygienists in extended functions.
(7) Registered dental hygienists in alternative practice.
(o) Professional clinical counselor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed clinical social workers.
(4) Licensed marriage and family therapists.
(5) Registered nurses.
(6) Licensed chiropractors.
(7) Licensed acupuncturists.
(8) Naturopathic doctors.
(p) Physical therapy corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed acupuncturists.
(4) Naturopathic doctors.
(5) Licensed occupational therapists.
(6) Licensed speech-language therapists.
(7) Licensed audiologists.
(8) Registered nurses.
(9) Licensed psychologists.
(10) Licensed physician assistants.
(q) Registered dental hygienist in alternative practice corporation.
(1) Registered dental assistants.
(2) Licensed dentists.
(3) Registered dental hygienists.
(4) Registered dental hygienists in extended functions.

SEC. 10. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because

the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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AMENDED IN SENATE APRIL 12, 2016

AMENDED IN SENATE APRIL 7, 2016

SENATE BILL No. 1039

Introduced by Senator Hill

February 12, 2016

An act to amend Sections 1636.4, 2423, 2460, 2461, 2475, 2479, 2486, 2488, 2492, 2499, 2733, 2746.51, 2786.5, 2811, 2811.5, 2815, 2815.5, 2816, 2830.7, 2836.3, 2838.2, 4128.2, 7137, 7153.3, 8031, 8516, ~~8518, and 8555~~ *and 8518* of, to amend, repeal, and add Section 4400 of, to add Section 2499.7 to, and to repeal Chapter 15 (commencing with Section 4999) of Division 2 of, the Business and Professions Code, to repeal Section 1348.8 of the Health and Safety Code, and to repeal Section 10279 of the Insurance Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1039, as amended, Hill. Professions and vocations.

(1) Existing law requires the Office of Statewide Health Planning and Development to establish the Health Professions Education Foundation to, among other things, solicit and receive funds for the purpose of providing scholarships, as specified.

The bill would state the intent of the Legislature to enact future legislation that would establish a Dental Corps Scholarship Program, as specified, to increase the supply of dentists serving in medically underserved areas.

(2) The Dental Practice Act provides for the licensure and regulation of persons engaged in the practice of dentistry by the Dental Board of California, which is within the Department of Consumer Affairs, and requires the board to be responsible for the approval of foreign dental

schools by evaluating foreign dental schools based on specified criteria. That act authorizes the board to contract with outside consultants or a national professional organization to survey and evaluate foreign dental schools, as specified. That act requires the board to establish a technical advisory group to review the survey and evaluation contracted for prior to the board taking any final action regarding a foreign dental school. That act also requires periodic surveys and evaluations of all approved schools be made to ensure compliance with the act.

This bill would ~~delete the authorization to contract with outside consultants and would instead~~ authorize the board, in lieu of conducting its own survey and evaluation of a foreign dental school, to accept the findings of any commission or accreditation agency approved by the board, if the findings meet specified standards and the foreign dental school is not under review by the board on January 1, 2017, and adopt those findings as the board's own. The bill would delete the requirement to establish a technical advisory group. The bill would instead authorize periodic surveys and evaluations be made to ensure compliance with that act.

(3) The Medical Practice Act creates, within the jurisdiction of the Medical Board of California, the California Board of Podiatric Medicine. Under the act, certificates to practice podiatric medicine and registrations of spectacle lens dispensers and contact lens dispensers, among others, expire on a certain date during the second year of a 2-year term if not renewed.

This bill would instead create the California Board of Podiatric Medicine in the Department of Consumer Affairs, and would make conforming and related changes. The bill would discontinue the above-described requirement for the expiration of the registrations of spectacle lens dispensers and contact lens dispensers.

(4) The Nursing Practice Act provides for the licensure and regulation of nurse practitioners by the Board of Registered Nursing, which is within the Department of Consumer Affairs, and requires the board to adopt regulations establishing standards for continuing education for licensees, as specified. That act requires providers of continuing education programs approved by the board to make records of continuing education courses given to registered nurses available for board inspection. That act also prescribes various fees to be paid by licensees and applicants for licensure, and requires these fees to be credited to the Board of Registered Nursing Fund, which is a continuously appropriated fund as it pertains to fees collected by the board.

This bill would require that the content of a continuing education course be based on generally accepted scientific principles. The bill would also require the board to audit continuing education providers, at least once every 5 years, to ensure adherence to regulatory requirements, and to withhold or rescind approval from any provider that is in violation of regulatory requirements. The bill would raise specified fees, and would provide for additional fees, to be paid by licensees and applicants for licensure pursuant to that act. By increasing fees deposited into a continuously appropriated fund, this bill would make an appropriation.

(5) The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy within the Department of Consumer Affairs. That law prescribes various fees to be paid by licensees and applicants for licensure, and requires all fees collected on behalf of the board to be credited to the Pharmacy Board Contingent Fund, which is a continuously appropriated fund as it pertains to fees collected by the board.

This bill ~~would discontinue the fee for issuance or annual renewal of a centralized hospital packaging pharmacy license. The bill~~ would, on and after July 1, 2017, ~~also~~ modify ~~other~~ specified fees to be paid by licensees and applicants for licensure pursuant to that act. By increasing fees deposited into a continuously appropriated fund, this bill would make an appropriation.

(6) Existing law requires certain businesses that provide telephone medical advice services to a patient at a California address to be registered with the Telephone Medical Advice Services Bureau and further requires telephone medical advice services to comply with the requirements established by the Department of Consumer Affairs, among other provisions, as specified.

This bill would repeal those provisions.

(7) The Contractors' State License Law provides for the licensure and regulation of contractors by the Contractors' State License Board within the Department of Consumer Affairs. That law also prescribes various fees to be paid by licensees and applicants for licensure, and requires fees and civil penalties received under that law to be deposited in the Contractors' License Fund, which is a continuously appropriated fund as it pertains to fees collected by the board.

This bill would raise specified fees and would require the board to establish criteria for the approval of expedited processing of applications,

as specified. By increasing fees deposited into a continuously appropriated fund, this bill would make an appropriation.

(8) Existing law provides for the licensure and regulation of shorthand reporters by the Court Reporters Board of California within the Department of Consumer Affairs. That law authorizes the board, by resolution, to establish a fee for the renewal of a certificate issued by the board, and prohibits the fee from exceeding $125, as specified. Under existing law, all fees and revenues received by the board are deposited into the Court Reporters' Fund, which is a continuously appropriated fund as it pertains to fees collected by the board.

This bill would raise that fee limit to $250. By authorizing an increase in a fee deposited into a continuously appropriated fund, this bill would make an appropriation.

(9) Existing law provides for the licensure and regulation of structural pest control operators and registered companies by the Structural Pest Control Board, which is within the Department of Consumer Affairs, and requires a licensee to pay a specified license fee. Existing law makes any violation of those provisions punishable as a misdemeanor. Existing law places certain requirements on a registered company or licensee with regards to wood destroying pests or organisms, including that a registered company or licensee is prohibited from commencing work on a contract until an inspection has been made by a licensed Branch 3 field representative or operator, that the address of each property inspected or upon which work was completed is required to be reported to the board, as specified, and that a written inspection report be prepared and delivered to the person requesting the inspection or his or her agent. Existing law requires the original inspection report to be submitted to the board upon demand. Existing law requires that written report to contain certain information, including a foundation diagram or sketch of the structure or portions of the structure inspected, and requires the report, and any contract entered into, to expressly state if a guarantee for the work is made, and if so, the terms and time period of the guarantee. Existing law establishes the Structural Pest Control Fund, which is a continuously appropriated fund as it pertains to fees collected by the board.

This bill would require the operator who is conducting the inspection prior to the commencement of work to be employed by a registered company, except as specified. The bill would not require the address of an inspection report prepared for use by an attorney for litigation to be reported to the board or assessed a filing fee. The bill would require

instead that the written inspection report be prepared and delivered to the person requesting it, the property owner, or the property owner's designated agent, as specified. The bill would allow an inspection report to be a complete, limited, supplemental, or reinspection report, as defined. The bill would require all inspection reports to be submitted to the board and maintained with field notes, activity forms, and notices of completion until one year after the guarantee expires if the guarantee extends beyond 3 years. The bill would require the inspection report to clearly list the infested or infected wood members or parts of the structure identified in the required diagram or sketch. By placing new requirements on a registered company or licensee, this bill would expand an existing crime and would, therefore, impose a state-mandated local program.

Existing law requires a registered company to prepare a notice of work completed to give to the owner of the property when the work is completed.

This bill would make this provision only applicable to work relating to wood destroying pests and organisms.

~~Existing law provides that the laws governing structural pest control operators, including licensure, do not apply to persons engaged in the live capture and removal of vertebrate pests, bees, or wasps from a structure without the use of pesticides.~~

~~This bill would instead apply those laws to persons that engage in the live capture and removal of vertebrate pests without the use of pesticides. By requiring persons that engage in the live capture and removal of vertebrate pests without the use of pesticides to comply with the laws governing structural pest control operators, this bill would expand an existing crime, and would, therefore, impose a state-mandated local program. By requiring those persons to be licensed, this bill would require them to pay a license fee that would go into a continuously appropriated fund, which would, therefore, result in an appropriation.~~

(10) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature to enact future legislation that would establish a Dental Corps Scholarship Program within the Health Professions Education Foundation to increase the supply of dentists serving in medically underserved areas.

SEC. 2. Section 1636.4 of the Business and Professions Code is amended to read:

1636.4. (a) The Legislature recognizes the need to ensure that graduates of foreign dental schools who have received an education that is equivalent to that of accredited institutions in the United States and that adequately prepares their students for the practice of dentistry shall be subject to the same licensure requirements as graduates of approved dental schools or colleges. It is the purpose of this section to provide for the evaluation of foreign dental schools and the approval of those foreign dental schools that provide an education that is equivalent to that of similar accredited institutions in the United States and that adequately prepare their students for the practice of dentistry.

(b) The board shall be responsible for the approval of foreign dental schools based on standards established pursuant to subdivision (c). *The board may contract with outside consultants or a national professional organization to survey and evaluate foreign dental schools. The consultant or organization shall report to the board regarding its findings in the survey and evaluation.* The board may, in lieu of conducting its own survey and evaluation of a foreign dental school, accept the findings of any commission or accreditation agency approved by the board if the findings meet the standards of subdivision (c) and adopt those findings as the board's own. This subdivision shall not apply to foreign dental schools seeking board approval that are under review by the board on January 1, 2017.

(c) Any foreign dental school that wishes to be approved pursuant to this section shall make application to the board for this approval, which shall be based upon a finding by the board that the educational program of the foreign dental school is equivalent to that of similar accredited institutions in the United States and adequately prepares its students for the practice of dentistry. Curriculum, faculty qualifications, student attendance, plant and

facilities, and other relevant factors shall be reviewed and evaluated. The board shall identify by rule the standards and review procedures and methodology to be used in the approval process consistent with this subdivision. The board shall not grant approval if deficiencies found are of such magnitude as to prevent the students in the school from receiving an educational base suitable for the practice of dentistry.

(d) Periodic surveys and evaluations of all approved schools may be made to ensure continued compliance with this section. Approval shall include provisional and full approval. The provisional form of approval shall be for a period determined by the board, not to exceed three years, and shall be granted to an institution, in accordance with rules established by the board, to provide reasonable time for the school seeking permanent approval to overcome deficiencies found by the board. Prior to the expiration of a provisional approval and before the full approval is granted, the school shall be required to submit evidence that deficiencies noted at the time of initial application have been remedied. A school granted full approval shall provide evidence of continued compliance with this section. In the event that the board denies approval or reapproval, the board shall give the school a specific listing of the deficiencies that caused the denial and the requirements for remedying the deficiencies, and shall permit the school, upon request, to demonstrate by satisfactory evidence, within 90 days, that it has remedied the deficiencies listed by the board.

(e) A school shall pay a registration fee established by rule of the board, not to exceed one thousand dollars ($1,000), at the time of application for approval and shall pay all reasonable costs and expenses incurred for conducting the approval survey.

(f) The board shall renew approval upon receipt of a renewal application, accompanied by a fee not to exceed five hundred dollars ($500). Each fully approved institution shall submit a renewal application every seven years. Any approval that is not renewed shall automatically expire.

SEC. 3. Section 2423 of the Business and Professions Code is amended to read:

2423. (a) Notwithstanding Section 2422:

(1) All physician and surgeon’s certificates and certificates to practice midwifery shall expire at 12 midnight on the last day of

the birth month of the licensee during the second year of a two-year term if not renewed.

(2) Registrations of dispensing opticians will expire at midnight on the last day of the month in which the license was issued during the second year of a two-year term if not renewed.

(b) The board shall establish by regulation procedures for the administration of a birth date renewal program, including, but not limited to, the establishment of a system of staggered license expiration dates such that a relatively equal number of licenses expire monthly.

(c) To renew an unexpired license, the licensee shall, on or before the dates on which it would otherwise expire, apply for renewal on a form prescribed by the licensing authority and pay the prescribed renewal fee.

SEC. 4. Section 2460 of the Business and Professions Code is amended to read:

2460. (a) There is created within the Department of Consumer Affairs a California Board of Podiatric Medicine.

(b) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the California Board of Podiatric Medicine subject to review by the appropriate policy committees of the Legislature.

SEC. 5. Section 2461 of the Business and Professions Code is amended to read:

2461. As used in this article:

(a) "Board" means the California Board of Podiatric Medicine.

(b) "Podiatric licensing authority" refers to any officer, board, commission, committee, or department of another state that may issue a license to practice podiatric medicine.

SEC. 6. Section 2475 of the Business and Professions Code is amended to read:

2475. Unless otherwise provided by law, no postgraduate trainee, intern, resident postdoctoral fellow, or instructor may engage in the practice of podiatric medicine, or receive compensation therefor, or offer to engage in the practice of podiatric medicine unless he or she holds a valid, unrevoked, and unsuspended certificate to practice podiatric medicine issued by the board. However, a graduate of an approved college or school

of podiatric medicine upon whom the degree doctor of podiatric medicine has been conferred, who is issued a resident's license, which may be renewed annually for up to eight years for this purpose by the board, and who is enrolled in a postgraduate training program approved by the board, may engage in the practice of podiatric medicine whenever and wherever required as a part of that program and may receive compensation for that practice under the following conditions:

(a) A graduate with a resident's license in an approved internship, residency, or fellowship program may participate in training rotations outside the scope of podiatric medicine, under the supervision of a physician and surgeon who holds a medical doctor or doctor of osteopathy degree wherever and whenever required as a part of the training program, and may receive compensation for that practice. If the graduate fails to receive a license to practice podiatric medicine under this chapter within three years from the commencement of the postgraduate training, all privileges and exemptions under this section shall automatically cease.

(b) Hospitals functioning as a part of the teaching program of an approved college or school of podiatric medicine in this state may exchange instructors or resident or assistant resident doctors of podiatric medicine with another approved college or school of podiatric medicine not located in this state, or those hospitals may appoint a graduate of an approved school as such a resident for purposes of postgraduate training. Those instructors and residents may practice and be compensated as provided in this section, but that practice and compensation shall be for a period not to exceed two years.

SEC. 7. Section 2479 of the Business and Professions Code is amended to read:

2479. The board shall issue a certificate to practice podiatric medicine to each applicant who meets the requirements of this chapter. Every applicant for a certificate to practice podiatric medicine shall comply with the provisions of Article 4 (commencing with Section 2080) which are not specifically applicable to applicants for a physician's and surgeon's certificate, in addition to the provisions of this article.

SEC. 8. Section 2486 of the Business and Professions Code is amended to read:

2486. The board shall issue a certificate to practice podiatric medicine if the applicant has submitted directly to the board from the credentialing organizations verification that he or she meets all of the following requirements:

(a) The applicant has graduated from an approved school or college of podiatric medicine and meets the requirements of Section 2483.

(b) The applicant, within the past 10 years, has passed parts I, II, and III of the examination administered by the National Board of Podiatric Medical Examiners of the United States or has passed a written examination that is recognized by the board to be the equivalent in content to the examination administered by the National Board of Podiatric Medical Examiners of the United States.

(c) The applicant has satisfactorily completed the postgraduate training required by Section 2484.

(d) The applicant has passed within the past 10 years any oral and practical examination that may be required of all applicants by the board to ascertain clinical competence.

(e) The applicant has committed no acts or crimes constituting grounds for denial of a certificate under Division 1.5 (commencing with Section 475).

(f) The board determines that no disciplinary action has been taken against the applicant by any podiatric licensing authority and that the applicant has not been the subject of adverse judgments or settlements resulting from the practice of podiatric medicine that the board determines constitutes evidence of a pattern of negligence or incompetence.

(g) A disciplinary databank report regarding the applicant is received by the board from the Federation of Podiatric Medical Boards.

SEC. 9. Section 2488 of the Business and Professions Code is amended to read:

2488. Notwithstanding any other law, the board shall issue a certificate to practice podiatric medicine by credentialing if the applicant has submitted directly to the board from the credentialing organizations verification that he or she is licensed as a doctor of podiatric medicine in any other state and meets all of the following requirements:

(a) The applicant has graduated from an approved school or college of podiatric medicine.

(b) The applicant, within the past 10 years, has passed either part III of the examination administered by the National Board of Podiatric Medical Examiners of the United States or a written examination that is recognized by the board to be the equivalent in content to the examination administered by the National Board of Podiatric Medical Examiners of the United States.

(c) The applicant has satisfactorily completed a postgraduate training program approved by the Council on Podiatric Medical Education.

(d) The applicant, within the past 10 years, has passed any oral and practical examination that may be required of all applicants by the board to ascertain clinical competence.

(e) The applicant has committed no acts or crimes constituting grounds for denial of a certificate under Division 1.5 (commencing with Section 475).

(f) The board determines that no disciplinary action has been taken against the applicant by any podiatric licensing authority and that the applicant has not been the subject of adverse judgments or settlements resulting from the practice of podiatric medicine that the board determines constitutes evidence of a pattern of negligence or incompetence.

(g) A disciplinary databank report regarding the applicant is received by the board from the Federation of Podiatric Medical Boards.

SEC. 10. Section 2492 of the Business and Professions Code is amended to read:

2492. (a) The board shall examine every applicant for a certificate to practice podiatric medicine to ensure a minimum of entry-level competence at the time and place designated by the board in its discretion, but at least twice a year.

(b) Unless the applicant meets the requirements of Section 2486, applicants shall be required to have taken and passed the examination administered by the National Board of Podiatric Medical Examiners.

(c) The board may appoint qualified persons to give the whole or any portion of any examination as provided in this article, who shall be designated as examination commissioners. The board may

fix the compensation of those persons subject to the provisions of applicable state laws and regulations.

(d) The provisions of Article 9 (commencing with Section 2170) shall apply to examinations administered by the board except where those provisions are in conflict with or inconsistent with the provisions of this article.

SEC. 11. Section 2499 of the Business and Professions Code is amended to read:

2499. There is in the State Treasury the Board of Podiatric Medicine Fund. Notwithstanding Section 2445, the board shall report to the Controller at the beginning of each calendar month for the month preceding the amount and source of all revenue received by the board, pursuant to this chapter, and shall pay the entire amount thereof to the Treasurer for deposit into the fund. All revenue received by the board from fees authorized to be charged relating to the practice of podiatric medicine shall be deposited in the fund as provided in this section, and shall be used to carry out the provisions of this chapter relating to the regulation of the practice of podiatric medicine.

SEC. 12. Section 2499.7 is added to the Business and Professions Code, to read:

2499.7. (a) Certificates to practice podiatric medicine shall expire at 12 midnight on the last day of the birth month of the licensee during the second year of a two-year term.

(b) To renew an unexpired certificate, the licensee, on or before the date on which the certificate would otherwise expire, shall apply for renewal on a form prescribed by the board and pay the prescribed renewal fee.

SEC. 13. Section 2733 of the Business and Professions Code is amended to read:

2733. (a) (1) (A) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (k) of Section 2815, the board may issue a temporary license to practice professional nursing, and a temporary certificate to practice as a certified public health nurse for a period of six months from the date of issuance.

(B) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (d) of Section 2838.2, the board may

issue a temporary certificate to practice as a certified clinical nurse specialist for a period of six months from the date of issuance.

(C) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (e) of Section 2815.5, the board may issue a temporary certificate to practice as a certified nurse midwife for a period of six months from the date of issuance.

(D) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (d) of Section 2830.7, the board may issue a temporary certificate to practice as a certified nurse anesthetist for a period of six months from the date of issuance.

(E) Upon approval of an application filed pursuant to subdivision (b) of Section 2732.1, and upon the payment of the fee prescribed by subdivision (p) of Section 2815, the board may issue a temporary certificate to practice as a certified nurse practitioner for a period of six months from the date of issuance.

(2) A temporary license or temporary certificate shall terminate upon notice thereof by certified mail, return receipt requested, if it is issued by mistake or if the application for permanent licensure is denied.

(b) Upon written application, the board may reissue a temporary license or temporary certificate to any person who has applied for a regular renewable license pursuant to subdivision (b) of Section 2732.1 and who, in the judgment of the board has been excusably delayed in completing his or her application for or the minimum requirements for a regular renewable license, but the board may not reissue a temporary license or temporary certificate more than twice to any one person.

SEC. 14. Section 2746.51 of the Business and Professions Code is amended to read:

2746.51. (a) Neither this chapter nor any other provision of law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule II, III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), when all of the following apply:

(1) The drugs or devices are furnished or ordered incidentally to the provision of any of the following:

(A) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.

(B) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.

(C) Care rendered, consistent with the certified nurse-midwife's educational preparation or for which clinical competency has been established and maintained, to persons within a facility specified in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the Health and Safety Code, a clinic as specified in Section 1204 of the Health and Safety Code, a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code, a licensed birth center as defined in Section 1204.3 of the Health and Safety Code, or a special hospital specified as a maternity hospital in subdivision (f) of Section 1250 of the Health and Safety Code.

(2) The drugs or devices are furnished or ordered by a certified nurse-midwife in accordance with standardized procedures or protocols. For purposes of this section, standardized procedure means a document, including protocols, developed and approved by the supervising physician and surgeon, the certified nurse-midwife, and the facility administrator or his or her designee. The standardized procedure covering the furnishing or ordering of drugs or devices shall specify all of the following:

(A) Which certified nurse-midwife may furnish or order drugs or devices.

(B) Which drugs or devices may be furnished or ordered and under what circumstances.

(C) The extent of physician and surgeon supervision.

(D) The method of periodic review of the certified nurse-midwife's competence, including peer review, and review of the provisions of the standardized procedure.

(3) If Schedule II or III controlled substances, as defined in Sections 11055 and 11056 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon. For Schedule II controlled substance protocols, the provision for furnishing the Schedule II controlled substance shall address the diagnosis of the illness, injury, or

condition for which the Schedule II controlled substance is to be furnished.

(4) The furnishing or ordering of drugs or devices by a certified nurse-midwife occurs under physician and surgeon supervision. For purposes of this section, no physician and surgeon shall supervise more than four certified nurse-midwives at one time. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

(A) Collaboration on the development of the standardized procedure or protocol.

(B) Approval of the standardized procedure or protocol.

(C) Availability by telephonic contact at the time of patient examination by the certified nurse-midwife.

(b) (1) The furnishing or ordering of drugs or devices by a certified nurse-midwife is conditional on the issuance by the board of a number to the applicant who has successfully completed the requirements of paragraph (2). The number shall be included on all transmittals of orders for drugs or devices by the certified nurse-midwife. The board shall maintain a list of the certified nurse-midwives that it has certified pursuant to this paragraph and the number it has issued to each one. The board shall make the list available to the California State Board of Pharmacy upon its request. Every certified nurse-midwife who is authorized pursuant to this section to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.

(2) The board has certified in accordance with paragraph (1) that the certified nurse-midwife has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section. The board shall establish the requirements for satisfactory completion of this paragraph. The board may charge the applicant a fee to cover all necessary costs to implement this section, that shall be not less than four hundred dollars ($400) nor more than one thousand five hundred dollars ($1,500) for an initial application, nor less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000) for an application for renewal. The board may charge a penalty fee for failure to renew a furnishing number within the prescribed

time that shall be not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(3) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.

(4) A copy of the standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a certified nurse-midwife shall be provided upon request to any licensed pharmacist who is uncertain of the authority of the certified nurse-midwife to perform these functions.

(5) Certified nurse-midwives who are certified by the board and hold an active furnishing number, who are currently authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration shall provide documentation of continuing education specific to the use of Schedule II controlled substances in settings other than a hospital based on standards developed by the board.

(c) Drugs or devices furnished or ordered by a certified nurse-midwife may include Schedule II controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) under the following conditions:

(1) The drugs and devices are furnished or ordered in accordance with requirements referenced in paragraphs (2) to (4), inclusive, of subdivision (a) and in paragraphs (1) to (3), inclusive, of subdivision (b).

(2) When Schedule II controlled substances, as defined in Section 11055 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon.

(d) Furnishing of drugs or devices by a certified nurse-midwife means the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure or protocol. Use of the term “furnishing” in this section shall include the following:

(1) The ordering of a drug or device in accordance with the standardized procedure or protocol.

(2) Transmitting an order of a supervising physician and surgeon.

(e) "Drug order" or "order" for purposes of this section means an order for medication or for a drug or device that is dispensed to or for an ultimate user, issued by a certified nurse-midwife as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by certified nurse-midwives; and (3) the signature of a certified nurse-midwife on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

SEC. 15. Section 2786.5 of the Business and Professions Code is amended to read:

2786.5. (a) An institution of higher education or a private postsecondary school of nursing approved by the board pursuant to subdivision (b) of Section 2786 shall remit to the board for deposit in the Board of Registered Nursing Fund the following fees, in accordance with the following schedule:

(1) The fee for approval of a school of nursing shall be fixed by the board at not less than forty thousand dollars ($40,000) nor more than eighty thousand dollars ($80,000).

(2) The fee for continuing approval of a nursing program established after January 1, 2013, shall be fixed by the board at not less than fifteen thousand dollars ($15,000) nor more than thirty thousand dollars ($30,000).

(3) The processing fee for authorization of a substantive change to an approval of a school of nursing shall be fixed by the board at not less than two thousand five hundred dollars ($2,500) nor more than five thousand dollars ($5,000).

(b) If the board determines that the annual cost of providing oversight and review of a school of nursing, as required by this article, is less than the amount of any fees required to be paid by that institution pursuant to this article, the board may decrease the fees applicable to that institution to an amount that is proportional to the board's costs associated with that institution.

SEC. 16. Section 2811 of the Business and Professions Code is amended to read:

2811. (a) Each person holding a regular renewable license under this chapter, whether in an active or inactive status, shall apply for a renewal of his license and pay the biennial renewal fee required by this chapter each two years on or before the last day of the month following the month in which his birthday occurs, beginning with the second birthday following the date on which the license was issued, whereupon the board shall renew the license.

(b) Each such license not renewed in accordance with this section shall expire but may within a period of eight years thereafter be reinstated upon payment of the fee required by this chapter and upon submission of such proof of the applicant's qualifications as may be required by the board, except that during such eight-year period no examination shall be required as a condition for the reinstatement of any such expired license which has lapsed solely by reason of nonpayment of the renewal fee. After the expiration of such eight-year period the board may require as a condition of reinstatement that the applicant pass such examination as it deems necessary to determine his present fitness to resume the practice of professional nursing.

(c) A license in an inactive status may be restored to an active status if the licensee meets the continuing education standards of Section 2811.5.

SEC. 17. Section 2811.5 of the Business and Professions Code is amended to read:

2811.5. (a) Each person renewing his or her license under Section 2811 shall submit proof satisfactory to the board that, during the preceding two-year period, he or she has been informed of the developments in the registered nurse field or in any special area of practice engaged in by the licensee, occurring since the last renewal thereof, either by pursuing a course or courses of continuing education in the registered nurse field or relevant to the practice of the licensee, and approved by the board, or by other means deemed equivalent by the board.

(b) For purposes of this section, the board shall, by regulation, establish standards for continuing education. The standards shall be established in a manner to ensure that a variety of alternative forms of continuing education are available to licensees, including,

but not limited to, academic studies, in-service education, institutes, seminars, lectures, conferences, workshops, extension studies, and home study programs. The standards shall take cognizance of specialized areas of practice, and content shall be relevant to the practice of nursing and shall be related to the scientific knowledge or technical skills required for the practice of nursing or be related to direct or indirect patient or client care. The continuing education standards established by the board shall not exceed 30 hours of direct participation in a course or courses approved by the board, or its equivalent in the units of measure adopted by the board.

(c) The board shall audit continuing education providers at least once every five years to ensure adherence to regulatory requirements, and shall withhold or rescind approval from any provider that is in violation of the regulatory requirements.

(d) The board shall encourage continuing education in spousal or partner abuse detection and treatment. In the event the board establishes a requirement for continuing education coursework in spousal or partner abuse detection or treatment, that requirement shall be met by each licensee within no more than four years from the date the requirement is imposed.

(e) In establishing standards for continuing education, the board shall consider including a course in the special care needs of individuals and their families facing end-of-life issues, including, but not limited to, all of the following:

(1) Pain and symptom management.

(2) The psycho-social dynamics of death.

(3) Dying and bereavement.

(4) Hospice care.

(f) In establishing standards for continuing education, the board may include a course on pain management.

(g) This section shall not apply to licensees during the first two years immediately following their initial licensure in California or any other governmental jurisdiction.

(h) The board may, in accordance with the intent of this section, make exceptions from continuing education requirements for licensees residing in another state or country, or for reasons of health, military service, or other good cause.

SEC. 18. Section 2815 of the Business and Professions Code is amended to read:

2815. Subject to the provisions of Section 128.5, the amount of the fees prescribed by this chapter in connection with the issuance of licenses for registered nurses under its provisions is that fixed by the following schedule:

(a) (1) The fee to be paid upon the filing by a graduate of an approved school of nursing in this state of an application for a licensure by examination shall be fixed by the board at not less than three hundred dollars ($300) nor more than one thousand dollars ($1,000).

(2) The fee to be paid upon the filing by a graduate of a school of nursing in another state, district, or territory of the United States of an application for a licensure by examination shall be fixed by the board at not less than three hundred fifty dollars ($350) nor more than one thousand dollars ($1,000).

(3) The fee to be paid upon the filing by a graduate of a school of nursing in another country of an application for a licensure by examination shall be fixed by the board at not less than seven hundred fifty dollars ($750) nor more than one thousand five hundred dollars ($1,500).

(4) The fee to be paid upon the filing of an application for licensure by a repeat examination shall be fixed by the board at not less than two hundred fifty dollars ($250) and not more than one thousand dollars ($1,000).

(b) The fee to be paid for taking each examination shall be the actual cost to purchase an examination from a vendor approved by the board.

(c) (1) The fee to be paid for application by a person who is licensed or registered as a nurse in another state, district, or territory of the United States for licensure by endorsement shall be fixed by the board at not less than three hundred fifty dollars ($350) nor more than one thousand dollars ($1,000).

(2) The fee to be paid for application by a person who is licensed or registered as a nurse in another country for licensure by endorsement shall be fixed by the board at not less than seven hundred fifty dollars ($750) nor more than one thousand five hundred dollars ($1,500).

(d) (1) The biennial fee to be paid upon the filing of an application for renewal of the license shall be not less than one hundred eighty dollars ($180) nor more than seven hundred fifty dollars ($750). In addition, an assessment of ten dollars ($10) shall

be collected and credited to the Registered Nurse Education Fund, pursuant to Section 2815.1.

(2) The fee to be paid upon the filing of an application for reinstatement pursuant to subdivision (b) of Section 2811 shall be not less than three hundred fifty dollars ($350) nor more than one thousand dollars ($1,000).

(e) The penalty fee for failure to renew a license within the prescribed time shall be fixed by the board at not more than 50 percent of the regular renewal fee, but not less than ninety dollars ($90) nor more than three hundred seventy-five dollars ($375).

(f) The fee to be paid for approval of a continuing education provider shall be fixed by the board at not less than five hundred dollars ($500) nor more than one thousand dollars ($1,000).

(g) The biennial fee to be paid upon the filing of an application for renewal of provider approval shall be fixed by the board at not less than seven hundred fifty dollars ($750) nor more than one thousand dollars ($1,000).

(h) The penalty fee for failure to renew provider approval within the prescribed time shall be fixed at not more than 50 percent of the regular renewal fee, but not less than one hundred twenty-five dollars ($125) nor more than five hundred dollars ($500).

(i) The penalty for submitting insufficient funds or fictitious check, draft or order on any bank or depository for payment of any fee to the board shall be fixed at not less than fifteen dollars ($15) nor more than thirty dollars ($30).

(j) The fee to be paid for an interim permit shall be fixed by the board at not less than one hundred dollars ($100) nor more than two hundred fifty dollars ($250).

(k) The fee to be paid for a temporary license shall be fixed by the board at not less than one hundred dollars ($100) nor more than two hundred fifty dollars ($250).

(*l*) The fee to be paid for processing endorsement papers to other states shall be fixed by the board at not less than one hundred dollars ($100) nor more than two hundred dollars ($200).

(m) The fee to be paid for a certified copy of a school transcript shall be fixed by the board at not less than fifty dollars ($50) nor more than one hundred dollars ($100).

(n) (1) The fee to be paid for a duplicate pocket license shall be fixed by the board at not less than fifty dollars ($50) nor more than seventy-five dollars ($75).

(2) The fee to be paid for a duplicate wall certificate shall be fixed by the board at not less than sixty dollars ($60) nor more than one hundred dollars ($100).

(o) (1) The fee to be paid by a registered nurse for an evaluation of his or her qualifications to use the title "nurse practitioner" shall be fixed by the board at not less than five hundred dollars ($500) nor more than one thousand five hundred dollars ($1,500).

(2) The fee to be paid by a registered nurse for a temporary certificate to practice as a nurse practitioner shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than five hundred dollars ($500).

(3) The fee to be paid upon the filing of an application for renewal of a certificate to practice as a nurse practitioner shall be not less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000).

(4) The penalty fee for failure to renew a certificate to practice as a nurse practitioner within the prescribed time shall be not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(p) The fee to be paid by a registered nurse for listing as a "psychiatric mental health nurse" shall be fixed by the board at not less than three hundred fifty dollars ($350) nor more than seven hundred fifty dollars ($750).

(q) The fee to be paid for duplicate National Council Licensure Examination for registered nurses (NCLEX-RN) examination results shall be not less than sixty dollars ($60) nor more than one hundred dollars ($100).

(r) The fee to be paid for a letter certifying a license shall be not less than twenty dollars ($20) nor more than thirty dollars ($30).

No further fee shall be required for a license or a renewal thereof other than as prescribed by this chapter.

SEC. 19. Section 2815.5 of the Business and Professions Code is amended to read:

2815.5. The amount of the fees prescribed by this chapter in connection with the issuance of certificates as nurse-midwives is that fixed by the following schedule:

(a) The fee to be paid upon the filing of an application for a certificate shall be fixed by the board at not less than five hundred

dollars ($500) nor more than one thousand five hundred dollars ($1,500).

(b) The biennial fee to be paid upon the application for a renewal of a certificate shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000).

(c) The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(d) The fee to be paid upon the filing of an application for the nurse-midwife equivalency examination shall be fixed by the board at not less than one hundred dollars ($100) nor more than two hundred dollars ($200).

(e) The fee to be paid for a temporary certificate shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than five hundred dollars ($500).

SEC. 20. Section 2816 of the Business and Professions Code is amended to read:

2816. The nonrefundable fee to be paid by a registered nurse for an evaluation of his or her qualifications to use the title "public health nurse" shall be equal to the fees set out in subdivision (o) of Section 2815. The fee to be paid ~~for~~ upon the application for renewal of the certificate to practice as a public health nurse shall be fixed by the board at not less than one hundred twenty-five dollars ($125) and not more than five hundred dollars ($500). All fees payable under this section shall be collected by and paid to the Registered Nursing Fund. It is the intention of the Legislature that the costs of carrying out the purposes of this article shall be covered by the revenue collected pursuant to this section.

SEC. 21. Section 2830.7 of the Business and Professions Code is amended to read:

2830.7. The amount of the fees prescribed by this chapter in connection with the issuance of certificates as nurse anesthetists is that fixed by the following schedule:

(a) The fee to be paid upon the filing of an application for a certificate shall be fixed by the board at not less than five hundred dollars ($500) nor more than one thousand five hundred dollars ($1,500).

(b) The biennial fee to be paid upon the application for a renewal of a certificate shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000).

(c) The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(d) The fee to be paid for a temporary certificate shall be fixed by the board at not less than one hundred fifty dollars ($150) nor more than five hundred dollars ($500).

SEC. 22. Section 2836.3 of the Business and Professions Code is amended to read:

2836.3. (a) The furnishing of drugs or devices by nurse practitioners is conditional on issuance by the board of a number to the nurse applicant who has successfully completed the requirements of subdivision (g) of Section 2836.1. The number shall be included on all transmittals of orders for drugs or devices by the nurse practitioner. The board shall make the list of numbers issued available to the Board of Pharmacy. The board may charge the applicant a fee to cover all necessary costs to implement this section, that shall be not less than four hundred dollars ($400) nor more than one thousand five hundred dollars ($1,500) for an initial application, nor less than one hundred fifty dollars ($150) nor more than one thousand dollars ($1,000) for an application for renewal. The board may charge a penalty fee for failure to renew a furnishing number within the prescribed time that shall be not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(b) The number shall be renewable at the time of the applicant's registered nurse license renewal.

(c) The board may revoke, suspend, or deny issuance of the numbers for incompetence or gross negligence in the performance of functions specified in Sections 2836.1 and 2836.2.

SEC. 23. Section 2838.2 of the Business and Professions Code is amended to read:

2838.2. (a) A clinical nurse specialist is a registered nurse with advanced education, who participates in expert clinical practice, education, research, consultation, and clinical leadership as the major components of his or her role.

(b) The board may establish categories of clinical nurse specialists and the standards required to be met for nurses to hold themselves out as clinical nurse specialists in each category. The standards shall take into account the types of advanced levels of nursing practice that are or may be performed and the clinical and didactic education, experience, or both needed to practice safety at those levels. In setting the standards, the board shall consult with clinical nurse specialists, physicians and surgeons appointed by the Medical Board with expertise with clinical nurse specialists, and health care organizations that utilize clinical nurse specialists.

(c) A registered nurse who meets one of the following requirements may apply to become a clinical nurse specialist:

(1) Possession of a master's degree in a clinical field of nursing.

(2) Possession of a master's degree in a clinical field related to nursing with course work in the components referred to in subdivision (a).

(3) On or before July 1, 1998, meets the following requirements:

(A) Current licensure as a registered nurse.

(B) Performs the role of a clinical nurse specialist as described in subdivision (a).

(C) Meets any other criteria established by the board.

(d) (1) A nonrefundable fee of not less than five hundred dollars ($500), but not to exceed one thousand five hundred dollars ($1,500) shall be paid by a registered nurse applying to be a clinical nurse specialist for the evaluation of his or her qualifications to use the title "clinical nurse specialist."

(2) The fee to be paid for a temporary certificate to practice as a clinical nurse specialist shall be not less than thirty dollars ($30) nor more than fifty dollars ($50).

(3) A biennial renewal fee shall be paid upon submission of an application to renew the clinical nurse specialist certificate and shall be established by the board at no less than one hundred fifty dollars ($150) and no more than one thousand dollars ($1,000).

(4) The penalty fee for failure to renew a certificate within the prescribed time shall be 50 percent of the renewal fee in effect on the date of the renewal of the license, but not less than seventy-five dollars ($75) nor more than five hundred dollars ($500).

(5) The fees authorized by this subdivision shall not exceed the amount necessary to cover the costs to the board to administer this section.

SEC. 24. Section 4128.2 of the Business and Professions Code is amended to read:

4128.2. (a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

SEC. 25. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars ($200) and may be increased to two hundred sixty dollars ($260).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars ($125) and may be increased to one hundred sixty-five dollars ($165).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section

4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year’s operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars ($80) and may be increased to one hundred five dollars ($105). The fee for renewal of a pharmacy technician license shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars ($405) and may be increased to four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars ($780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) This section shall become inoperative on July 1, 2017, and as of January 1, 2018, is repealed.

SEC. 26. Section 4400 is added to the Business and Professions Code, to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be

two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three

hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(x) This section shall become operative on July 1, 2017.

SEC. 27. Chapter 15 (commencing with Section 4999) of Division 2 of the Business and Professions Code is repealed.

SEC. 28. Section 7137 of the Business and Professions Code is amended to read:

7137. The board shall set fees by regulation. These fees shall not exceed the following schedule:

(a) (1) The application fee for an original license in a single classification shall not be more than three hundred sixty dollars ($360).

(2) The application fee for each additional classification applied for in connection with an original license shall not be more than seventy-five dollars ($75).

(3) The application fee for each additional classification pursuant to Section 7059 shall not be more than three hundred dollars ($300).

(4) The application fee to replace a responsible managing officer, responsible managing manager, responsible managing member, or responsible managing employee pursuant to Section 7068.2 shall not be more than three hundred dollars ($300).

(5) The application fee to add personnel, other than a qualifying individual, to an existing license shall not be more than one hundred fifty dollars ($150).

(b) The fee for rescheduling an examination for an applicant who has applied for an original license, additional classification, a change of responsible managing officer, responsible managing manager, responsible managing member, or responsible managing employee, or for an asbestos certification or hazardous substance removal certification, shall not be more than sixty dollars ($60).

(c) The fee for scheduling or rescheduling an examination for a licensee who is required to take the examination as a condition of probation shall not be more than sixty dollars ($60).

(d) The initial license fee for an active or inactive license shall not be more than two hundred twenty dollars ($220).

(e) (1) The renewal fee for an active license shall not be more than four hundred thirty dollars ($430).

(2) The renewal fee for an inactive license shall not be more than two hundred twenty dollars ($220).

(f) The delinquency fee is an amount equal to 50 percent of the renewal fee, if the license is renewed after its expiration.

(g) The registration fee for a home improvement salesperson shall not be more than ninety dollars ($90).

(h) The renewal fee for a home improvement salesperson registration shall not be more than ninety dollars ($90).

(i) The application fee for an asbestos certification examination shall not be more than ninety dollars ($90).

(j) The application fee for a hazardous substance removal or remedial action certification examination shall not be more than ninety dollars ($90).

(k) In addition to any other fees charged to C-10 and C-7 contractors, the board may charge a fee not to exceed twenty dollars ($20), which shall be used by the board to enforce provisions of the Labor Code related to electrician certification.

(*l*) The board shall, by regulation, establish criteria for the approval of expedited processing of applications. Approved expedited processing of applications for licensure or registration, as required by other provisions of law, shall not be subject to this subdivision.

SEC. 29. Section 7153.3 of the Business and Professions Code is amended to read:

7153.3. (a) To renew a home improvement salesperson registration, which has not expired, the registrant shall before the time at which the registration would otherwise expire, apply for renewal on a form prescribed by the registrar and pay a renewal fee prescribed by this chapter. Renewal of an unexpired registration shall continue the registration in effect for the two-year period following the expiration date of the registration, when it shall expire if it is not again renewed.

(b) An application for renewal of registration is delinquent if the application is not postmarked or received via electronic transmission as authorized by Section 7156.6 by the date on which the registration would otherwise expire. A registration may, however, still be renewed at any time within three years after its expiration upon the filing of an application for renewal on a form prescribed by the registrar and the payment of the renewal fee prescribed by this chapter and a delinquent renewal penalty equal to 50 percent of the renewal fee. If a registration is not renewed within three years, the person shall make a new application for registration pursuant to Section 7153.1.

(c) The registrar may refuse to renew a registration for failure by the registrant to complete the application for renewal of registration. If a registrant fails to return the application rejected for insufficiency or incompleteness within 90 days from the original date of rejection, the application and fee shall be deemed abandoned. Any application abandoned may not be reinstated. However, the person may file a new application for registration pursuant to Section 7153.1.

The registrar may review and accept the petition of a person who disputes the abandonment of his or her renewal application upon a showing of good cause. This petition shall be received within 90 days of the date the application for renewal is deemed abandoned.

SEC. 30. Section 8031 of the Business and Professions Code is amended to read:

8031. The amount of the fees required by this chapter is that fixed by the board in accordance with the following schedule:

(a) The fee for filing an application for each examination shall be no more than forty dollars ($40).

(b) The fee for examination and reexamination for the written or practical part of the examination shall be in an amount fixed by the board, which shall be equal to the actual cost of preparing, administering, grading, and analyzing the examination, but shall not exceed seventy-five dollars ($75) for each separate part, for each administration.

(c) The initial certificate fee is an amount equal to the renewal fee in effect on the last regular renewal date before the date on which the certificate is issued, except that, if the certificate will expire less than 180 days after its issuance, then the fee is 50 percent of the renewal fee in effect on the last regular renewal date before the date on which the certificate is issued, or fifty dollars ($50), whichever is greater. The board may, by appropriate regulation, provide for the waiver or refund of the initial certificate fee where the certificate is issued less than 45 days before the date on which it will expire.

(d) By a resolution adopted by the board, a renewal fee may be established in such amounts and at such times as the board may deem appropriate to meet its operational expenses and funding responsibilities as set forth in this chapter. The renewal fee shall not be more than two hundred fifty dollars ($250) nor less than ten dollars ($10) annually, with the following exception:

Any person who is employed full time by the State of California as a hearing reporter and who does not otherwise render shorthand reporting services for a fee shall be exempt from licensure while in state employment and shall not be subject to the renewal fee provisions of this subdivision until 30 days after leaving state employment. The renewal fee shall, in addition to the amount fixed by this subdivision, include any unpaid fees required by this section plus any delinquency fee.

(e) The duplicate certificate fee shall be no greater than ten dollars ($10).

(f) The penalty for failure to notify the board of a change of name or address as required by Section 8024.6 shall be no greater than fifty dollars ($50).

SEC. 31. Section 8516 of the Business and Professions Code is amended to read:

8516. (a) This section, and Section 8519, apply only to wood destroying pests or organisms.

(b) A registered company or licensee shall not commence work on a contract, or sign, issue, or deliver any documents expressing an opinion or statement relating to the absence or presence of wood destroying pests or organisms until an inspection has been made by a licensed Branch 3 field representative or operator employed by a registered company, except as provided in Section 8519.5. The address of each property inspected or upon which work is completed shall be reported on a form prescribed by the board and shall be filed with the board no later than 10 business days after the commencement of an inspection or upon completed work.

Every property inspected pursuant to this subdivision or Section 8518 shall be assessed a filing fee pursuant to Section 8674.

Failure of a registered company to report and file with the board the address of any property inspected or work completed pursuant to Section 8518 or this section is grounds for disciplinary action and shall subject the registered company to a fine of not more than two thousand five hundred dollars ($2,500). The address of an inspection report prepared for use by an attorney for litigation purposes shall not be required to be reported to the board and shall not be assessed a filing fee.

A written inspection report conforming to this section and a form approved by the board shall be prepared and delivered to the person requesting the inspection and the property owner, or to the property

owner's designated agent, within 10 business days from the start of the inspection, except that an inspection report prepared for use by an attorney for litigation purposes is not required to be reported to the board or the property owner. An inspection report may be a complete, limited, supplemental, or reinspection report, as defined by Section 1993 of Title 16 of the California Code of Regulations. The report shall be delivered before work is commenced on any property. The registered company shall retain for three years all inspection reports, field notes, and activity forms.

Reports shall be made available for inspection and reproduction to the executive officer of the board or his or her duly authorized representative during business hours. All inspection reports or copies thereof shall be submitted to the board upon demand within two business days. The following shall be set forth in the report:

(1) The start date of the inspection and the name of the licensed field representative or operator making the inspection.

(2) The name and address of the person or firm ordering the report.

(3) The name and address of the property owner and any person who is a party in interest.

(4) The address or location of the property.

(5) A general description of the building or premises inspected.

(6) A foundation diagram or sketch of the structure or structures or portions of the structure or structures inspected, including the approximate location of any infested or infected areas evident, and the parts of the structure where conditions that would ordinarily subject those parts to attack by wood destroying pests or organisms exist. Reporting of the infested or infected wood members, or parts of the structure identified, shall be listed in the inspection report to clearly identify them, as is typical in standard construction components, including, but not limited to, siding, studs, rafters, floor joists, fascia, subfloor, sheathing, and trim boards.

(7) Information regarding the substructure, foundation walls and footings, porches, patios and steps, air vents, abutments, attic spaces, roof framing that includes the eaves, rafters, fascias, exposed timbers, exposed sheathing, ceiling joists, and attic walls, or other parts subject to attack by wood destroying pests or organisms. Conditions usually deemed likely to lead to infestation or infection, such as earth-wood contacts, excessive cellulose

debris, faulty grade levels, excessive moisture conditions, evidence of roof leaks, and insufficient ventilation are to be reported.

(8) One of the following statements, as appropriate, printed in bold type:

(A) The exterior surface of the roof was not inspected. If you want the water tightness of the roof determined, you should contact a roofing contractor who is licensed by the Contractors' State License Board.

(B) The exterior surface of the roof was inspected to determine whether or not wood destroying pests or organisms are present.

(9) Indication or description of any areas that are inaccessible or not inspected with recommendation for further inspection if practicable. If, after the report has been made in compliance with this section, authority is given later to open inaccessible areas, a supplemental report on conditions in these areas shall be made.

(10) Recommendations for corrective measures.

(11) Information regarding the pesticide or pesticides to be used for their control or prevention as set forth in subdivision (a) of Section 8538.

(12) The inspection report shall clearly disclose that if requested by the person ordering the original report, a reinspection of the structure will be performed if an estimate or bid for making repairs was given with the original inspection report, or thereafter.

An estimate or bid shall be given separately allocating the costs to perform each and every recommendation for corrective measures as specified in subdivision (c) with the original inspection report if the person who ordered the original inspection report so requests, and if the registered company is regularly in the business of performing each corrective measure.

If no estimate or bid was given with the original inspection report, or thereafter, then the registered company shall not be required to perform a reinspection.

A reinspection shall be an inspection of those items previously listed on an original report to determine if the recommendations have been completed. Each reinspection shall be reported on an original inspection report form and shall be labeled "Reinspection." Each reinspection shall also identify the original report by date.

After four months from an original inspection, all inspections shall be original inspections and not reinspections.

Any reinspection shall be performed for not more than the price of the registered company's original inspection price and shall be completed within 10 business days after a reinspection has been ordered.

(13) The inspection report shall contain the following statement, printed in boldface type:

"NOTICE: Reports on this structure prepared by various registered companies should list the same findings (i.e. termite infestations, termite damage, fungus damage, etc.). However, recommendations to correct these findings may vary from company to company. You have a right to seek a second opinion from another company."

(c) At the time a report is ordered, the registered company or licensee shall inform the person or entity ordering the report, that a separate report is available pursuant to this subdivision. If a separate report is requested at the time the inspection report is ordered, the registered company or licensee shall separately identify on the report each recommendation for corrective measures as follows:

(1) The infestation or infection that is evident.

(2) The conditions that are present that are deemed likely to lead to infestation or infection.

If a registered company or licensee fails to inform as required by this subdivision and a dispute arises, or if any other dispute arises as to whether this subdivision has been complied with, a separate report shall be provided within 24 hours of the request but, in no event, later than the next business day, and at no additional cost.

(d) When a corrective condition is identified, either as paragraph (1) or (2) of subdivision (c), and the property owner or the property owner's designated agent chooses not to correct those conditions, the registered company or licensee shall not be liable for damages resulting from a failure to correct those conditions or subject to any disciplinary action by the board. Nothing in this subdivision, however, shall relieve a registered company or a licensee of any liability resulting from negligence, fraud, dishonest dealing, other violations pursuant to this chapter, or contractual obligations

between the registered company or licensee and the responsible parties.

(e) The inspection report form prescribed by the board shall separately identify the infestation or infection that is evident and the conditions that are present that are deemed likely to lead to infestation or infection. If a separate form is requested, the form shall explain the infestation or infection that is evident and the conditions that are present that are deemed likely to lead to infestation or infection and the difference between those conditions. In no event, however, shall conditions deemed likely to lead to infestation or infection be characterized as actual "defects" or as actual "active" infestations or infections or in need of correction as a precondition to issuing a certification pursuant to Section 8519.

(f) The report and any contract entered into shall also state specifically when any guarantee for the work is made, and if so, the specific terms of the guarantee and the period of time for which the guarantee shall be in effect. If a guarantee extends beyond three years, the registered company shall maintain all original inspection reports, field notes, activity forms, and notices of completion for the duration of the guarantee period and for one year after the guarantee expires.

(g) For purposes of this section, "control service agreement" means an agreement, including extended warranties, to have a licensee conduct over a period of time regular inspections and other activities related to the control or eradication of wood destroying pests and organisms. Under a control service agreement a registered company shall refer to the original report and contract in a manner as to identify them clearly, and the report shall be assumed to be a true report of conditions as originally issued, except it may be modified after a control service inspection. A registered company is not required to issue a report as outlined in paragraphs (1) to (11), inclusive, of subdivision (b) after each control service inspection. If after control service inspection, no modification of the original report is made in writing, then it will be assumed that conditions are as originally reported. A control service contract shall state specifically the particular wood destroying pests or organisms and the portions of the buildings or structures covered by the contract.

(h) A registered company or licensee may enter into and maintain a control service agreement provided the following requirements are met:

(1) The control service agreement shall be in writing, signed by both parties, and shall specifically include the following:

(A) The wood destroying pests and organisms covered by the control service agreement.

(B) Any wood destroying pest or organism that is not covered must be specifically listed.

(C) The type and manner of treatment to be used to correct the infestations or infections.

(D) The structures or buildings, or portions thereof, covered by the agreement, including a statement specifying whether the coverage for purposes of periodic inspections is limited or full. Any exclusions from those described in the original report must be specifically listed.

(E) A reference to the original inspection report.

(F) The frequency of the inspections to be provided, the fee to be charged for each renewal, and the duration of the agreement.

(G) Whether the fee includes structural repairs.

(H) If the services provided are guaranteed, and, if so, the terms of the guarantee.

(I) A statement that all corrections of infestations or infections covered by the control service agreement shall be completed within six months of discovery, unless otherwise agreed to in writing by both parties.

(2) The original inspection report, the control service agreement, and completion report shall be maintained for three years after the cancellation of the control service agreement.

(3) Inspections made pursuant to a control service agreement shall be conducted by a Branch 3 licensee. Section 8506.1 does not modify this provision.

(4) A full inspection of the property covered by the control service agreement shall be conducted and a report filed pursuant to subdivision (b) at least once every three years from the date that the agreement was entered into, unless the consumer cancels the contract within three years from the date the agreement was entered into.

(5) Under a control service agreement, a written report shall be required for the correction of any infestation or infection unless all of the following conditions are met:

(A) The infestation or infection has been previously reported.

(B) The infestation or infection is covered by the control service agreement.

(C) There is no additional charge for correcting the infestation or infection.

(D) Correction of the infestation or infection takes place within 45 days of its discovery.

(E) Correction of the infestation or infection does not include fumigation.

(6) All notice requirements pursuant to Section 8538 shall apply to all pesticide treatments conducted under control service agreements.

(i) All work recommended by a registered company, where an estimate or bid for making repairs was given with the original inspection report, or thereafter, shall be recorded on this report or a separate work agreement and shall specify a price for each recommendation. This information shall be provided to the person requesting the inspection, and shall be retained by the registered company with the inspection report copy for three years.

SEC. 32. Section 8518 of the Business and Professions Code is amended to read:

8518. (a) When a registered company completes work under a contract, it shall prepare, on a form prescribed by the board, a notice of work completed and not completed, and shall furnish that notice to the owner of the property or the owner's agent within 10 business days after completing the work. The notice shall include a statement of the cost of the completed work and estimated cost of work not completed.

(b) The address of each property inspected or upon which work was completed shall be reported on a form prescribed by the board and shall be filed with the board no later than 10 business days after completed work.

(c) A filing fee shall be assessed pursuant to Section 8674 for every property upon which work is completed.

(d) Failure of a registered company to report and file with the board the address of any property upon which work was completed pursuant to subdivision (b) of Section 8516 or this section is

grounds for disciplinary action and shall subject the registered company to a fine of not more than two thousand five hundred dollars ($2,500).

(e) The registered company shall retain for three years all original notices of work completed, work not completed, and activity forms.

(f) Notices of work completed and not completed shall be made available for inspection and reproduction to the executive officer of the board or his or her duly authorized representative during business hours. Original notices of work completed or not completed or copies thereof shall be submitted to the board upon request within two business days.

(g) This section shall only apply to work relating to wood destroying pests or organisms.

~~SEC. 33. Section 8555 of the Business and Professions Code is amended to read:~~

~~8555. This chapter does not apply to:~~

~~(a) Public utilities operating under the regulations of the Public Utilities Commission, except to work performed upon property of the utilities not subject to the jurisdiction of the Public Utilities Commission or work done by the utility for hire.~~

~~(b) Persons engaged only in agricultural pest control work under permit or license by the Department of Pesticide Regulation or a county agricultural commissioner.~~

~~(c) Pest control performed by persons upon property that they own, lease, or rent, except that the persons shall be subject to the limitations imposed by Article 3 of this chapter.~~

~~(d) Governmental agencies, state, federal, city, or county officials, and their employees while officially engaged.~~

~~(e) Authorized representatives of an educational institution or state or federal agency engaged in research or study of pest control, or engaged in investigation or preparation for expert opinion or testimony. A professional engaging in research, study, investigation, or preparation for expert opinion or testimony on his or her own behalf shall comply with the requirements of this chapter.~~

~~(f) Certified architects and registered civil engineers, acting solely within their professional capacity, except that they shall be subject to the limitations imposed by Article 3 of this chapter.~~

~~(g) Persons engaged in the live capture and removal or exclusion of bees or wasps from a structure without the use of pesticides, provided those persons maintain insurance coverage as described in Section 8692.~~

~~SEC. 34.~~

SEC. 33. Section 1348.8 of the Health and Safety Code is repealed.

~~SEC. 35.~~

SEC. 34. Section 10279 of the Insurance Code is repealed.

~~SEC. 36.~~

SEC. 35. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Attachment 8

Draft article for *The Script*

End of Life Option Act is Enacted in California

On October 5, 2015, Governor Brown signed the End of Life Option Act (Act). The provisions will take effect June 9, 2016. A copy of Chapter 1, Statutes of 2015-16 Second Extraordinary Session, is available here: http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520162AB15

Recognizing that pharmacists are trained to utilize corresponding responsibility upon dispensing controlled substances prescriptions, the Board recommends that each pharmacist be aware of the fact that lethal doses of controlled substances may now be prescribed by providers who follow the requirements of this new law, and to be aware of this new law when contacted by a provider informing the pharmacist of the patient's decision.

This law allows a Californian with a terminal illness and who complies with specified criteria to end his or her life through the voluntary self-administration of lethal medications, expressly prescribed by a physician for that purpose. The law is very specific and contains procedures that physicians, pharmacists and patients need to follow. There are no exceptions to the requirements specified in the law.

Very generally, to qualify for a prescription for medication under the End of Life Option Act, a patient must be:

- A resident of California (specific qualifying criteria are provided in the law);
- 18 years of age or older;
- Mentally competent, i.e., capable of making and communicating his or her health care decisions; and
- Diagnosed with a terminal illness that will, within reasonable medical judgment, lead to death within six months.

The patient must be able to self-administer and ingest the prescribed medication. Two physicians must determine whether all the prescribed criteria have been met before the prescription is written and transmitted to the pharmacy. There are also requirements for completion of specified documents (see sections 443.10 - 443.11, and 443.22).

The Act provides that after a patient has made the necessary decisions, and the attending physician has performed his or her required duties under the Act, a prescriber may prescribe may issue a prescription for the aid in dying drug. (see section 443.59(b)(2))

The Act requires that a specified request form for an aid-in-dying drug include, among other things, the following statement:

I request that my attending physician prescribe an aid-in-dying drug that will end my life in a humane and dignified manner if I choose to take it, and I authorize my attending physician to contact any pharmacist about my request.

What Is an "Aid in Dying Drug"?

An aid in dying drug is defined as "a drug determined and prescribed by a physician for a qualified individual, which the qualified individual may choose to self-administer to bring about his or her death due to a terminal disease." (see section 443.1(b)).

The Act also recognizes the need for ancillary medication intended to minimize the qualified individual's discomfort. (see section 443.5(b)(1)). An "ancillary medication" may be an anti-emetic that is prescribed concurrently to avoid nausea and vomiting after the administration of a lethal medication dose.

What are Examples of Aid in Dying Drugs?

Oregon has had a similar law to California's End of Life Options Act since 1997. The most common drugs prescribed for this purpose in Oregon are secobarbital and pentobarbital. According the Medscape, the lethal dose prescribed is typically 9 g of secobarbital in capsules or 10 g of pentobarbital liquid. In either case, all the medication is to be consumed at one time and taken with juice or a preferred drink to mask the bitter taste.

Patients are typically prescribed an antiemetic at the same time, which they are directed to self-ingest about one hour before taking either medication to prevent nausea and vomiting.

How Will a Pharmacist Know If a Prescription Is Written for an End of Life Purpose?

After the attending physician performs the specified duties in the Act and with the consent of the qualified individual (the patient), the attending physician will contact a pharmacist, informing the pharmacist of the forthcoming prescription and delivering the prescription to the pharmacist in written form personally, by mail or electronically. The pharmacist may dispense the drug to the qualified individual, the attending physician or to a person expressly designated by the qualified individual after he or she provides a written or verbal designation to the pharmacist.

What Information Should a Pharmacist Provide During Counseling to the Patient or Family Member?

Given that nausea and vomiting are common with lethal medication doses, the pharmacist should counsel the patient or family member to contact the attending physician for assistance if the patient vomits after taking the medication.

If a patient changes his or her mind after taking an aid in dying drug, emergency medical services must be contacted immediately.

All medication not in active use should be stored away from where others, including children, could access the medication.

May a Pharmacist Refuse to Dispense an Aid in Dying Drug?

A pharmacist (and other health care providers) may refuse to perform activities authorized under the Act, which are mandated to be voluntary. The Act specifies: "a person or entity that elects, for reasons of conscience, morality , or ethics, not to engage in activities authorized pursuant to this part is not required to take any action in support of an individual's decision" under the Act. (see section 443.14(e)) The pharmacist's actions shall be in keeping with Business and Professions Code 733.

What Advice May Be Provided to Patients or Family Members Who Contact the Pharmacy with a Request to Dispose of Unwanted Aid in Dying Medication?

The law requires that a person who has custody or control of any unused aid-in-dying drugs prescribed pursuant to the Act after the death of the patient or which will go unused because the patient has changed his or her mind, shall personally deliver the unused aid-in-dying drugs for disposal by delivering it to the nearest qualified facility that properly disposes of controlled substances, or – if none is available – the person shall dispose of it by lawful means in accordance with guidelines promulgated by the California State Board of Pharmacy or a federal Drug Enforcement Administration approved take-back program. *See box to the right of this article.*

For more information:

1. Here is a link to the law:
http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520162AB15

2. Here is a link to background information about right to life option: see page 12 of http://www.mbc.ca.gov/Publications/Newsletters/newsletter_2016_01.pdf

In a side bar to the main article:

Pharmacists may need to assist patients or families seeking to dispose of unused aid-in-dying drugs. The law directs that:

> A person who has custody or control of any unused aid-in-dying drugs prescribed pursuant to this part after the death of the patient shall personally deliver the

> unused aid-in-dying drugs for disposal by delivering it to the nearest qualified facility that properly disposes of controlled substances, or if none is available, ***shall dispose of it by lawful means in accordance with guidelines promulgated by the California State Board of Pharmacy or a federal Drug Enforcement Administration approved take-back program (see section 443.20 California Health and Safety Code).***

The DEA drug-take back requirements are currently in effect. They allow pharmacies and other specified entities to assist patients with the destruction of their unwanted medication, which would include unused aid-in-dying medications.

Law enforcement agencies are one source authorized by the DEA to do such collection. Another source is to use "mail back" envelopes that are preaddressed with postage prepaid to specially licensed facilities that are licensed to destroy unwanted pharmaceuticals in a manner compliant with the DEA requirements.

Additionally there are some pharmacies that are operating DEA-registered collection receptacles that conform to the federal requirements to accept unwanted pharmaceuticals from patients.

The board is in the process of promulgating drug-take back regulations, and is currently reviewing public comments. The regulations that define the manner in which pharmaceutical take back bins may be operated within pharmacies is expected to be final near the end of 2016.

The Board of Pharmacy may assist pharmacists and the public who are seeking solutions to destroy unwanted aid-in-dying drugs by using one of these sources above. To obtain information, please contact the "ask an inspector" program at ask.inspector@pharmacy.ca.gov or call the board at 916-574-7900.

Assembly Bill No. 15

CHAPTER 1

An act to add and repeal Part 1.85 (commencing with Section 443) of Division 1 of the Health and Safety Code, relating to end of life.

[Approved by Governor October 5, 2015. Filed with Secretary of State October 5, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 15, Eggman. End of life.

Existing law authorizes an adult to give an individual health care instruction and to appoint an attorney to make health care decisions for that individual in the event of his or her incapacity pursuant to a power of attorney for health care.

This bill, until January 1, 2026, would enact the End of Life Option Act authorizing an adult who meets certain qualifications, and who has been determined by his or her attending physician to be suffering from a terminal disease, as defined, to make a request for a drug prescribed pursuant to these provisions for the purpose of ending his or her life. The bill would establish the procedures for making these requests. The bill would also establish specified forms to request an aid-in-dying drug, under specified circumstances, an interpreter declaration to be signed subject to penalty of perjury, thereby creating a crime and imposing a state-mandated local program, and a final attestation for an aid-in-dying drug. This bill would require specified information to be documented in the individual's medical record, including, among other things, all oral and written requests for an aid-in-dying drug.

This bill would prohibit a provision in a contract, will, or other agreement from being conditioned upon, or affected by, a person making or rescinding a request for the above-described drug. The bill would prohibit the sale, procurement, or issuance of any life, health, or annuity policy, health care service plan contract, or health benefit plan, or the rate charged for any policy or plan contract, from being conditioned upon or affected by the request. The bill would prohibit an insurance carrier from providing any information in communications made to an individual about the availability of an aid-in-dying drug absent a request by the individual or his or her attending physician at the behest of the individual. The bill would also prohibit any communication from containing both the denial of treatment and information as to the availability of aid-in-dying drug coverage.

This bill would provide a person, except as provided, immunity from civil or criminal liability solely because the person was present when the qualified individual self-administered the drug, or the person assisted the qualified individual by preparing the aid-in-dying drug so long as the person did not

assist with the ingestion of the drug, and would specify that the immunities and prohibitions on sanctions of a health care provider are solely reserved for conduct of a health care provider provided for by the bill. The bill would make participation in activities authorized pursuant to its provisions voluntary, and would make health care providers immune from liability for refusing to engage in activities authorized pursuant to its provisions. The bill would also authorize a health care provider to prohibit its employees, independent contractors, or other persons or entities, including other health care providers, from participating in activities under the act while on the premises owned or under the management or direct control of that prohibiting health care provider, or while acting within the course and scope of any employment by, or contract with, the prohibiting health care provider.

This bill would make it a felony to knowingly alter or forge a request for drugs to end an individual's life without his or her authorization or to conceal or destroy a withdrawal or rescission of a request for a drug, if it is done with the intent or effect of causing the individual's death. The bill would make it a felony to knowingly coerce or exert undue influence on an individual to request a drug for the purpose of ending his or her life, to destroy a withdrawal or rescission of a request, or to administer an aid-in-dying drug to an individual without their knowledge or consent. By creating a new crime, the bill would impose a state-mandated local program. The bill would provide that nothing in its provisions is to be construed to authorize ending a patient's life by lethal injection, mercy killing, or active euthanasia, and would provide that action taken in accordance with the act shall not constitute, among other things, suicide or homicide.

This bill would require physicians to submit specified forms and information to the State Department of Public Health after writing a prescription for an aid-in-dying drug and after the death of an individual who requested an aid-in-dying drug. The bill would authorize the Medical Board of California to update those forms and would require the State Department of Public Health to publish the forms on its Internet Web site. The bill would require the department to annually review a sample of certain information and records, make a statistical report of the information collected, and post that report to its Internet Web site.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Part 1.85 (commencing with Section 443) is added to Division 1 of the Health and Safety Code, to read:

PART 1.85. END OF LIFE OPTION ACT

443. This part shall be known and may be cited as the End of Life Option Act.

443.1. As used in this part, the following definitions shall apply:

(a) "Adult" means an individual 18 years of age or older.

(b) "Aid-in-dying drug" means a drug determined and prescribed by a physician for a qualified individual, which the qualified individual may choose to self-administer to bring about his or her death due to a terminal disease.

(c) "Attending physician" means the physician who has primary responsibility for the health care of an individual and treatment of the individual's terminal disease.

(d) "Attending physician checklist and compliance form" means a form, as described in Section 443.22, identifying each and every requirement that must be fulfilled by an attending physician to be in good faith compliance with this part should the attending physician choose to participate.

(e) "Capacity to make medical decisions" means that, in the opinion of an individual's attending physician, consulting physician, psychiatrist, or psychologist, pursuant to Section 4609 of the Probate Code, the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make and communicate an informed decision to health care providers.

(f) "Consulting physician" means a physician who is independent from the attending physician and who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding an individual's terminal disease.

(g) "Department" means the State Department of Public Health.

(h) "Health care provider" or "provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of this code; and any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of this code.

(i) "Informed decision" means a decision by an individual with a terminal disease to request and obtain a prescription for a drug that the individual may self-administer to end the individual's life, that is based on an understanding and acknowledgment of the relevant facts, and that is made after being fully informed by the attending physician of all of the following:

(1) The individual's medical diagnosis and prognosis.

(2) The potential risks associated with taking the drug to be prescribed.

(3) The probable result of taking the drug to be prescribed.

(4) The possibility that the individual may choose not to obtain the drug or may obtain the drug but may decide not to ingest it.

(5) The feasible alternatives or additional treatment opportunities, including, but not limited to, comfort care, hospice care, palliative care, and pain control.

(j) "Medically confirmed" means the medical diagnosis and prognosis of the attending physician has been confirmed by a consulting physician who has examined the individual and the individual's relevant medical records.

(k) "Mental health specialist assessment" means one or more consultations between an individual and a mental health specialist for the purpose of determining that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

(*l*) "Mental health specialist" means a psychiatrist or a licensed psychologist.

(m) "Physician" means a doctor of medicine or osteopathy currently licensed to practice medicine in this state.

(n) "Public place" means any street, alley, park, public building, any place of business or assembly open to or frequented by the public, and any other place that is open to the public view, or to which the public has access.

(o) "Qualified individual" means an adult who has the capacity to make medical decisions, is a resident of California, and has satisfied the requirements of this part in order to obtain a prescription for a drug to end his or her life.

(p) "Self-administer" means a qualified individual's affirmative, conscious, and physical act of administering and ingesting the aid-in-dying drug to bring about his or her own death.

(q) "Terminal disease" means an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, result in death within six months.

443.2. (a) An individual who is an adult with the capacity to make medical decisions and with a terminal disease may make a request to receive a prescription for an aid-in-dying drug if all of the following conditions are satisfied:

(1) The individual's attending physician has diagnosed the individual with a terminal disease.

(2) The individual has voluntarily expressed the wish to receive a prescription for an aid-in-dying drug.

(3) The individual is a resident of California and is able to establish residency through any of the following means:

(A) Possession of a California driver license or other identification issued by the State of California.

(B) Registration to vote in California.

(C) Evidence that the person owns or leases property in California.

(D) Filing of a California tax return for the most recent tax year.

(4) The individual documents his or her request pursuant to the requirements set forth in Section 443.3.

(5) The individual has the physical and mental ability to self-administer the aid-in-dying drug.

(b) A person shall not be considered a "qualified individual" under the provisions of this part solely because of age or disability.

(c) A request for a prescription for an aid-in-dying drug under this part shall be made solely and directly by the individual diagnosed with the terminal disease and shall not be made on behalf of the patient, including, but not limited to, through a power of attorney, an advance health care directive, a conservator, health care agent, surrogate, or any other legally recognized health care decisionmaker.

443.3. (a) An individual seeking to obtain a prescription for an aid-in-dying drug pursuant to this part shall submit two oral requests, a minimum of 15 days apart, and a written request to his or her attending physician. The attending physician shall directly, and not through a designee, receive all three requests required pursuant to this section.

(b) A valid written request for an aid-in-dying drug under subdivision (a) shall meet all of the following conditions:

(1) The request shall be in the form described in Section 443.11.

(2) The request shall be signed and dated, in the presence of two witnesses, by the individual seeking the aid-in-dying drug.

(3) The request shall be witnessed by at least two other adult persons who, in the presence of the individual, shall attest that to the best of their knowledge and belief the individual is all of the following:

(A) An individual who is personally known to them or has provided proof of identity.

(B) An individual who voluntarily signed this request in their presence.

(C) An individual whom they believe to be of sound mind and not under duress, fraud, or undue influence.

(D) Not an individual for whom either of them is the attending physician, consulting physician, or mental health specialist.

(c) Only one of the two witnesses at the time the written request is signed may:

(1) Be related to the qualified individual by blood, marriage, registered domestic partnership, or adoption or be entitled to a portion of the individual's estate upon death.

(2) Own, operate, or be employed at a health care facility where the individual is receiving medical treatment or resides.

(d) The attending physician, consulting physician, or mental health specialist of the individual shall not be one of the witnesses required pursuant to paragraph (3) of subdivision (b).

443.4. (a) An individual may at any time withdraw or rescind his or her request for an aid-in-dying drug, or decide not to ingest an aid-in-dying drug, without regard to the individual's mental state.

(b) A prescription for an aid-in-dying drug provided under this part may not be written without the attending physician directly, and not through a designee, offering the individual an opportunity to withdraw or rescind the request.

443.5. (a) Before prescribing an aid-in-dying drug, the attending physician shall do all of the following:

(1) Make the initial determination of all of the following:

(A) (i) Whether the requesting adult has the capacity to make medical decisions.

(ii) If there are indications of a mental disorder, the physician shall refer the individual for a mental health specialist assessment.

(iii) If a mental health specialist assessment referral is made, no aid-in-dying drugs shall be prescribed until the mental health specialist determines that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

(B) Whether the requesting adult has a terminal disease.

(C) Whether the requesting adult has voluntarily made the request for an aid-in-dying drug pursuant to Sections 443.2 and 443.3.

(D) Whether the requesting adult is a qualified individual pursuant to subdivision (o) of Section 443.1.

(2) Confirm that the individual is making an informed decision by discussing with him or her all of the following:

(A) His or her medical diagnosis and prognosis.

(B) The potential risks associated with ingesting the requested aid-in-dying drug.

(C) The probable result of ingesting the aid-in-dying drug.

(D) The possibility that he or she may choose to obtain the aid-in-dying drug but not take it.

(E) The feasible alternatives or additional treatment options, including, but not limited to, comfort care, hospice care, palliative care, and pain control.

(3) Refer the individual to a consulting physician for medical confirmation of the diagnosis and prognosis, and for a determination that the individual has the capacity to make medical decisions and has complied with the provisions of this part.

(4) Confirm that the qualified individual's request does not arise from coercion or undue influence by another person by discussing with the qualified individual, outside of the presence of any other persons, except for an interpreter as required pursuant to this part, whether or not the qualified individual is feeling coerced or unduly influenced by another person.

(5) Counsel the qualified individual about the importance of all of the following:

(A) Having another person present when he or she ingests the aid-in-dying drug prescribed pursuant to this part.

(B) Not ingesting the aid-in-dying drug in a public place.

(C) Notifying the next of kin of his or her request for an aid-in-dying drug. A qualified individual who declines or is unable to notify next of kin shall not have his or her request denied for that reason.

(D) Participating in a hospice program.

(E) Maintaining the aid-in-dying drug in a safe and secure location until the time that the qualified individual will ingest it.

(6) Inform the individual that he or she may withdraw or rescind the request for an aid-in-dying drug at any time and in any manner.

(7) Offer the individual an opportunity to withdraw or rescind the request for an aid-in-dying drug before prescribing the aid-in-dying drug.

(8) Verify, immediately before writing the prescription for an aid-in-dying drug, that the qualified individual is making an informed decision.

(9) Confirm that all requirements are met and all appropriate steps are carried out in accordance with this part before writing a prescription for an aid-in-dying drug.

(10) Fulfill the record documentation required under Sections 443.8 and 443.19.

(11) Complete the attending physician checklist and compliance form, as described in Section 443.22, include it and the consulting physician compliance form in the individual's medical record, and submit both forms to the State Department of Public Health.

(12) Give the qualified individual the final attestation form, with the instruction that the form be filled out and executed by the qualified individual within 48 hours prior to the qualified individual choosing to self-administer the aid-in-dying drug.

(b) If the conditions set forth in subdivision (a) are satisfied, the attending physician may deliver the aid-in-dying drug in any of the following ways:

(1) Dispensing the aid-in-dying drug directly, including ancillary medication intended to minimize the qualified individual's discomfort, if the attending physician meets all of the following criteria:

(A) Is authorized to dispense medicine under California law.

(B) Has a current United States Drug Enforcement Administration (USDEA) certificate.

(C) Complies with any applicable administrative rule or regulation.

(2) With the qualified individual's written consent, contacting a pharmacist, informing the pharmacist of the prescriptions, and delivering the written prescriptions personally, by mail, or electronically to the pharmacist, who may dispense the drug to the qualified individual, the attending physician, or a person expressly designated by the qualified individual and with the designation delivered to the pharmacist in writing or verbally.

(c) Delivery of the dispensed drug to the qualified individual, the attending physician, or a person expressly designated by the qualified individual may be made by personal delivery, or, with a signature required on delivery, by United Parcel Service, United States Postal Service, Federal Express, or by messenger service.

443.6. Before a qualified individual obtains an aid-in-dying drug from the attending physician, the consulting physician shall perform all of the following:

(a) Examine the individual and his or her relevant medical records.

(b) Confirm in writing the attending physician's diagnosis and prognosis.

(c) Determine that the individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision.

(d) If there are indications of a mental disorder, refer the individual for a mental health specialist assessment.

(e) Fulfill the record documentation required under this part.

(f) Submit the compliance form to the attending physician.

443.7. Upon referral from the attending or consulting physician pursuant to this part, the mental health specialist shall:

(a) Examine the qualified individual and his or her relevant medical records.

(b) Determine that the individual has the mental capacity to make medical decisions, act voluntarily, and make an informed decision.

(c) Determine that the individual is not suffering from impaired judgment due to a mental disorder.

(d) Fulfill the record documentation requirements of this part.

443.8. All of the following shall be documented in the individual's medical record:

(a) All oral requests for aid-in-dying drugs.

(b) All written requests for aid-in-dying drugs.

(c) The attending physician's diagnosis and prognosis, and the determination that a qualified individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision, or that the attending physician has determined that the individual is not a qualified individual.

(d) The consulting physician's diagnosis and prognosis, and verification that the qualified individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision, or that the consulting physician has determined that the individual is not a qualified individual.

(e) A report of the outcome and determinations made during a mental health specialist's assessment, if performed.

(f) The attending physician's offer to the qualified individual to withdraw or rescind his or her request at the time of the individual's second oral request.

(g) A note by the attending physician indicating that all requirements under Sections 443.5 and 443.6 have been met and indicating the steps taken to carry out the request, including a notation of the aid-in-dying drug prescribed.

443.9. (a) Within 30 calendar days of writing a prescription for an aid-in-dying drug, the attending physician shall submit to the State Department of Public Health a copy of the qualifying patient's written request, the attending physician checklist and compliance form, and the consulting physician compliance form.

(b) Within 30 calendar days following the qualified individual's death from ingesting the aid-in-dying drug, or any other cause, the attending physician shall submit the attending physician followup form to the State Department of Public Health.

443.10. A qualified individual may not receive a prescription for an aid-in-dying drug pursuant to this part unless he or she has made an informed decision. Immediately before writing a prescription for an aid-in-dying drug under this part, the attending physician shall verify that the individual is making an informed decision.

443.11. (a) A request for an aid-in-dying drug as authorized by this part shall be in the following form:

REQUEST FOR AN AID-IN-DYING DRUG TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER I, ..., am an adult of sound mind and a resident of the State of California.

I am suffering from ....., which my attending physician has determined is in its terminal phase and which has been medically confirmed.

I have been fully informed of my diagnosis and prognosis, the nature of the aid-in-dying drug to be prescribed and potential associated risks, the expected result, and the feasible alternatives or additional treatment options, including comfort care, hospice care, palliative care, and pain control.

I request that my attending physician prescribe an aid-in-dying drug that will end my life in a humane and dignified manner if I choose to take it, and I authorize my attending physician to contact any pharmacist about my request.

INITIAL ONE:

..... I have informed one or more members of my family of my decision and taken their opinions into consideration.

..... I have decided not to inform my family of my decision.

..... I have no family to inform of my decision.

I understand that I have the right to withdraw or rescind this request at any time.

I understand the full import of this request and I expect to die if I take the aid-in-dying drug to be prescribed. My attending physician has counseled me about the possibility that my death may not be immediately upon the consumption of the drug.

I make this request voluntarily, without reservation, and without being coerced.

Signed:.....

Dated:.....

DECLARATION OF WITNESSES

We declare that the person signing this request:

(a) is personally known to us or has provided proof of identity;

(b) voluntarily signed this request in our presence;

(c) is an individual whom we believe to be of sound mind and not under duress, fraud, or undue influence; and

(d) is not an individual for whom either of us is the attending physician, consulting physician, or mental health specialist.
.....Witness 1/Date
.....Witness 2/Date
NOTE: Only one of the two witnesses may be a relative (by blood, marriage, registered domestic partnership, or adoption) of the person signing this request or be entitled to a portion of the person's estate upon death. Only one of the two witnesses may own, operate, or be employed at a health care facility where the person is a patient or resident.

(b) (1) The written language of the request shall be written in the same translated language as any conversations, consultations, or interpreted conversations or consultations between a patient and his or her attending or consulting physicians.

(2) Notwithstanding paragraph (1), the written request may be prepared in English even when the conversations or consultations or interpreted conversations or consultations were conducted in a language other than English if the English language form includes an attached interpreter's declaration that is signed under penalty of perjury. The interpreter's declaration shall state words to the effect that:

I, (INSERT NAME OF INTERPRETER), am fluent in English and (INSERT TARGET LANGUAGE).
On (insert date) at approximately (insert time), I read the "Request for an Aid-In-Dying Drug to End My Life" to (insert name of individual/patient) in (insert target language).
Mr./Ms. (insert name of patient/qualified individual) affirmed to me that he/she understood the content of this form and affirmed his/her desire to sign this form under his/her own power and volition and that the request to sign the form followed consultations with an attending and consulting physician.
I declare that I am fluent in English and (insert target language) and further declare under penalty of perjury that the foregoing is true and correct.
Executed at (insert city, county, and state) on this (insert day of month) of (insert month), (insert year).
X_____Interpreter signature
X_____Interpreter printed name
X_____Interpreter address

(3) An interpreter whose services are provided pursuant to paragraph (2) shall not be related to the qualified individual by blood, marriage, registered domestic partnership, or adoption or be entitled to a portion of the person's estate upon death. An interpreter whose services are provided pursuant to paragraph (2) shall meet the standards promulgated by the California Healthcare Interpreting Association or the National Council on Interpreting in Health Care or other standards deemed acceptable by the department for health care providers in California.

(c) The final attestation form given by the attending physician to the qualified individual at the time the attending physician writes the prescription shall appear in the following form:

FINAL ATTESTATION FOR AN AID-IN-DYING DRUG TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER I, ..., am an adult of sound mind and a resident of the State of California.
I am suffering from ....., which my attending physician has determined is in its terminal phase and which has been medically confirmed.
I have been fully informed of my diagnosis and prognosis, the nature of the aid-in-dying drug to be prescribed and potential associated risks, the expected result, and the feasible alternatives or additional treatment options, including comfort care, hospice care, palliative care, and pain control.
I have received the aid-in-dying drug and am fully aware that this aid-in-dying drug will end my life in a humane and dignified manner.
INITIAL ONE:
..... I have informed one or more members of my family of my decision and taken their opinions into consideration.
..... I have decided not to inform my family of my decision.
..... I have no family to inform of my decision.
My attending physician has counseled me about the possibility that my death may not be immediately upon the consumption of the drug.
I make this decision to ingest the aid-in-dying drug to end my life in a humane and dignified manner. I understand I still may choose not to ingest the drug and by signing this form I am under no obligation to ingest the drug. I understand I may rescind this request at any time.

Signed:.....
Dated:.....
Time:.....

(1) Within 48 hours prior to the individual self-administering the aid-in-dying drug, the individual shall complete the final attestation form. If aid-in-dying medication is not returned or relinquished upon the patient's death as required in Section 443.20, the completed form shall be delivered

by the individual's health care provider, family member, or other representative to the attending physician to be included in the patient's medical record.

(2) Upon receiving the final attestation form the attending physician shall add this form to the medical records of the qualified individual.

443.12. (a) A provision in a contract, will, or other agreement executed on or after January 1, 2016, whether written or oral, to the extent the provision would affect whether a person may make, withdraw, or rescind a request for an aid-in-dying drug is not valid.

(b) An obligation owing under any contract executed on or after January 1, 2016, may not be conditioned or affected by a qualified individual making, withdrawing, or rescinding a request for an aid-in-dying drug.

443.13. (a) (1) The sale, procurement, or issuance of a life, health, or annuity policy, health care service plan contract, or health benefit plan, or the rate charged for a policy or plan contract may not be conditioned upon or affected by a person making or rescinding a request for an aid-in-dying drug.

(2) Pursuant to Section 443.18, death resulting from the self-administration of an aid-in-dying drug is not suicide, and therefore health and insurance coverage shall not be exempted on that basis.

(b) Notwithstanding any other law, a qualified individual's act of self-administering an aid-in-dying drug shall not have an effect upon a life, health, or annuity policy other than that of a natural death from the underlying disease.

(c) An insurance carrier shall not provide any information in communications made to an individual about the availability of an aid-in-dying drug absent a request by the individual or his or her attending physician at the behest of the individual. Any communication shall not include both the denial of treatment and information as to the availability of aid-in-dying drug coverage. For the purposes of this subdivision, "insurance carrier" means a health care service plan as defined in Section 1345 of this code or a carrier of health insurance as defined in Section 106 of the Insurance Code.

443.14. (a) Notwithstanding any other law, a person shall not be subject to civil or criminal liability solely because the person was present when the qualified individual self-administers the prescribed aid-in-dying drug. A person who is present may, without civil or criminal liability, assist the qualified individual by preparing the aid-in-dying drug so long as the person does not assist the qualified person in ingesting the aid-in-dying drug.

(b) A health care provider or professional organization or association shall not subject an individual to censure, discipline, suspension, loss of license, loss of privileges, loss of membership, or other penalty for participating in good faith compliance with this part or for refusing to participate in accordance with subdivision (e).

(c) Notwithstanding any other law, a health care provider shall not be subject to civil, criminal, administrative, disciplinary, employment, credentialing, professional discipline, contractual liability, or medical staff

action, sanction, or penalty or other liability for participating in this part, including, but not limited to, determining the diagnosis or prognosis of an individual, determining the capacity of an individual for purposes of qualifying for the act, providing information to an individual regarding this part, and providing a referral to a physician who participates in this part. Nothing in this subdivision shall be construed to limit the application of, or provide immunity from, Section 443.16 or 443.17.

(d) (1) A request by a qualified individual to an attending physician to provide an aid-in-dying drug in good faith compliance with the provisions of this part shall not provide the sole basis for the appointment of a guardian or conservator.

(2) No actions taken in compliance with the provisions of this part shall constitute or provide the basis for any claim of neglect or elder abuse for any purpose of law.

(e) (1) Participation in activities authorized pursuant to this part shall be voluntary. Notwithstanding Sections 442 to 442.7, inclusive, a person or entity that elects, for reasons of conscience, morality, or ethics, not to engage in activities authorized pursuant to this part is not required to take any action in support of an individual's decision under this part.

(2) Notwithstanding any other law, a health care provider is not subject to civil, criminal, administrative, disciplinary, employment, credentialing, professional discipline, contractual liability, or medical staff action, sanction, or penalty or other liability for refusing to participate in activities authorized under this part, including, but not limited to, refusing to inform a patient regarding his or her rights under this part, and not referring an individual to a physician who participates in activities authorized under this part.

(3) If a health care provider is unable or unwilling to carry out a qualified individual's request under this part and the qualified individual transfers care to a new health care provider, the individual may request a copy of his or her medical records pursuant to law.

443.15. (a) Subject to subdivision (b), notwithstanding any other law, a health care provider may prohibit its employees, independent contractors, or other persons or entities, including other health care providers, from participating in activities under this part while on premises owned or under the management or direct control of that prohibiting health care provider or while acting within the course and scope of any employment by, or contract with, the prohibiting health care provider.

(b) A health care provider that elects to prohibit its employees, independent contractors, or other persons or entities, including health care providers, from participating in activities under this part, as described in subdivision (a), shall first give notice of the policy prohibiting participation under this part to the individual or entity. A health care provider that fails to provide notice to an individual or entity in compliance with this subdivision shall not be entitled to enforce such a policy against that individual or entity.

(c) Subject to compliance with subdivision (b), the prohibiting health care provider may take action, including, but not limited to, the following, as applicable, against any individual or entity that violates this policy:

(1) Loss of privileges, loss of membership, or other action authorized by the bylaws or rules and regulations of the medical staff.

(2) Suspension, loss of employment, or other action authorized by the policies and practices of the prohibiting health care provider.

(3) Termination of any lease or other contract between the prohibiting health care provider and the individual or entity that violates the policy.

(4) Imposition of any other nonmonetary remedy provided for in any lease or contract between the prohibiting health care provider and the individual or entity in violation of the policy.

(d) Nothing in this section shall be construed to prevent, or to allow a prohibiting health care provider to prohibit, any other health care provider, employee, independent contractor, or other person or entity from any of the following:

(1) Participating, or entering into an agreement to participate, in activities under this part, while on premises that are not owned or under the management or direct control of the prohibiting provider or while acting outside the course and scope of the participant's duties as an employee of, or an independent contractor for, the prohibiting health care provider.

(2) Participating, or entering into an agreement to participate, in activities under this part as an attending physician or consulting physician while on premises that are not owned or under the management or direct control of the prohibiting provider.

(e) In taking actions pursuant to subdivision (c), a health care provider shall comply with all procedures required by law, its own policies or procedures, and any contract with the individual or entity in violation of the policy, as applicable.

(f) For purposes of this section:

(1) "Notice" means a separate statement in writing advising of the prohibiting health care provider policy with respect to participating in activities under this part.

(2) "Participating, or entering into an agreement to participate, in activities under this part" means doing or entering into an agreement to do any one or more of the following:

(A) Performing the duties of an attending physician as specified in Section 443.5.

(B) Performing the duties of a consulting physician as specified in Section 443.6.

(C) Performing the duties of a mental health specialist, in the circumstance that a referral to one is made.

(D) Delivering the prescription for, dispensing, or delivering the dispensed aid-in-dying drug pursuant to paragraph (2) of subdivision (b) of, and subdivision (c) of, Section 443.5.

(E) Being present when the qualified individual takes the aid-in-dying drug prescribed pursuant to this part.

(3) "Participating, or entering into an agreement to participate, in activities under this part" does not include doing, or entering into an agreement to do, any of the following:

(A) Diagnosing whether a patient has a terminal disease, informing the patient of the medical prognosis, or determining whether a patient has the capacity to make decisions.

(B) Providing information to a patient about this part.

(C) Providing a patient, upon the patient's request, with a referral to another health care provider for the purposes of participating in the activities authorized by this part.

(g) Any action taken by a prohibiting provider pursuant to this section shall not be reportable under Sections 800 to 809.9, inclusive, of the Business and Professions Code. The fact that a health care provider participates in activities under this part shall not be the sole basis for a complaint or report by another health care provider of unprofessional or dishonorable conduct under Sections 800 to 809.9, inclusive, of the Business and Professions Code.

(h) Nothing in this part shall prevent a health care provider from providing an individual with health care services that do not constitute participation in this part.

443.16. (a) A health care provider may not be sanctioned for any of the following:

(1) Making an initial determination pursuant to the standard of care that an individual has a terminal disease and informing him or her of the medical prognosis.

(2) Providing information about the End of Life Option Act to a patient upon the request of the individual.

(3) Providing an individual, upon request, with a referral to another physician.

(b) A health care provider that prohibits activities under this part in accordance with Section 443.15 shall not sanction an individual health care provider for contracting with a qualified individual to engage in activities authorized by this part if the individual health care provider is acting outside of the course and scope of his or her capacity as an employee or independent contractor of the prohibiting health care provider.

(c) Notwithstanding any contrary provision in this section, the immunities and prohibitions on sanctions of a health care provider are solely reserved for actions of a health care provider taken pursuant to this part. Notwithstanding any contrary provision in this part, health care providers may be sanctioned by their licensing board or agency for conduct and actions constituting unprofessional conduct, including failure to comply in good faith with this part.

443.17. (a) Knowingly altering or forging a request for an aid-in-dying drug to end an individual's life without his or her authorization or concealing or destroying a withdrawal or rescission of a request for an aid-in-dying drug is punishable as a felony if the act is done with the intent or effect of causing the individual's death.

(b) Knowingly coercing or exerting undue influence on an individual to request or ingest an aid-in-dying drug for the purpose of ending his or her life or to destroy a withdrawal or rescission of a request, or to administer an aid-in-dying drug to an individual without his or her knowledge or consent, is punishable as a felony.

(c) For purposes of this section, "knowingly" has the meaning provided in Section 7 of the Penal Code.

(d) The attending physician, consulting physician, or mental health specialist shall not be related to the individual by blood, marriage, registered domestic partnership, or adoption, or be entitled to a portion of the individual's estate upon death.

(e) Nothing in this section shall be construed to limit civil liability.

(f) The penalties in this section do not preclude criminal penalties applicable under any law for conduct inconsistent with the provisions of this section.

443.18. Nothing in this part may be construed to authorize a physician or any other person to end an individual's life by lethal injection, mercy killing, or active euthanasia. Actions taken in accordance with this part shall not, for any purposes, constitute suicide, assisted suicide, homicide, or elder abuse under the law.

443.19. (a) The State Department of Public Health shall collect and review the information submitted pursuant to Section 443.9. The information collected shall be confidential and shall be collected in a manner that protects the privacy of the patient, the patient's family, and any medical provider or pharmacist involved with the patient under the provisions of this part. The information shall not be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding.

(b) On or before July 1, 2017, and each year thereafter, based on the information collected in the previous year, the department shall create a report with the information collected from the attending physician followup form and post that report to its Internet Web site. The report shall include, but not be limited to, all of the following based on the information that is provided to the department and on the department's access to vital statistics:

(1) The number of people for whom an aid-in-dying prescription was written.

(2) The number of known individuals who died each year for whom aid-in-dying prescriptions were written, and the cause of death of those individuals.

(3) For the period commencing January 1, 2016, to and including the previous year, cumulatively, the total number of aid-in-dying prescriptions written, the number of people who died due to use of aid-in-dying drugs, and the number of those people who died who were enrolled in hospice or other palliative care programs at the time of death.

(4) The number of known deaths in California from using aid-in-dying drugs per 10,000 deaths in California.

(5) The number of physicians who wrote prescriptions for aid-in-dying drugs.

(6) Of people who died due to using an aid-in-dying drug, demographic percentages organized by the following characteristics:

(A) Age at death.

(B) Education level.

(C) Race.

(D) Sex.

(E) Type of insurance, including whether or not they had insurance.

(F) Underlying illness.

(c) The State Department of Public Health shall make available the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician followup form, as described in Section 443.22, by posting them on its Internet Web site.

443.20. A person who has custody or control of any unused aid-in-dying drugs prescribed pursuant to this part after the death of the patient shall personally deliver the unused aid-in-dying drugs for disposal by delivering it to the nearest qualified facility that properly disposes of controlled substances, or if none is available, shall dispose of it by lawful means in accordance with guidelines promulgated by the California State Board of Pharmacy or a federal Drug Enforcement Administration approved take-back program.

443.21. Any governmental entity that incurs costs resulting from a qualified individual terminating his or her life pursuant to the provisions of this part in a public place shall have a claim against the estate of the qualified individual to recover those costs and reasonable attorney fees related to enforcing the claim.

443.215. This part shall remain in effect only until January 1, 2026, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2026, deletes or extends that date.

443.22. (a) The Medical Board of California may update the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician followup form, based on those provided in subdivision (b). Upon completion, the State Department of Public Health shall publish the updated forms on its Internet Web site.

(b) Unless and until updated by the Medical Board of California pursuant to this section, the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician followup form shall be in the following form:

ATTENDING PHYSICIAN CHECKLIST & COMPLIANCE FORM

A	PATIENT INFORMATION	
	PATIENT'S NAME (LAST, FIRST, M.I.)	DATE OF BIRTH
	PATIENT RESIDENTIAL ADDRESS (STREET, CITY, ZIP CODE)	

B	ATTENDING PHYSICIAN INFORMATION	
	PHYSICIAN'S NAME (LAST, FIRST, M.I.)	TELEPHONE NUMBER ( ) —
	MAILING ADDRESS (STREET, CITY, ZIP CODE)	
	PHYSICIAN'S LICENSE NUMBER	

C	CONSULTING PHYSICIAN INFORMATION	
	PHYSICIAN'S NAME (LAST, FIRST, M.I.)	TELEPHONE NUMBER ( ) —
	MAILING ADDRESS (STREET, CITY, ZIP CODE)	
	PHYSICIAN'S LICENSE NUMBER	

D	ELIGIBILITY DETERMINATION
	1. TERMINAL DISEASE
	2. CHECK BOXES FOR COMPLIANCE: ☐ 1. Determination that the patient has a terminal disease. ☐ 2. Determination that patient is a resident of California. ☐ 3. Determination that patient has the capacity to make medical decisions** ☐ 4. Determination that patient is acting voluntarily. ☐ 5. Determination of capacity by mental health specialist, if necessary. ☐ 6. Determination that patient has made his/her decision after being fully informed of: ☐ a) His or her medical diagnosis; and ☐ b) His or her prognosis; and ☐ c) The potential risks associated with ingesting the requested aid-in-dying drug; ☐ d) The probable result of ingesting the aid-in-dying drug; ☐ e) The possibility that he or she may choose to obtain the aid-in-dying drug but not take it

ATTENDING PHYSICIAN CHECKLIST &
COMPLIANCE FORM

E	ADDITIONAL COMPLIANCE REQUIREMENTS

☐ 1. Counseled patient about the importance of all of the following:
☐ a) Maintaining the aid-in-dying drug in a safe and secure location until the time the qualified individual will ingest it;
☐ b) Having another person present when he or she ingests the aid-in-dying drug;
☐ c) Not ingesting the aid-in-dying drug in a public place;
☐ d) Notifying the next of kin of his or her request for an aid-in-dying drug. (an individual who declines or is unable to notify next of kin shall not have his or her request denied for that reason); and
☐ e) Participating in a hospice program or palliative care program.
☐ 2. Informed patient of right to rescind request (1st time)
☐ 3. Discussed the feasible alternatives, including, but not limited to, comfort care, hospice care, palliative care and pain control.
☐ 4. Met with patient one-on-one, except in the presence of an interpreter, to confirm the request is not coming from coercion
☐ 5. First oral request for aid-in-dying: _____/_____/_____ Attending physician initials:_____
☐ 6. Second oral request for aid-in-dying:_____/_____/_____ Attending physician initials:_____
☐ 7. Written request submitted: _____/_____/_____ Attending physician initials:_____
☐ 8. Offered patient right to rescind (2nd time)

F	PATIENT'S MENTAL STATUS

Check one of the following **(required)**:

☐ I have determined that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

☐ I have referred the patient to the mental health specialist**** listed below for one or more consultations to determine that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

☐ If a referral was made to a mental health specialist, the mental health specialist has determined that the patient is not suffering from impaired judgment due to a mental disorder

Mental health specialist's information, if applicable:

MENTAL HEALTH SPECIALIST NAME

MENTAL HEALTH SPECIALIST TITLE & LICENSE NUMBER

MENTAL HEALTH SPECIALIST ADDRESS (STREET, CITY, ZIP CODE)

ATTENDING PHYSICIAN CHECKLIST & COMPLIANCE FORM

G	MEDICATION PRESCRIBED	
	PHARMACIST NAME	TELEPHONE NUMBER ( ) —

1. Aid-in-dying medication prescribed:
   - ☐ a. Name:_____
   - ☐ b. Dosage:_____
2. Antiemetic medication prescribed:
   - ☐ a. Name:_____
   - ☐ b. Dosage:_____
3. Method prescription was delivered:
   - ☐ a. In person
   - ☐ b. By mail
   - ☐ c. Electronically
4. Date medication was prescribed:_____/_____/_____

		PHYSICIAN'S SIGNATURE	DATE
	X	NAME (PLEASE PRINT)	

** "Capacity to make medical decisions" means that, in the opinion of an individual's attending physician, consulting physician, psychiatrist, or psychologist, pursuant to Section 4609 of the Probate Code, the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make

****"Mental Health Specialist" means a psychiatrist or a licensed psychologist.

CONSULTING PHYSICIAN COMPLIANCE FORM

A	PATIENT INFORMATION	
	PATIENT'S NAME (LAST, FIRST, M.I.)	DATE OF BIRTH

B	ATTENDING PHYSICIAN	
	ATTENDING PHYSICIAN'S NAME (LAST, FIRST, M.I.)	TELEPHONE NUMBER ( ) . —

C CONSULTING PHYSICIAN'S REPORT

1. TERMINAL DISEASE	DATE OF EXAMINATION(S)

2. Check boxes for compliance. *(Both the attending and consulting physicians must make these determinations.)*

- ☐ 1. Determination that the patient has a terminal disease.
- ☐ 2. Determination that patient has the mental capacity to make medical decisions.**
- ☐ 3. Determination that patient is acting voluntarily.
- ☐ 4. Determination that patient has made his/her decision after being fully informed of:
- ☐ a) His or her medical diagnosis; and
- ☐ b) His or her prognosis; and
- ☐ c) The potential risks associated with taking the drug to be prescribed; and
- ☐ d) The potential result of taking the drug to be prescribed; and
- ☐ e) The feasible alternatives, including, but not limited to, comfort care, hospice care, palliative care and pain control.

D PATIENT'S MENTAL STATUS

Check one of the following **(required)**:

- ☐ I have determined that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.
- ☐ I have referred the patient to the mental health specialist**** listed below for one or more consultations to determine that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.
- ☐ If a referral was made to a mental health specialist, the mental health specialist has determined that the patient is not suffering from impaired judgment due to a mental disorder

MENTAL HEALTH SPECIALIST'S NAME	TELEPHONE NUMBER ( ) —	DATE

E CONSULTANT'S INFORMATION

X	PHYSICIAN'S SIGNATURE	DATE
	NAME (PLEASE PRINT)	
MAILING ADDRESS		
CITY, STATE AND ZIP CODE		TELEPHONE NUMBER ( ) —

** "Capacity to make medical decisions" means that, in the opinion of an individual's attending physician, consulting physician, psychiatrist, or psychologist, pursuant to Section 4609 of the Probate Code, the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make

****"Mental Health Specialist" means a psychiatrist or a licensed psychologist.

ATTENDING PHYSICIAN FOLLOW-UP FORM

The End of Life Option Act requires physicians who write a prescription for an aid-in-dying drug to complete this follow-up form within **30 calendar days** of a patient's death, whether from ingestion of the aid-in-dying drug obtained under the Act or from any other cause.

For the State Department of Public Health to accept this form, it must be signed by the attending physician, whether or not he or she was present at the patient's time of death.

This form should be mailed or sent electronically to the State Department of Public Health. All information is kept strictly confidential.

Date: _____/_____/_____

Patient name: _____

Attending physician name: _____

Did the patient die from ingesting the aid-in-dying drug, from their underlying illness, or from another cause such as terminal sedation or ceasing to eat or drink?

- ☐ **Aid-in-dying drug** (lethal dose) → Please sign below and go to page 2.
  Attending physician signature:_____
- ☐ **Underlying illness** → There is no need to complete the rest of the form. Please sign below.
  Attending physician signature:_____
- ☐ **Other** → There is no need to complete the rest of the form. Please specify the circumstances surrounding the patient's death and sign
  Please specify:
  _____
  _____

Attending physician signature:_____

PART A and PART B should only be completed if the patient died from ingesting the lethal dose of the aid-in-dying drug.

Please read carefully the following to determine which situation applies. Check the box that indicates the scenario and complete the remainder of the form accordingly.

- ☐ The attending physician was present at the time of death.
  → The attending physician must complete this form in its entirety and sign Part A and Part B.
- ☐ The attending physician was not present at the time of death, but another licensed health care provider was present.
  → The licensed health care provider must complete and sign Part A of this form. The attending physician must complete and sign Part B of the form.
- ☐ Neither the attending physician nor another licensed health care provider was present at the time of death.
  → Part A may be left blank. The attending physician must complete and sign Part B of the form.

ATTENDING PHYSICIAN FOLLOW-UP FORM

PART A: To be completed and signed by the attending physician or another licensed health care provider present at death:

1. Was the attending physician at the patient's bedside when the patient took the aid-in-dying drug?
   - ☐ Yes
   - ☐ No

If no: Was another physician or trained health care provider present when the patient ingested the aid-in-dying drug?
   - ☐ Yes, another physician
   - ☐ Yes, a trained health-care provider/volunteer
   - ☐ No
   - ☐ Unknown

2. Was the attending physician at the patient's bedside at the time of death?
   - ☐ Yes
   - ☐ No

If no: Was another physician or a licensed health care provider present at the patient's time of death?
   - ☐ Yes, another physician or licensed health care provider
   - ☐ No
   - ☐ Unknown

3. On what day did the patient consume the lethal dose of the aid-in-dying?
_____/_____/_____ (month/day/year) ☐ Unknown

4. On what day did the patient die after consuming the lethal dose of the aid-in-dying drug?
_____/____/_____ (month/day/year) ☐ Unknown

5. Where did the patient ingest the lethal dose of the aid-in-dying drug?
   - ☐ Private home
   - ☐ Assisted-living residence
   - ☐ Nursing home
   - ☐ Acute care hospital in-patient
   - ☐ In-patient hospice resident
   - ☐ Other (specify)_____
   - ☐ Unknown

6. What was the time between the ingestion of the lethal dose of aid-in-dying drug and unconsciousness?
Minutes_____ and/or Hours_____ ☐Unknown

7. What was the time between lethal medication ingestion and death?
Minutes_____ and/or Hours_____ ☐Unknown

ATTENDING PHYSICIAN FOLLOW-UP FORM

8. Were there any complications that occurred after the patient took the lethal dose of the aid-in-dying drug?

- ☐ Yes- vomiting, emesis
- ☐ Yes-regained consciousness
- ☐ No Complications
- ☐ Other- Please describe:_____
- ☐ Unknown

9. Was the Emergency Medical System activated for any reason after ingesting the lethal dose of the aid-in-dying drug?

- ☐ Yes- Please describe:_____
- ☐ No
- ☐ Unknown

10. At the time of ingesting the lethal dose of the aid-in-dying drug, was the patient receiving hospice care?

- ☐ Yes
- ☐ No, refused care
- ☐ No, other (specify) _____

Signature of attending physician present at time of death: _____

Name of Licensed Health Care Provider present at time of death if not attending physician:_____

Signature of Licensed Health Care Provider: _____

ATTENDING PHYSICIAN FOLLOW-UP FORM

PART B: To be completed and signed by the attending physician

12. On what date was the prescription written for the aid-in-dying drug? ____/____/____

13. When the patient initially requested a prescription for the aid-in-dying drug, was the patient receiving hospice care?

- ☐ Yes
- ☐ No, refused care
- ☐ No, other (specify) _____

14. What type of health-care coverage did the patient have for their underlying illness? (*Check all that apply.*)

- ☐ Medicare
- ☐ Medi-cal
- ☐ Covered California
- ☐ V.A.
- ☐ Private Insurance
- ☐ No insurance
- ☐ Had insurance, don't know type

15. Possible concerns that may have contributed to the patient's decision to request a prescription for aid-in-dying drug Please check "yes," "no," or "Don't' know," depending on whether or not you believe that concern contributed to their request (Please check as many boxes as you think may apply)

A concern about . . .

- **His or her terminal condition representing a steady loss of autonomy**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **The decreasing ability to participate in activities that made life enjoyable**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **The loss of control of bodily functions**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **Persistent and uncontrollable pain and suffering**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **A loss of Dignity**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **Other concerns** (specify): _____

Signature of attending physician: _____

SEC. 2. The Legislature finds and declares that Section 1 of this act, which adds Section 443.19 to the Health and Safety Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

(a) Any limitation to public access to personally identifiable patient data collected pursuant to Section 443.19 of the Health and Safety Code as proposed to be added by this act is necessary to protect the privacy rights of the patient and his or her family.

(b) The interests in protecting the privacy rights of the patient and his or her family in this situation strongly outweigh the public interest in having access to personally identifiable data relating to services.

(c) The statistical report to be made available to the public pursuant to subdivision (b) of Section 443.19 of the Health and Safety Code is sufficient to satisfy the public's right to access.

SEC. 3. The provisions of this part are severable. If any provision of this part or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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