



LEGISLATION AND REGULATION COMMITTEE REPORT

Greg Lippe, CPA, Chairperson, Public Member

Lavanza Butler, RPh, Professional Member

Ramon Castellblanch, Ph.D., Public Member

Albert Wong, PharmD, Professional Member

Debbie Veale, RPh, Professional Member

LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee did not meet this quarter.

Part 1: LEGISLATION REPORT

a. Board Sponsored Legislation

Copies of board-sponsored bills, whether enacted or pending, are provided in **Attachment 1**.

1. AB 1073 (Ting) Pharmacy: Prescription Drug Labels, Chapter 784, Statutes of 2015

Assembly Bill 1073 was approved by the Governor on October 11, 2015. The bill requires a pharmacist to use professional judgment to provide a patient with directions for use of a prescription, consistent with the prescriber's instructions.

AB 1073 also requires a prescriber to provide translated directions for use, if requested, and authorizes the dispenser to use the translations made available on the board's website to comply with the requirement. Dispensers are not *required* to provide translated directions for use beyond what the board has made available. However, the bill does authorize a dispenser to provide his or her own translated directions for use to comply with the requirement. Veterinarians are exempt from the requirement to provide translated directions for use. The provisions of the bill go into effect on January 1, 2016.

2. SB 590 (Stone) Pharmacy: Intern Licenses, Chapter 147, Statutes of 2015

Senate Bill 590 was approved by the Governor on August 7, 2015. The bill amends section 4209 of the Business and Professions Code to streamline the application process for graduates from an ACPE accredited school or school of pharmacy recognized by the board for purposes of confirming completion of the required

pharmacy practice experience requirements. The provisions go into effect on January 1, 2016.

3. SB 619 (Morrell) Pharmacy: Outsourcing Facilities: Licensure
Status: 2-Year Bill

As reported at the July Board Meeting, Senate Bill 619 would have established the regulatory framework for licensure of outsourcing facilities that compound non-patient specific medications for administration to California patients.

The bill was held on suspense and died in Senate Appropriations in May. The proposal will need to be pursued in 2016 when the Legislature reconvenes.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

A copy of each bill is provided in **Attachment 2**.

1. AB 45 (Mullin) Household Hazardous Waste
Status: 2-Year Bill
Board Position: Oppose Unless Amended

AB 45 states that it is the intent of the Legislature to enact legislation that would establish various household hazardous waste collection programs, including curbside, door-to-door and residential pickup services as a principal means of collection such waste and diverting it from California's landfills and waterways. This measure would require each jurisdiction that provides for residential collection and disposal of solid waste, including household pharmaceutical waste, to increase its collection and diversion of such waste by 15% by July 1, 2020 unless otherwise specified. Board staff offered amendments to require the use of mail-back programs unless the jurisdiction complies with the provisions of federal law relating to the safe collection and disposal of such waste, but our amendment was not accepted. Board staff has continued to try to find a workable solution, and the board's Enforcement Committee has begun discussions on the matter.

2. AB 339 (Gordon) Health Care Coverage: Outpatient Prescription Drugs, Chapter 619, Statutes of 2015
Board Position: None

Assembly Bill 339 requires health plans and health insurers that provide coverage for outpatient prescription drugs to have formularies that do not discourage the enrollment of individuals with health conditions, and requires combination antiretroviral drug treatment coverage of a single-tablet that is as effective as a multitablet regimen for treatment of HIV/AIDS, as specified. The bill places in state law, federal requirements related to pharmacy and therapeutics committees, access to

in-network retail pharmacies, standardized formulary requirements, formulary tier requirements similar to those required of health plans and insurers participating in Covered California and copayment caps of \$250 and \$500 for a supply of up to 30 days for an individual prescription, as specified. The provisions go into effect on January 1, 2016.

3. AB 486 (Bonilla) Centralized Hospital Packaging Pharmacies: Medication Labels, Chapter 241, Statute 2015 (Urgency)

Board Position: Support

Assembly Bill provides an alternative method to maintain certain medication information that shall be readable at the patient's bedside, either via a barcode scan or human-readable, for unit dose medications prepared in a centralized hospital packaging facility. The provisions of the bill went into effect on September 2, 2015.

With the enactment of AB 486, centralized hospital packaging pharmacies no longer require waivers from the board regarding the labeling of unit dose medications packaged in these centralized pharmacies.

4. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program

Status: 2-Year Bill

Board Position: Oppose Unless Amended

AB 1069 would expand the provisions under which a county established repository and distribution program allow the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

Prior to the Legislative recess, board staff worked with the author's office to secure amendments to address many of the legal conflicts the measure initially contained. There are still some concerns with the bill in its current form. Currently, the bill would remove a pharmacist from several aspects of the redistribution program of prescription drugs; would allow a "participating entity" to transfer drugs like a distributor without appropriate licensure and control; and would permit what is currently unlawful repackaging and co-mingling of previously dispensed medications, including donated medications from various sources ... all to the detriment of patient safety. Staff will continue to work with the author's office on this measure.

5. AB 679 (Allen) CURES, Chapter 778, Statutes of 2015 (Urgency)

Board Position: None

Assembly Bill 679 amended Health and Safety Code 11165.1 related to the requirement that prescribers and dispensers apply to the Department of Justice to obtain approval to access information contained in the CURES database regarding the controlled

substance history of a patient under his or her care register for access to CURES by one of the following, whichever respective event occurs later:

- by July 1, 2016, or
- upon licensure, in the case of a pharmacist or
- upon receipt of a federal Drug Enforcement Administration registration, in the case of another health care practitioner authorized to prescribe, order, administer, furnish, or dispense controlled substances.

Prior law required registration by January 1, 2016. Because the bill contained an urgency clause, the provisions went into effect on October 11, 2015.

c. Legislation Impacting Board Operations

A copy of each bill is provided in **Attachment 3**.

1. AB 12 (Cooley) State Government: Administrative Regulations Review

Status: 2-Year Bill

Board Position: Oppose

Summary: Assembly Bill 12 would require state agencies and departments to review, adopt, amend, or repeal any application regulations that are duplicative, overlapping, inconsistent, or out of date by January 1, 2018. The measure also would establish notice and reporting requirements.

The board has determined that AB 12 would have a significant impact to its current operations. Given the complexity of the board's regulatory structure, board staff has concerns that the board would not be able to achieve compliance within the time allotted for completion of the review (2 years), without having a significant impact on other areas of the board's operations.

2. AB 85 (Wilk) Open Meetings

Status: Veto

Board Position: Oppose

Assembly Bill 85 would have required that when an advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body is acting in an official capacity of a state body, the entity (regardless of the committee size) is subject to the Open Meeting Act. The board opposed the measure. At the request of the author, board staff offered technical changes that would have addressed some of the concerns with the measure, but they were not accepted. The bill was Enrolled but was vetoed by the Governor on September 28th.

3. AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion

Status: Veto

Board Position: Oppose Unless Amended

Assembly Bill 1351 would have changed the existing deferred entry of judgment program into a pretrial diversion program. Under the pretrial diversion program created by this bill, a defendant qualifies if they have no prior conviction for any offense involving controlled substances (other than the offense that qualifies for the program), the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualifies for the program) and the defendant has no prior conviction for a serious or violent felony in the five years prior to the alleged commission of the charged offense.

The bill had the potential to significantly increase the board's costs of prosecution or lead to the dismissal of certain disciplinary charges, to the detriment of public safety. By enacting provisions where by a defendant would not have to enter a guilty plea, the board would not have been able to use a guilty plea as an admission of guilt; and when a defendant participates in a pretrial diversion program, the board can't consider that an admission of guilt.

Staff regularly worked with the author's office to identify language that could have resolved the board's concerns – but all requested amendments were rejected. The bill was enrolled, but was vetoed by the Governor on October 8th.

4. AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea, Chapter 646, Statutes of 2015

Board Position: Oppose

Assembly Bill 1352 will allow a defendant who was granted deferred entry of judgment on or after January 1, 1997, after pleading guilty or nolo contendere to the charged offense, to withdraw his or her prior guilty plea and enter a plea of not guilty if the charges were dismissed after the defendant performed satisfactorily during the deferred entry of judgment period and the defendant shows that the plea may result in the denial or loss to the defendant of any employment, benefit, license, or certificate, including, but not limited to, causing a noncitizen defendant to potentially be found inadmissible, deportable, or subject to any other kind of adverse immigration consequence.

The amendments to the Penal code will significantly impact the Board's ability to prove in disciplinary proceedings that a licensee or applicant is engaged, or has been engaged, in illicit drug activities. The bill is likely to increase the board's costs of prosecution or could lead to the dismissal of certain disciplinary charges, to the detriment of public safety.

d. Other Pieces of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations

During the meeting the board may hear comments on measures involving the regulation of prescription drugs and/or controlled substances; application, licensing and renewal requirements for board licensees; authorities granted to board licensees; measures adding, modifying or removing requirements that impact the board and its operations or that of the Department of Consumer Affairs.

Part 2: REGULATION REPORT

a. Board Approved – Awaiting Review by Control Agencies

Board approved language can be found on the Board's website:

<http://www.pharmacy.ca.gov/lawsregs/regulations.shtml>

1. Amendment of Title 16 California Code of Regulations (CCR) section 1793.5 Related to Pharmacy Technician Application

At the July 2014 Board Meeting, the board approved a proposal to amend Title 16 California Code of Regulations (CCR) section 1793.5 to change the wording of the criminal conviction question on the Pharmacy Technician Application, which is incorporated by reference in the regulation. The 45-day comment period concluded in April 2015. A 15-day comment period ran from May 26, 2015 to June 15, 2015, and no comments were received during this period. Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process at the end of July. On October 8, 2015, the file was submitted to the Office of Administrative Law for final review.

2. Amendment of Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26

At the October 2014 Board Meeting, the board directed staff to initiate a formal rulemaking process to amend the text of 16 California Code of Regulations sections 1715 and 1784 and to amend the Self-Assessment Forms incorporated by reference in those sections. Existing regulation requires a pharmacy, wholesaler and hospital to complete a self-assessment by July 1 of each odd-numbered year, and at other times, as specified in the regulation(s). A 45-day comment period ran from March 20 to May 6, 2015; however, due to issues with the Notice, a second 45-day comment period ran from May 29 to July 13, 2015. Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process at the end of July 2015. As of September 25, 2015, the file was being reviewed by Agency. Once approved by Agency, the

file will be submitted to the Office of Administrative Law for final review, pursuant to the Administrative Procedures Act.

3. Addition of Title 16 CCR section 1746.1 Related to Self-Administered Hormonal Contraception

At the March 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to add text to 16 California Code of Regulations section 1746.1 for Self-Administered Hormonal Contraception. The 45-day comment period ran from May 8 to June 22, 2015. The Board approved the final language at the September 2015 Board Meeting. Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on October 13, 2015. Once approved by the Department and Agency, the file will be submitted to the Office of Administrative Law for final review.

4. Addition of Title 16 CCR section 1746.2 Related to Nicotine Replacement Products

At the April 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the emergency regulation text of 16 CCR section 1746.3. The 45-day comment period ran from May 22 to July 13, 2015. A 15-day comment period was required due to an error made with the incorrect proposed text being noticed in May. The 15-day comment period ran from September 4 to September 19, 2015, and the board approved the final language at the September 2015 Board Meeting. Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on the October 16, 2015. Once approved by the Department and Agency, the file will be submitted to the Office of Administrative Law for final review.

5. Addition of Title 16 CCR section 1746.3 Related to Naloxone Hydrochloride (Non-Emergency)

At the April 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the emergency regulation text of 16 California Code of Regulations Section 1746.3. The 45-day comment period began on May 22, 2015 and ended on July 13, 2015. A 15-day comment period was required due to an error made with the incorrect proposed text being noticed in May. This comment period ran from September 4 to September 19, 2015, and thereafter, at the September Board Meeting, the board approved the final language. In accordance with the board's motion, board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on the October 16, 2015. Once approved by the Department and Agency, the file will be submitted to the Office of Administrative Law for final review.

b. Board Approved – Recently Noticed

The text of each proposed regulation, as approved by the board, is provided in **Attachment 4**.

1. Proposal to Add Title 16 CCR section 1730 Related to Advanced Practice Pharmacist

At the June 2015 Board Meeting, the board approved proposed text to add Section 1730 to Title 16 of the California Code of Regulations related to Advanced Practice Pharmacist. Staff prepared the required notice documents and on July 31, 2015, issued the 45-day text. The comment period ran from July 31 to September 14, 2015. In response the comments received, modifications were made to the text. At the September Board Meeting, the board approved the noticing of modified text; the 15-day comment period began October 9, 2015 and ended October 23, 2015. An update on this rulemaking will be provided at the Board meeting.

2. Proposal to Add Title 16 CCR section 1746.4 Related to Vaccinations

At the June 2015 Board Meeting, the board approved proposed text to add Section 1746.4 to Title 16 CCR related to Vaccinations. The 45-day comment period began on July 24, 2015 and ended on September 7, 2015. In response the comments received, the board approved modifications to the text and authorized a 15-day comment period. The 15-day comment period began on October 8, 2015 and ended October 22, 2015. An update on this rulemaking will be provided at the Board meeting.

3. Proposal to Add Title 16 CCR section 1746.5 Related to Travel Medications

At the June 2015 Board Meeting, the board approved proposed text to add Section 1746.5 to Title 16 CCR related to Travel Medications. The 45-day comment period began on September 25, 2015 and will end on November 9, 2015.

4. Proposal to Amend Title 16 CCR section 1744 Related to Drug Warnings

At the April 2015 Board Meeting, the board approved proposed text to amend Section 1744 of Title 16 CCF related to drug warnings. The 45-day comment period began on September 25, 2015 and will end on November 9, 2015.

5. Proposal to Amend title 16 CCR section 1760 Related to Disciplinary Guidelines

At the July 2015 Board Meeting, the board approved proposed text to amend Section 1760 of Title 16 of the California Code of Regulations related to Disciplinary Guidelines. The 45-day comment period began on September 4, 2015 and ended on October 19, 2015. This regulation will be discussed under Agenda Item XVI.

c. Board Approved – Awaiting Notice

A copy of each proposal, as approved by the board for public notice, is provided in **Attachment 5**. Staff is preparing the required notice documents for each, as noted.

1. Combined Rulemaking – Proposal to Amend Title 16 CCR sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements

A proposal to amend sections 1702 and 1702.5, and to add sections 1702.1 and 1702.2 to Title 16 CCR was approved by the board at the July 2013 Board Meeting. These proposals will be noticed as a combined rulemaking.

2. Combined Rulemaking – Proposal to Amend Title 16 CCR sections 1732.05, 1732.2, and 1732.5 Related to Continuing Education

In 2013, the board approved a proposal to initial a formal rulemaking to amend the text of Title 16 CCR sections 1732.05, 1732.2, and 1732.5 relative to continuing education. At the October 2014 board meeting, the board discussed and thereafter voted to add “compounding education” as a sixth area of subject-specific continuing education in section 1732.5. At the April 2015 board meeting, the board discussed and thereafter voted to add “Including Indicated of Red Flags and a Pharmacist’s Corresponding Responsibility” to area five “Substance Abuse.”

3. Proposal to Amend Title 16 CCR Section 1703 Related to “Section 100” Regulatory Actions

A proposal to amend Title 16 CCR section 1703 to delegate to the Executive Officer the authority to initiate a rulemaking to adopt “changes without regulatory effect” was approved at the October 2013 Board Meeting.

4. Proposal to Amend Title 16 California Code of Regulations Section 1780-1786 Related to Third-Party Logistics Providers

A proposal to amend Title 16 California Code of Regulations Section 1780-1786 related to Third-Party Logistics Providers was approved at the July 2015 Board Meeting.

Legislation and Regulation Committee

Attachment 1

AMENDED IN SENATE APRIL 6, 2015

SENATE BILL

No. 619

**Introduced by Senator Morrell
(Coauthor: Senator Stone)**

February 27, 2015

~~An act to amend Section 14105.455 of the Welfare and Institutions Code, relating to Medi-Cal. An act to amend Section 4400 of, to add Section 4034 to, and to add Article 7.7 (commencing with Section 4129) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.~~

LEGISLATIVE COUNSEL'S DIGEST

SB 619, as amended, Morrell. ~~Medi-Cal.~~ *Pharmacy: outsourcing facilities: licensure.*

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. The 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, a continuously appropriated fund.

This 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 provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services, including pharmacy services and drugs. Existing law requires pharmacy providers to submit their usual and customary charge when billing the Medi-Cal program for prescribed drugs.~~

~~This bill would make a technical, nonsubstantive change to that provision.~~

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

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

- 1 SECTION 1. Section 4034 is added to the Business and
- 2 Professions Code, to read:
- 3 4034. "Outsourcing facility" means a facility that meets all of
- 4 the following:
- 5 (a) Is located within the United States of America at one address
- 6 that is engaged in the compounding of sterile drugs and nonsterile
- 7 drugs.
- 8 (b) Has registered as an outsourcing facility with the federal
- 9 Food and Drug Administration under Section 503B of the Federal
- 10 Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).
- 11 (c) Is doing business within or into California.

1 (d) *Is licensed with the board as an outsourcing facility.*

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

5
6 Article 7.7. *Outsourcing Facilities*
7

8 4129. (a) *An entity licensed as an outsourcing facility with*
9 *the federal Food and Drug Administration (FDA) shall be*
10 *concurrently licensed with the board as an outsourcing facility if*
11 *it compounds sterile medication or nonsterile medication for*
12 *patients or practitioners within or into California. A product*
13 *compounded by an outsourcing facility shall be distributed without*
14 *a patient-specific prescription.*

15 (b) *A facility premises licensed with the board as a sterile*
16 *compounding pharmacy shall not be concurrently licensed with*
17 *the board as an outsourcing facility at the same location. A sterile*
18 *compounding pharmacy compounds and dispenses pursuant to a*
19 *prescription.*

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

25 (d) *The board shall review any formal requirements or guidance*
26 *documents developed by the FDA regarding outsourcing facilities*
27 *within 90 days after the release in order to determine whether*
28 *revisions are necessary for any regulations.*

29 (e) *An outsourcing facility licensed by the board shall not*
30 *perform the duties of a pharmacy, such as filling individual*
31 *prescriptions for individual patients, within the outsourcing facility.*
32 *Patient-specific compounding shall be performed only by a licensed*
33 *pharmacy. An outsourcing facility shall not be located in the same*
34 *licensed premises as a pharmacy.*

35 4129.1. (a) *An outsourcing facility that is licensed with the*
36 *FDA and with an address in this state shall also be licensed by*
37 *the board as an outsourcing facility before doing business within*
38 *or into this state. The license shall be renewed annually and is not*
39 *transferable.*

1 (b) An outsourcing facility shall compound all sterile products
2 and nonsterile products in compliance with current federal good
3 manufacturing practices.

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

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

9 (1) Reviews a current copy of the outsourcing facility's policies
10 and procedures for sterile compounding and nonsterile
11 compounding.

12 (2) Is provided with copies of all inspection reports of the
13 outsourcing facility's premises conducted in the prior 12 months.

14 (3) Receives a list of all sterile drugs and nonsterile drugs
15 compounded by the outsourcing facility as reported to the FDA in
16 the last 12 months.

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

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

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

23 (3) Notice within 24 hours after learning of adverse effects
24 reported or potentially attributable to an outsourcing facility's
25 products.

26 4129.2. (a) An outsourcing facility that is licensed with the
27 FDA as an outsourcing facility and has an address outside of this
28 state but in the United States of America is a nonresident
29 outsourcing facility. A nonresident outsourcing facility shall not
30 compound sterile drug products or nonsterile drug products for
31 shipment into this state without an outsourcing license issued by
32 the board pursuant to this section. The license shall be renewed
33 annually and shall not be transferable.

34 (b) A nonresident outsourcing facility shall compound all sterile
35 products and nonsterile products in compliance with current
36 federal good manufacturing practices.

37 (c) A license for a nonresident outsourcing facility shall not be
38 issued or renewed until the location is inspected by the board and
39 found in compliance with this article and any regulations adopted
40 by the board. The nonresident outsourcing facility shall reimburse

1 *the board for all actual and necessary costs incurred by the board*
2 *in conducting an inspection of the nonresident outsourcing facility*
3 *at least once annually pursuant to subdivision (x) of Section 4400.*

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

6 *(1) Reviews a current copy of the nonresident outsourcing*
7 *facility's policies and procedures for sterile compounding and*
8 *nonsterile compounding.*

9 *(2) Is provided with copies of all inspection reports of the*
10 *nonresident outsourcing facility's premises conducted in the prior*
11 *12 months.*

12 *(3) Receives a list of all sterile drug products and nonsterile*
13 *drug products compounded by the pharmacy as reported to the*
14 *FDA within the prior 12 months.*

15 *(e) A nonresident outsourcing facility licensed pursuant to this*
16 *section shall do all of the following:*

17 *(1) Provide the board with a copy of any disciplinary or other*
18 *action taken by another state or the FDA within 10 days of the*
19 *action.*

20 *(2) Provide the board notice within 24 hours of any recall notice*
21 *issued by the nonresident outsourcing facility.*

22 *(3) Advise the board of any complaint it receives from a*
23 *provider, pharmacy, or patient in California.*

24 *(f) A nonresident outsourcing facility shall provide to the board*
25 *notice within 24 hours after learning of adverse effects reported*
26 *or potentially attributable to a nonresident outsourcing facility's*
27 *products.*

28 *4129.3. (a) On or before January 1, 2018, the board shall*
29 *provide a report to the Legislature regarding the regulation of*
30 *nonresident outsourcing facilities. The report shall be submitted*
31 *to the Legislature in the manner required pursuant to Section 9795*
32 *of the Government Code. At a minimum, the report shall address*
33 *all of the following:*

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

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

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

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

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

14 4129.4. (a) *Whenever the board has a reasonable belief, based*
15 *on information obtained during an inspection or investigation by*
16 *the board, that an outsourcing facility compounding sterile drug*
17 *products or nonsterile drug products poses an immediate threat*
18 *to the public health or safety, the executive officer of the board*
19 *may issue an order to the outsourcing facility to immediately cease*
20 *and desist compounding sterile drug products or nonsterile drug*
21 *products. The cease and desist order shall remain in effect for no*
22 *more than 30 days or the date of a hearing seeking an interim*
23 *suspension order, whichever is earlier.*

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

28 (c) *The cease and desist order shall state that the owner, within*
29 *15 days of receipt of the notice, may request a hearing before the*
30 *president of the board to contest the cease and desist order.*
31 *Consideration of the owner's contest of the cease and desist order*
32 *shall comply with the requirements of Section 11425.10 of the*
33 *Government Code. The hearing shall be held no later than five*
34 *days after the date the request of the owner is received by the*
35 *board. The president shall render a written decision within five*
36 *days after the hearing. In the absence of the president of the board,*
37 *the vice president of the board may conduct the hearing permitted*
38 *by this subdivision. Review of the decision may be sought by the*
39 *owner or person in possession or control of the outsourcing facility*
40 *pursuant to Section 1094.5 of the Code of Civil Procedure.*

1 (d) Failure to comply with a cease and desist order issued
2 pursuant to this section is unprofessional conduct.

3 4129.5. Notwithstanding any other law, a violation of this
4 article, or regulation adopted pursuant thereto, may subject the
5 person or entity that committed the violation to a fine of up to five
6 thousand dollars (\$5,000) per occurrence pursuant to a citation
7 issued by the board.

8 4129.6. For purposes of this article, “sterile compounded
9 products” means compounded preparations for injection
10 administration into the eye, or inhalation.

11 4129.8. The board, at its discretion, may issue a temporary
12 license to an outsourcing facility when the ownership of the
13 outsourcing facility is transferred from one person to another,
14 upon the conditions and for any periods of time as the board
15 determines to be in the public interest. A temporary license fee
16 shall be required as specified in subdivision (w) of Section 4400.
17 When needed to protect public safety, a temporary license may be
18 issued for a period not to exceed 180 days, and may be issued
19 subject to terms and conditions the board deems necessary. If the
20 board determines a temporary license was issued by mistake or
21 denies the application for a permanent license, the temporary
22 license shall terminate upon the earlier of personal service of the
23 notice of termination upon the licenseholder or service by certified
24 mail with return receipt requested at the licenseholder’s address
25 of record with the board. The temporary licenseholder shall not
26 be deemed to have a vested property right or interest in the license
27 for purposes of retaining a temporary license or for purposes of
28 any disciplinary or license denial proceeding before the board.

29 4129.9. (a) An outsourcing facility licensed pursuant to Section
30 4129.1 or 4129.2 that issues a recall notice for a sterile drug or
31 nonsterile drug compounded by the outsourcing facility, in addition
32 to any other duties, shall contact the recipient pharmacy,
33 prescriber, or patient of the recalled drug and the board as soon
34 as possible within 24 hours of the recall notice if both of the
35 following apply:

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

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

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

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

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

11 SEC. 3. Section 4400 of the Business and Professions Code is
12 amended to read:

13 4400. The amount of fees and penalties prescribed by this
14 chapter, except as otherwise provided, is that fixed by the board
15 according to the following schedule:

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

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

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

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

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

35 (f) The fee for a nongovernmental wholesaler or third-party
36 logistics provider license and annual renewal shall be seven
37 hundred eighty dollars (\$780) and may be decreased to no less
38 than six hundred dollars (\$600). The application fee for any
39 additional location after licensure of the first 20 locations shall be
40 three hundred dollars (\$300) and may be decreased to no less than

1 two hundred twenty-five dollars (\$225). A temporary license fee
2 shall be seven hundred fifteen dollars (\$715) and may be decreased
3 to no less than five hundred fifty dollars (\$550).

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

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

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

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

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

25 (j) (1) The application fee for a nonresident wholesaler or
26 third-party logistics provider license issued pursuant to Section
27 4161 shall be seven hundred eighty dollars (\$780) and may be
28 decreased to no less than six hundred dollars (\$600).

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

39 (3) The annual renewal fee for a nonresident wholesaler license
40 or third-party logistics provider license issued pursuant to Section

1 4161 shall be seven hundred eighty dollars (\$780) and may be
2 decreased to no less than six hundred dollars (\$600).

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

6 (l) The fee for an intern pharmacist license shall be ninety dollars
7 (\$90) and may be increased to one hundred fifteen dollars (\$115).

8 The fee for transfer of intern hours or verification of licensure to
9 another state shall be twenty-five dollars (\$25) and may be
10 increased to thirty dollars (\$30).

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

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

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

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

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

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

37 (s) The fee for a veterinary food-animal drug retailer license
38 shall be four hundred five dollars (\$405) and may be increased to
39 four hundred twenty-five dollars (\$425). The annual renewal fee
40 for a veterinary food-animal drug retailer license shall be two

1 hundred fifty dollars (\$250) and may be increased to three hundred
2 twenty-five dollars (\$325).

3 (t) The fee for issuance of a retired license pursuant to Section
4 4200.5 shall be thirty-five dollars (\$35) and may be increased to
5 forty-five dollars (\$45).

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

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

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

27 (w) *The fee for issuance or renewal of a nongovernmental*
28 *outsourcing facility license shall be seven hundred eighty dollars*
29 *(\$780). The fee for a temporary outsourcing facility license shall*
30 *be seven hundred fifteen dollars (\$715).*

31 (x) *The fee for the issuance or renewal of a nonresident*
32 *outsourcing facility license shall be seven hundred eighty dollars*
33 *(\$780). In addition to paying that application fee, the nonresident*
34 *outsourcing facility shall deposit, when submitting the application,*
35 *a reasonable amount, as determined by the board, necessary to*
36 *cover the board's estimated cost of performing the inspection*
37 *required by Section 4129.2. If the required deposit is not submitted*
38 *with the application, the application shall be deemed to be*
39 *incomplete. If the actual cost of the inspection exceeds the amount*
40 *deposited, the board shall provide to the applicant a written invoice*

1 *for the remaining amount and shall not take action on the*
2 *application until the full amount has been paid to the board. If the*
3 *amount deposited exceeds the amount of actual and necessary*
4 *costs incurred, the board shall remit the difference to the applicant.*

5 SECTION 1. ~~Section 14105.455 of the Welfare and Institutions~~
6 ~~Code is amended to read:~~

7 ~~14105.455.— (a) Pharmacy providers shall submit their usual~~
8 ~~and customary charge when billing the Medi-Cal program for~~
9 ~~prescribed drugs.~~

10 ~~(b) “Usual and customary charge” means the lower of either of~~
11 ~~the following:~~

12 ~~(1) The lowest price reimbursed to the pharmacy by other~~
13 ~~third-party payers in California, excluding Medi-Cal managed care~~
14 ~~plans and Medicare Part D prescription drug plans.~~

15 ~~(2) The lowest price routinely offered to any segment of the~~
16 ~~general public.~~

17 ~~(c) Donations or discounts provided to a charitable organization~~
18 ~~are not considered usual and customary charges.~~

19 ~~(d) Pharmacy providers shall keep and maintain records of their~~
20 ~~usual and customary charges for a period of three years from the~~
21 ~~date the service was rendered.~~

22 ~~(e) Payment to pharmacy providers shall be the lower of the~~
23 ~~pharmacy’s usual and customary charge or the reimbursement rate~~
24 ~~pursuant to subdivision (b) of Section 14105.45.~~

25 ~~(f) Notwithstanding Chapter 3.5 (commencing with Section~~
26 ~~11340) of Part 1 of Division 3 of Title 2 of the Government Code,~~
27 ~~the department may implement, interpret, or make specific this~~
28 ~~section by means of a provider bulletin or notice, policy letter, or~~
29 ~~other similar instructions, without taking regulatory action.~~

Senate Bill No. 590

CHAPTER 147

An act to amend Section 4209 of the Business and Professions Code, relating to pharmacy.

[Approved by Governor August 7, 2015. Filed with
Secretary of State August 7, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

SB 590, Stone. Pharmacy: intern pharmacists.

Existing law, the Pharmacy Law, establishes the California State Board of Pharmacy within the Department of Consumer Affairs and sets forth its powers and duties over the licensing and regulation of the practice of pharmacies, pharmacists, intern pharmacists, and pharmacy technicians. A knowing violation of these provisions is a crime.

Existing law requires an intern pharmacist to complete 1,500 hours of pharmacy practice or intern experience before applying for the pharmacist licensure examination. Existing law authorizes an applicant for examination who has been licensed as a pharmacist in any state for at least one year to submit certification to satisfy the required 1,500 hours of intern experience if that applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist.

This bill would instead require, for all applicants, that 900 hours of the 1,500 required pharmacy practice experience include experience in a pharmacy, including experience in both a community and institutional pharmacy practice setting.

Existing law requires the pharmacy practice to comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education (ACPE) or with regulations adopted by the board. Existing law requires an intern pharmacist to submit proof of his or her experience under penalty of perjury.

This bill would require that an applicant for the licensure examination who has graduated after January 1, 2016, from an ACPE accredited college of pharmacy or school of pharmacy recognized by the board, be deemed by the board to have satisfied the required hours of pharmacy practice experience, as specified.

By expanding the scope of an existing crime, this bill would create a state-mandated local program.

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. Section 4209 of the Business and Professions Code is amended to read:

4209. (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice experience before applying for the pharmacist licensure examination.

(2) This pharmacy practice experience shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education (ACPE) or with regulations adopted by the board.

(3) This pharmacy practice experience shall include 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and shall include pharmacy practice experience in both a community and institutional pharmacy practice setting.

(b) An intern pharmacist shall submit proof of his or her pharmacy practice experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision the experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Pharmacy practice experience earned in another state may be certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of pharmacy practice experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and has pharmacy practice experience in both a community and institutional pharmacy practice setting. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

(d) An applicant for the examination who has graduated after January 1, 2016, from an ACPE accredited college of pharmacy or school of pharmacy recognized by the board shall be deemed to have satisfied the pharmacy practice experience requirements specified in subdivisions (a) and (b).

SEC. 2. 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

Assembly Bill No. 1073

CHAPTER 784

An act to amend Sections 4076 and 4199 of, and to add Section 4076.6 to, the Business and Professions Code, relating to pharmacy.

[Approved by Governor October 11, 2015. Filed with Secretary of State October 11, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1073, Ting. Pharmacy: prescription drug labels.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. That law requires a pharmacist to dispense a prescription in a container that, among other things, is correctly labeled with the directions for use of the drug, and requires the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. Existing regulations of the board implement that requirement, establishing standardized directions for use to be used when applicable, and requiring that the board publish on its Internet Web site translation of those directions for use into at least 5 languages other than English. A violation of that law is a crime.

This bill would require a pharmacist to use professional judgment to provide a patient with directions for use of a prescription that enhance the patient's understanding of those directions, consistent with the prescriber's instructions. The bill would also require a dispenser, excluding a veterinarian, upon the request of a patient or patient's representative, to provide translated directions for use as prescribed. The bill would authorize a dispenser to use translations made available by the board pursuant to those existing regulations. The bill would make a dispenser responsible for the accuracy of English-language directions for use provided to the patient. By imposing new requirements on dispensers, the violation of which would be a crime, this bill would impose a state-mandated local program.

The Pharmacy Law also provides for the licensure and regulation of veterinary food-animal drug retailers by the board. That law subjects to specific prescription drug labeling requirements any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food-producing animals from a veterinary food-animal drug retailer pursuant to that law.

This bill would also subject any veterinary food-animal drug so dispensed to the above drug labeling requirements relating to standardized directions for use.

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. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.

SEC. 2. Section 4076.6 is added to the Business and Professions Code, to read:

4076.6. (a) Upon the request of a patient or patient's representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document. If translated directions for use appear on a prescription container or label, the English-language version of the directions for use shall also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. When it is not possible for the English-language directions for use to appear on the container or label, it shall be provided on a supplemental document.

(b) A dispenser may use translations made available by the board pursuant to subdivision (b) of Section 1707.5 of Title 16 of the California Code of Regulations to comply with this section.

(c) A dispenser shall not be required to provide translated directions for use beyond the languages that the board has made available or beyond the directions that the board has made available in translated form.

(d) A dispenser may provide his or her own translated directions for use to comply with the requirements of this section, and nothing in this section shall be construed to prohibit a dispenser from providing translated directions for use in languages beyond those that the board has made available or beyond the directions that the board has made available in translated form.

(e) A dispenser shall be responsible for the accuracy of the English-language directions for use provided to the patient. This section shall not affect a dispenser's existing responsibility to correctly label a prescription pursuant to Section 4076.

(f) For purposes of this section, a dispenser does not include a veterinarian.

SEC. 3. Section 4199 of the Business and Professions Code is amended to read:

4199. (a) Any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food producing animals from a veterinary food-animal drug retailer pursuant to this chapter is subject to the labeling requirements of Sections 4076, 4076.6, and 4077.

(b) All prescriptions filled by a veterinary food-animal drug retailer shall be kept on file and maintained for at least three years in accordance with Section 4333.

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.

Legislation and Regulation Committee

Attachment 2

AMENDED IN ASSEMBLY APRIL 30, 2015

AMENDED IN ASSEMBLY APRIL 23, 2015

AMENDED IN ASSEMBLY APRIL 13, 2015

AMENDED IN ASSEMBLY MARCH 19, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 45

Introduced by Assembly Member Mullin

December 1, 2014

An act to add Article 3.4 (commencing with Section 47120) to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to hazardous waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 45, as amended, Mullin. Household hazardous waste.

The California Integrated Waste Management Act of 1989, which is administered by the Department of Resources Recycling and Recovery, requires, among other things, each city and each county to prepare a household hazardous waste element containing specified components, and to submit that element to the department for approval. Existing law requires the department to approve the element if the local agency demonstrates that it will comply with specified requirements. A city or county is required to submit an annual report to the department summarizing its progress in reducing solid waste, including an update of the jurisdiction's household hazardous waste element.

This bill would require each jurisdiction that provides for the residential collection and disposal of solid waste to increase the collection and diversion of household hazardous waste in its service

area, on or before July 1, 2020, by 15% over a baseline amount, to be determined in accordance with department regulations. The bill would authorize the department to adopt a model ordinance for a comprehensive program for the collection of household hazardous waste to facilitate compliance with those provisions, and would require each jurisdiction to annually report to the department on progress achieved in complying with those provisions. By imposing new duties on local agencies, the bill would impose a state-mandated local program.

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. Fiscal committee: yes.
 State-mandated local program: yes.

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

- 1 SECTION 1. (a) The Legislature finds and declares all of the
- 2 following:
- 3 (1) Household hazardous waste is creating environmental,
- 4 health, and workplace safety issues. Whether due to unused
- 5 pharmaceuticals, batteries, medical devices, or other disposable
- 6 consumer items, effective and efficient disposal remains an
- 7 extraordinary challenge.
- 8 (2) State and local efforts to address disposal of these items
- 9 have been well intended and, in some cases, effective. However,
- 10 even the most effective programs have very low consumer
- 11 participation. Other approaches being promoted throughout the
- 12 state would fragment the collection of household hazardous waste
- 13 and move collection away from consumer convenience.
- 14 (3) In addition to other programs for the collection of household
- 15 hazardous waste, a number of cities in California are already using
- 16 curbside household hazardous waste collection programs,
- 17 door-to-door household hazardous waste collection programs, and
- 18 household hazardous waste residential pickup services as
- 19 mechanisms for collecting and disposing of many commonly used
- 20 household items for which disposal has been the subject of state
- 21 legislation or local ordinances. The waste disposal companies and
- 22 local governments that have implemented these programs have

1 found them to be valuable components of a comprehensive
2 approach to the management of household hazardous waste.

3 (4) There is also an appropriate role for manufacturers and
4 distributors of these products in comprehensive efforts to more
5 effectively manage household hazardous waste. That role should
6 be based on the ability of manufacturers and distributors to
7 communicate with consumers.

8 (b) It is the intent of the Legislature to enact legislation that
9 would establish curbside household hazardous waste collection
10 programs, door-to-door household hazardous waste collection
11 programs, and household hazardous waste residential pickup
12 services as the principal means of collecting household hazardous
13 waste and diverting it from California’s landfills and waterways.

14 SEC. 2. Article 3.4 (commencing with Section 47120) is added
15 to Chapter 1 of Part 7 of Division 30 of the Public Resources Code,
16 to read:

17

18 Article 3.4. Household Hazardous Waste Collection and
19 Reduction

20

21 47120. For purposes of this article, the following terms have
22 the following meanings:

23 (a) “Comprehensive program for the collection of household
24 hazardous waste” means a local program that ~~includes~~ *may include*,
25 *but is not limited to*, the following components:

26 (1) Utilization of locally sponsored collection sites.

27 (2) Scheduled and publicly advertised drop off days.

28 (3) Door-to-door collection programs.

29 (4) Mobile collection programs.

30 (5) Dissemination of information about how consumers should
31 dispose of the various types of household hazardous waste.

32 (6) Education programs to promote consumer understanding
33 and use of the local components of a comprehensive program.

34 (b) “Household hazardous waste” includes, but is not limited
35 to, the following:

36 (1) Automotive products, including, but not limited to,
37 antifreeze, batteries, brake fluid, motor oil, oil filters, fuels, wax,
38 and polish.

39 (2) Garden chemicals, including, but not limited to, fertilizers,
40 herbicides, insect sprays, pesticides, and weed killers.

- 1 (3) Household chemicals, including, but not limited to, ammonia,
2 cleaners, strippers, and rust removers.
- 3 (4) Paint products, including, but not limited to, paint, caulk,
4 glue, stripper, thinner, and wood preservatives and stain.
- 5 (5) Consumer electronics, including, but not limited to,
6 televisions, computers, laptops, monitors, keyboards, DVD and
7 CD players, VCRs, MP3 players, cell phones, desktop printers,
8 scanners, fax machines, mice, mice, microwaves, and related cords.
- 9 (6) Swimming pool chemicals, including, but not limited to,
10 chlorine tablets and liquids, pool acids, and stabilizers.
- 11 (7) Household batteries. For purposes of this section, “household
12 batteries” means batteries that individually weigh two kilograms
13 or less of mercury, alkaline, carbon-zinc, or nickel-cadmium, and
14 any other batteries typically generated as household waste,
15 including, but not limited to, batteries used to provide power for
16 consumer electronic and personal goods often found in a household.
- 17 (8) Fluorescent tubes and compact florescent lamps.
- 18 (9) Mercury-containing items, including, but not limited to,
19 thermometers, thermostats, and switches.
- 20 (10) Home-generated sharps waste, as defined in Section 117671
21 of the Health and Safety Code.
- 22 (11) Home-generated pharmaceutical waste. For purposes of
23 this section, “home-generated pharmaceutical waste” means a
24 prescription or nonprescription drug, as specified in Section 4022
25 or 4025.1 of the Business and Professions Code, that is a waste
26 generated by a household or households. “Home-generated
27 pharmaceutical waste” shall not include drugs for which producers
28 provide a take-back program as a part of a United States Food and
29 Drug Administration managed risk evaluation and mitigation
30 strategy pursuant to Section 355-1 of Title 21 of the United States
31 Code, or waste generated by a business, corporation, limited
32 partnership, or an entity involved in a wholesale transaction
33 between a distributor and a retailer.
- 34 47121. (a) (1) On or before July 1, 2020, each jurisdiction
35 shall increase its collection and diversion of household hazardous
36 waste in its service area by 15 percent over its baseline amount,
37 as established pursuant to subdivision (b).
- 38 (2) Notwithstanding paragraph (1), a jurisdiction that has in
39 place or adopts an ordinance implementing a comprehensive
40 program for the collection of household hazardous waste shall

1 have an additional two years to meet the collection and diversion
2 objective in paragraph (1).

3 (b) No later than July 1, 2016, each jurisdiction shall inform the
4 department of its baseline amount of collection and diversion of
5 hazardous waste in accordance with regulations adopted by the
6 department. The baseline amount may be expressed in tonnage or
7 by the number of households participating, and may focus on
8 particular types of household hazardous waste.

9 47122. (a) The department shall adopt regulations to implement
10 this article.

11 (b) The department may adopt a model ordinance for a
12 comprehensive program for the collection of household hazardous
13 waste to facilitate compliance with this article.

14 47123. Commencing July 1, 2020, and annually thereafter,
15 each jurisdiction shall report to the department on progress
16 achieved in complying with this section. A jurisdiction shall make
17 a good faith effort to comply with this section, and the department
18 may determine whether a jurisdiction has made a good faith effort
19 for purposes of this program. To the maximum extent practicable,
20 it is the intent of the Legislature that reporting requirements under
21 this section be satisfied by submission of similar reports currently
22 required by law.

23 47124. This article does not apply to a jurisdiction that does
24 not provide for the residential collection and disposal of solid
25 waste.

26 SEC. 3. No reimbursement is required by this act pursuant to
27 Section 6 of Article XIII B of the California Constitution because
28 a local agency or school district has the authority to levy service
29 charges, fees, or assessments sufficient to pay for the program or
30 level of service mandated by this act, within the meaning of Section
31 17556 of the Government Code.

Assembly Bill No. 339

CHAPTER 619

An act to amend Section 1367.205 of, to add Sections 1367.41 and 1367.42 to, and to add and repeal Section 1342.71 of, the Health and Safety Code, and to amend Section 10123.192 of, to add Section 10123.201 to, and to add and repeal Section 10123.193 of, the Insurance Code, relating to health care coverage.

[Approved by Governor October 8, 2015. Filed with
Secretary of State October 8, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 339, Gordon. Health care coverage: outpatient prescription drugs.

(1) Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan or insurer that provides prescription drug benefits and maintains one or more drug formularies to make specified information regarding the formularies available to the public and other specified entities. Existing law also specifies requirements for those plans and insurers regarding coverage and cost sharing of specified prescription drugs.

This bill would prohibit the formulary or formularies for outpatient prescription drugs maintained by a health care service plan or health insurer from discouraging the enrollment of individuals with health conditions and from reducing the generosity of the benefit for enrollees or insureds with a particular condition. The bill, until January 1, 2020, would provide that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription shall not exceed \$250 for a supply of up to 30 days, except as specified, and would prohibit, for a nongrandfathered individual or small group plan contract or policy, the annual deductible for outpatient drugs from exceeding a specified amount. The bill would make these cost-sharing limits applicable only to covered outpatient prescription drugs that constitute essential health benefits, as defined. The bill would require a plan contract or policy to cover a single-tablet prescription drug regimen for combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, as specified. The bill, until January 1, 2020, would require a nongrandfathered individual or small group plan contract or policy to use specified definitions for each tier of a drug formulary. The bill would make related findings and declarations.

This bill would require a health care service plan contract or health insurance policy that provides coverage for outpatient prescription drugs to provide coverage for medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary, and, for an insurer, would require copayments, coinsurance, and other cost sharing for outpatient prescription drugs to be reasonable.

This bill would make these provisions applicable to nongrandfathered health care service plan contracts or health insurance policies that are offered, renewed, or amended on or after January 1, 2017.

(2) Existing law requires every health care service plan that provides prescription drug benefits to maintain specified information that is required to be made available to the Director of the Department of Managed Health Care upon request.

This bill would also impose these requirements on a health insurer that provides prescription drug benefits, as provided. The bill would authorize an insurer to require step therapy, as defined, when more than one drug is appropriate for the treatment of a medical condition, subject to specified requirements. The bill, with regard to an insured changing policies, would prohibit a new insurer from requiring the insured to repeat step therapy when that person is already being treated for a medical condition by a prescription drug, as specified. For plan years commencing on or after January 1, 2017, the bill, except as specified, would require a plan or insurer that provides essential health benefits to allow an enrollee or insured to access his or her prescription drug benefits at an in-network retail pharmacy, and would authorize a nongrandfathered individual or small group plan or insurer to charge an enrollee or insured a different cost sharing for obtaining a covered drug at a retail pharmacy, and would require that cost-sharing amount to count towards the plan's or insurer's annual out-of-pocket limitation, as specified.

This bill, commencing January 1, 2017, would require a plan or insurer to maintain a pharmacy and therapeutics committee that is responsible for developing, maintaining, and overseeing any drug formulary list, as provided. The bill would require the committee to, among other things, evaluate and analyze treatment protocols and procedures related to the plan's or insurer's drug formulary at least annually.

(3) Existing law requires the Department of Managed Health Care and the Department of Insurance to jointly develop a standard formulary template by January 1, 2017, and requires plans and insurers to use that template to display formularies, as specified. Existing law requires the standard formulary template to include specified information.

This bill would require the standard formulary template to include additional specified information, including which medications are covered, including both generic and brand name.

(4) Because a willful violation of the bill's requirements relative to health care service plans would be a crime, this bill would impose a state-mandated local program.

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. Section 1342.71 is added to the Health and Safety Code, to read:

1342.71. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered health care service plan contract that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the contract that constitute essential health benefits, as defined in Section 1367.005.

(c) A health care service plan contract that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this chapter.

(d) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health care service plan shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet

regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(e) (1) With respect to an individual or group health care service plan contract subject to Section 1367.006, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars (\$250), except as provided in paragraphs (2) and (3).

(2) With respect to products with actuarial value at, or equivalent to, the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars (\$500), except as provided in paragraph (3).

(3) For a health care service plan contract that is a “high deductible health plan” under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision shall apply only once an enrollee’s deductible has been satisfied for the year.

(4) For a nongrandfathered individual or small group health care service plan contract, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.

(5) For purposes of paragraphs (1) and (2), “any other form of cost sharing” shall not include deductible.

(f) (1) If a health care service plan contract for a nongrandfathered individual or small group product maintains a drug formulary grouped into tiers that includes a fourth tier, a health care service plan contract shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health care service plan’s pharmacy and therapeutics committee based on safety, efficacy, and cost.

(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health care service plan’s pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.

(D) Tier four shall consist of drugs that are biologics, drugs that the FDA or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the enrollee to have special training or clinical monitoring for self-administration, or drugs that cost the health plan more than six hundred dollars (\$600) net of rebates for a one-month supply.

(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the health care service plan shall take into account the other provisions of this section and this chapter.

(3) A health care service plan contract may maintain a drug formulary with fewer than four tiers.

(4) This section shall not be construed to limit a health care service plan from placing any drug in a lower tier.

(g) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(h) This section shall not be construed to require a health care service plan to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(i) This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

(j) In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.

(k) This section shall not apply to a health care service plan that contracts with the State Department of Health Care Services.

(l) This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.

SEC. 2. Section 1342.71 is added to the Health and Safety Code, to read:

1342.71. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered health care service plan contract that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section.

(c) A health care service plan contract that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this chapter.

(d) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health care service plan shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(e) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(f) This section shall not be construed to require a health care service plan to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(g) This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

(h) In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.

(i) This section shall not apply to a health care service plan that contracts with the State Department of Health Care Services.

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

SEC. 3. Section 1367.41 is added to the Health and Safety Code, immediately following Section 1367.4, to read:

1367.41. (a) Commencing January 1, 2017, a health care service plan shall maintain a pharmacy and therapeutics committee that shall be responsible for developing, maintaining, and overseeing any drug formulary list. If the plan delegates responsibility for the formulary to any entity, the obligation of the plan to comply with this chapter shall not be waived.

(b) The pharmacy and therapeutics committee board membership shall conform with both of the following:

(1) Represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.

(2) Consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health professionals who are licensed to prescribe drugs.

(c) Members of the board shall abstain from voting on any issue in which the member has a conflict of interest with respect to the issuer or a pharmaceutical manufacturer.

(d) At least 20 percent of the board membership shall not have a conflict of interest with respect to the issuer or any pharmaceutical manufacturer.

(e) The pharmacy and therapeutics committee shall meet at least quarterly and shall maintain written documentation of the rationale for its decisions regarding the development of, or revisions to, the formulary drug list.

(f) The pharmacy and therapeutics committee shall do all of the following:

(1) Develop and document procedures to ensure appropriate drug review and inclusion.

(2) Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmaco-economic studies, outcomes research data, and other related information.

(3) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.

(4) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.

(5) Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.

(6) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.

(7) Review new United States Food and Drug Administration-approved drugs and new uses for existing drugs.

(8) Ensure that the plan's formulary drug list or lists cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and do not discourage enrollment by any group of enrollees.

(9) Ensure that the plan's formulary drug list or lists provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

(g) This section shall be interpreted consistent with federal guidance issued under paragraph (3) of subdivision (a) of Section 156.122 of Title 45 of the Code of Federal Regulations. This section shall apply to the individual, small group, and large group markets.

SEC. 4. Section 1367.42 is added to the Health and Safety Code, to read:

1367.42. (a) For plan years commencing on or after January 1, 2017, a plan that provides essential health benefits shall allow an enrollee to access prescription drug benefits at an in-network retail pharmacy unless the prescription drug is subject to restricted distribution by the United States Food and Drug Administration or requires special handling, provider

coordination, or patient education that cannot be provided by a retail pharmacy.

(b) A nongrandfathered individual or small group health plan contract may charge an enrollee a different cost sharing for obtaining a covered drug at a retail pharmacy, but all cost sharing shall count toward the plan's annual limitation on cost sharing consistent with Section 1367.006.

SEC. 5. Section 1367.205 of the Health and Safety Code is amended to read:

1367.205. (a) In addition to the list required to be provided under Section 1367.20, a health care service plan that provides prescription drug benefits and maintains one or more drug formularies shall do all of the following:

(1) Post the formulary or formularies for each product offered by the plan on the plan's Internet Web site in a manner that is accessible and searchable by potential enrollees, enrollees, providers, the general public, the department, and federal agencies as required by federal law or regulations.

(2) Update the formularies posted pursuant to paragraph (1) with any change to those formularies on a monthly basis.

(3) No later than six months after the date that a standard formulary template is developed under subdivision (b), use that template to display the formulary or formularies for each product offered by the plan.

(b) (1) By January 1, 2017, the department and the Department of Insurance shall jointly, and with input from interested parties from at least one public meeting, develop a standard formulary template for purposes of paragraph (3) of subdivision (a). In developing the template, the department and Department of Insurance shall take into consideration existing requirements for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services. To the extent feasible, in developing the template, the department and the Department of Insurance shall evaluate a way to include on the template, in addition to the information required to be included under paragraph (2), cost-sharing information for drugs subject to coinsurance.

(2) The standard formulary template shall include the notification described in subdivision (c) of Section 1363.01, and as applied to a particular formulary for a product offered by a plan, shall do all of the following:

(A) Include information on cost-sharing tiers and utilization controls, including prior authorization or step therapy requirements, for each drug covered by the product.

(B) Indicate any drugs on the formulary that are preferred over other drugs on the formulary.

(C) Include information to educate enrollees about the differences between drugs administered or provided under a health care service plan's medical benefit and drugs prescribed under a health care service plan's prescription drug benefit and about how to obtain coverage information regarding drugs that are not covered under the plan's prescription drug benefit.

(D) Include information to educate enrollees that health care service plans that provide prescription drug benefits are required to have a method for enrollees to obtain prescription drugs not listed in the health plan drug formulary if the drugs are deemed medically necessary by a clinician pursuant to Section 1367.24.

(E) Include information on which medications are covered, including both generic and brand name.

(F) Include information on what tier of the plan's drug formulary each medication is in.

(c) For purposes of this section, "formulary" means the complete list of drugs preferred for use and eligible for coverage under a health care service plan product and includes the drugs covered under the pharmacy benefit of the product.

SEC. 6. Section 10123.192 of the Insurance Code is amended to read:

10123.192. (a) A health insurer that provides prescription drug benefits and maintains one or more drug formularies shall do all of the following:

(1) Post the formulary or formularies for each product offered by the insurer on the insurer's Internet Web site in a manner that is accessible and searchable by potential insureds, insureds, providers, the general public, the department, and federal agencies as required by federal law or regulations.

(2) Update the formularies posted pursuant to paragraph (1) with any change to those formularies on a monthly basis.

(3) No later than six months after the date that a standard formulary template is developed under subdivision (b), use that template to display the formulary or formularies for each product offered by the insurer.

(b) (1) By January 1, 2017, the department and the Department of Managed Health Care shall jointly, and with input from interested parties from at least one public meeting, develop a standard formulary template for purposes of paragraph (3) of subdivision (a). In developing the template, the department and Department of Managed Health Care shall take into consideration existing requirements for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services. To the extent feasible, in developing the template, the department and the Department of Managed Health Care shall evaluate a way to include on the template, in addition to the information required to be included under paragraph (2), cost-sharing information for drugs subject to coinsurance.

(2) The standard formulary template shall include a notification that the presence of a drug on the insurer's formulary does not guarantee that an insured will be prescribed that drug by his or her prescribing provider for a particular medical condition. As applied to a particular formulary for a product offered by an insurer, the standard formulary template shall do all of the following:

(A) Include information on cost-sharing tiers and utilization controls, including prior authorization or step therapy requirements, for each drug covered by the product.

(B) Indicate any drugs on the formulary that are preferred over other drugs on the formulary.

(C) Include information to educate insureds about the differences between drugs administered or provided under a health insurer's medical benefit and drugs prescribed under a health insurer's prescription drug benefit and about how to obtain coverage information about drugs that are not covered under the health insurer's prescription drug benefit.

(D) Include information to educate insureds that health insurers that provide prescription drug benefits are required to have a method for insureds to obtain prescription drugs not listed in the health insurer's drug formulary if the drugs are deemed to be medically necessary by a clinician pursuant to Section 1367.24 of the Health and Safety Code, as required by clause (iv) of subparagraph (A) of paragraph (2) of subdivision (a) of Section 10112.27.

(E) Include information on which medications are covered, including both generic and brand name.

(F) Include information on what tier of the health insurer's drug formulary each medication is in.

(c) The commissioner may adopt regulations as may be necessary to carry out the purposes of this section. In adopting regulations, the commissioner shall comply with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) For purposes of this section, "formulary" means the complete list of drugs preferred for use and eligible for coverage under a health insurance product and includes the drugs covered under the pharmacy benefit of the product.

SEC. 7. Section 10123.193 is added to the Insurance Code, to read:

10123.193. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered policy of health insurance that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the policy that constitute essential health benefits, as defined by Section 10112.27.

(c) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this part.

(d) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs.

(e) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health insurer shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for insureds with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a policy of health insurance shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(3) Any limitation or utilization management shall be consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

(f) (1) With respect to an individual or group policy of health insurance subject to Section 10112.28, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars (\$250), except as provided in paragraphs (2) and (3).

(2) With respect to products with actuarial value at or equivalent to the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars (\$500), except as provided in paragraph (3).

(3) For a policy of health insurance that is a “high deductible health plan” under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision shall apply only once an insured’s deductible has been satisfied for the year.

(4) For a nongrandfathered individual or small group policy of health insurance, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.

(5) For purposes of paragraphs (1) and (2), “any other form of cost sharing” shall not include deductible.

(g) (1) If a policy of health insurance offered, sold, or renewed in the nongrandfathered individual or small group market maintains a drug formulary grouped into tiers that includes a fourth tier, a policy of health insurance shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost.

(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.

(D) Tier four shall consist of drugs that are biologics, drugs that the FDA or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the insured to have special training or clinical monitoring for self-administration, or drugs that cost the health insurer more than six hundred dollars (\$600) net of rebates for a one-month supply.

(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the insurer shall take into account the other provisions of this section and this part.

(3) A policy of health insurance may maintain a drug formulary with fewer than four tiers.

(4) This section shall not be construed to limit a health insurer from placing any drug in a lower tier.

(h) This section shall not be construed to require a health insurer to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(i) A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(j) In the provision of outpatient prescription drug coverage, a health insurer may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this part.

(k) This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.

SEC. 8. Section 10123.193 is added to the Insurance Code, to read:

10123.193. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered policy of health insurance that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section.

(c) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this part.

(d) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs.

(e) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health insurer shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for insureds with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a policy of health insurance shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(3) Any limitation or utilization management shall be consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

(f) This section shall not be construed to require a health insurer to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(g) A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(h) In the provision of outpatient prescription drug coverage, a health insurer may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this part.

(i) This section shall become operative on January 1, 2020.

SEC. 9. Section 10123.201 is added to the Insurance Code, to read:

10123.201. (a) A policy of health insurance that covers outpatient prescription drugs shall cover medically necessary drugs. The policy may provide for step therapy and prior authorization consistent with Section

1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section.

(b) (1) Commencing January 1, 2017, an insurer shall maintain a pharmacy and therapeutics committee that shall be responsible for developing, maintaining, and overseeing any drug formulary list. If the insurer delegates responsibility for the formulary to any entity, the obligation of the insurer to comply with this part shall not be waived.

(2) The pharmacy and therapeutics committee board membership shall conform with both of the following:

(A) Represent a sufficient number of clinical specialties to adequately meet the needs of insureds.

(B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health professionals who are licensed to prescribe drugs.

(3) Members of the board shall abstain from voting on any issue in which the member has a conflict of interest with respect to the issuer or a pharmaceutical manufacturer.

(4) At least 20 percent of the board membership shall not have a conflict of interest with respect to the issuer or any pharmaceutical manufacturer.

(5) The pharmacy and therapeutics committee shall meet at least quarterly and shall maintain written documentation of the rationale for its decisions regarding the development of, or revisions to, the formulary drug list.

(6) The pharmacy and therapeutics committee shall do all of the following:

(A) Develop and document procedures to ensure appropriate drug review and inclusion.

(B) Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmaco-economic studies, outcomes research data, and other related information.

(C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.

(D) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.

(E) Evaluate and analyze treatment protocols and procedures related to the insurer's formulary at least annually.

(F) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.

(G) Review new United States Food and Drug Administration-approved drugs and new uses for existing drugs.

(H) Ensure the insurer's formulary drug list or lists cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not discourage enrollment by any group of insureds.

(I) Ensure the insurer's formulary drug list or lists provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

(7) This subdivision shall be interpreted consistent with federal guidance issued under paragraph (3) of subdivision (a) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall apply to the individual, small group, and large group markets.

(c) (1) A health insurer may impose prior authorization requirements on prescription drug benefits, consistent with the requirements of this part.

(2) (A) When there is more than one drug that is appropriate for the treatment of a medical condition, a health insurer may require step therapy.

(B) In circumstances where an insured is changing policies, the new policy shall not require the insureds to repeat step therapy when that insured is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the insured's condition. Nothing in this section shall preclude the new policy from imposing a prior authorization requirement pursuant to subdivision (a) for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former policy, or preclude the prescribing provider from prescribing another drug covered by the new policy that is medically appropriate for the insured.

(3) An insurer shall provide coverage for the medically necessary dosage and quantity of the drug prescribed for the treatment of a medical condition consistent with professionally recognized standards of practice.

(4) For plan years commencing on or after January 1, 2017, an insurer that provides essential health benefits shall allow an insured to access prescription drug benefits at an in-network retail pharmacy unless the prescription drug is subject to restricted distribution by the United States Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A nongrandfathered individual or small group health insurer may charge an insured a different cost sharing for obtaining a covered drug at a retail pharmacy, but all cost sharing shall count toward the policy's annual limitation on cost sharing consistent with Section 10112.28.

(d) Every health insurer that provides prescription drug benefits shall maintain all of the following information, which shall be made available to the commissioner upon request:

(1) The complete drug formulary or formularies of the insurer, if the insurer maintains a formulary, including a list of the prescription drugs on the formulary of the insurer by major therapeutic category with an indication of whether any drugs are preferred over other drugs.

(2) Records developed by the pharmacy and therapeutic committee of the insurer, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the insureds of the insurer, that fully describe the reasoning behind formulary decisions.

(3) Any insurer arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, contracting pharmaceutical benefit management companies, or other entities that are associated with activities of the insurer to encourage formulary compliance or otherwise manage prescription drug benefits.

(e) If an insurer provides prescription drug benefits, the commissioner shall, as part of its market conduct examination, review the performance of the insurer in providing those benefits, including, but not limited to, a review of the procedures and information maintained pursuant to this section, and describe the performance of the insurer as part of its report issued as part of its market conduct examination.

(f) The commissioner shall not publicly disclose any information reviewed pursuant to this section that is determined by the commissioner to be confidential pursuant to state law.

(g) For purposes of this section, the following definitions shall apply:

(1) “Authorization” means approval by the health insurer to provide payment for the prescription drug.

(2) “Step therapy” means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

(h) Nonformulary prescription drugs shall include any drug for which an insured’s copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation.

(i) Nothing in this section shall be construed to affect an insured’s or policyholder’s eligibility to submit a complaint to the department for review or to apply to the department for an independent medical review under Article 3.5 (commencing with Section 10169).

(j) Nothing in this section shall be construed to restrict or impair the application of any other provision of this part.

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.

Assembly Bill No. 486

CHAPTER 241

An act to amend Sections 4128, 4128.4, and 4128.5 of the Business and Professions Code, relating to pharmacy, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor September 2, 2015. Filed with
Secretary of State September 2, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 486, Bonilla. Centralized hospital packaging pharmacies: medication labels.

The Pharmacy Law provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law authorizes a centralized hospital packaging pharmacy to prepare medications for administration to inpatients within its own general acute care hospital or certain other commonly owned hospitals.

Existing law requires that these medications be barcoded to be readable at the inpatient's bedside in order to retrieve certain information, including, but not limited to, the date that the medication was prepared and the components used in the drug product.

This bill would require that this information be displayed on a human-readable unit-dose label, and that the information be retrievable by the pharmacist using the medication lot number or control number.

This bill would require that the medication's barcode be machine readable, using medication administration software, and that the software compare the information contained in the barcode to the electronic medical record of the inpatient in order to verify that the medication to be given is the correct medication, dosage, and route of administration for that patient.

Because a knowing violation of these provisions would be a crime, the bill would impose a state-mandated local program.

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.

This bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 4128 of the Business and Professions Code is amended to read:

4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.

(2) Preparing sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

(b) For purposes of this article, “common ownership” means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

SEC. 2. Section 4128.4 of the Business and Professions Code is amended to read:

4128.4. (a) Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be machine readable at the inpatient’s bedside using barcode medication administration software.

(b) The barcode medication administration software shall permit health care practitioners to ensure that, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software shall verify that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.

(c) For purposes of this section, “barcode medication administration software” means a computerized system designed to prevent medication errors in health care settings.

SEC. 3. Section 4128.5 of the Business and Professions Code is amended to read:

4128.5. (a) Any label for each unit dose medication produced by a centralized hospital packaging pharmacy shall display a human-readable label that contains all of the following:

- (1) The date that the medication was prepared.
- (2) The beyond-use date.
- (3) The established name of the drug.
- (4) The quantity of each active ingredient.

- (5) Special storage or handling requirements.
- (6) The lot number or control number assigned by the centralized hospital packaging pharmacy.
- (7) The name of the centralized hospital packaging pharmacy.
- (b) For quality control and investigative purposes, a pharmacist shall be able to retrieve all of the following information using the lot number or control number described in subdivision (a):
 - (1) The components used in the drug product.
 - (2) The expiration date of each of the drug's components.
 - (3) The National Drug Code Directory number.

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.

SEC. 5. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

To eliminate, at the earliest possible time, requirements that exceed the current technological capabilities of hospitals and that create overly burdensome administrative costs for the California State Board of Pharmacy, it is necessary this act take effect immediately.

AMENDED IN SENATE JULY 1, 2015
AMENDED IN ASSEMBLY MAY 6, 2015
AMENDED IN ASSEMBLY MARCH 26, 2015
CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1069

Introduced by Assembly Member Gordon
(Coauthors: Assembly Members Chu, Low, and Mark Stone)
(Coauthors: Senators Beall and Wieckowski)

February 26, 2015

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1069, as amended, Gordon. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy, including a pharmacy that is owned by, or contracts with, the county, may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law requires a county that establishes a depository and redistribution program to develop written procedures for, among other things, establishing eligibility for medically indigent patients who may participate in the program, and ensuring that patients eligible for the program are not charged for any medications provided under the program. Existing law also prohibits the donation of controlled substances to the repository and distribution program. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose

containers that meet the United States Pharmacopoeia standards, and that includes lot numbers and expiration dates, is eligible for donation to the program. Existing law authorizes a county-owned pharmacy participating in the program to transfer eligible donated medication to a county-owned pharmacy participating in the program within another adjacent county, as specified. Existing law prohibits medication that does not meet the requirements for donation and distribution from being sold, dispensed, or otherwise transferred to any other entity. Existing law requires medication donated to the repository and distribution program to be maintained in the donated packaging units.

This bill would authorize ~~a county-owned pharmacy~~ *an entity* participating in the medication repository and distribution program to transfer eligible donated medication to a participating ~~county-owned pharmacy~~ *entity* in any other county, as specified. *The bill would generally prohibit an entity from transferring more than 15% of its donated medications annually.* The bill would authorize medication donated to a medication repository and distribution program to be maintained in new, properly labeled ~~containers~~ *containers, as specified.* The bill would prohibit donated medication from being repackaged more than 2 times. This bill would also make a technical, nonsubstantive change to these provisions.

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

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

- 1 SECTION 1. Section 150204 of the Health and Safety Code
- 2 is amended to read:
- 3 150204. (a) (1) A county may establish, by an action of the
- 4 county board of supervisors or by an action of the public health
- 5 officer of the county, as directed by the county board of
- 6 supervisors, a repository and distribution program for purposes of
- 7 this division. The county shall advise the California State Board
- 8 of Pharmacy within 30 days from the date it establishes a repository
- 9 and distribution program.
- 10 (2) Only an eligible entity, pursuant to Section 150201, may
- 11 participate in this program to dispense medication donated to the
- 12 drug repository and distribution program.
- 13 (3) An eligible entity that seeks to participate in the program
- 14 shall inform the county health department and the California State

1 Board of Pharmacy in writing of its intent to participate in the
2 program. An eligible entity may not participate in the program
3 until it has received written or electronic documentation from the
4 county health department confirming that the department has
5 received its notice of intent.

6 (4) (A) A participating entity shall disclose to the county health
7 department on a quarterly basis the name and location of the source
8 of all donated medication it receives.

9 (B) A participating primary care clinic, as described in Section
10 150201, shall disclose to the county health department the name
11 of the licensed physician who shall be accountable to the California
12 State Board of Pharmacy for the clinic's program operations
13 pursuant to this division. This physician shall be the professional
14 director, as defined in subdivision (c) of Section 4182 of the
15 Business and Professions Code.

16 (C) The county board of supervisors or public health officer of
17 the county shall, upon request, make available to the California
18 State Board of Pharmacy the information in this division.

19 (5) The county board of supervisors, the public health officer
20 of the county, and the California State Board of Pharmacy may
21 prohibit an eligible or participating entity from participating in the
22 program if the entity does not comply with the provisions of the
23 program, pursuant to this division. If the county board of
24 supervisors, the public health officer of the county, or the California
25 State Board of Pharmacy prohibits an eligible or participating
26 entity from participating in the program, it shall provide written
27 notice to the prohibited entity within 15 days of making this
28 determination. The county board of supervisors, the public health
29 officer of the county, and the California State Board of Pharmacy
30 shall ensure that this notice also is provided to one another.

31 (b) A county that elects to establish a repository and distribution
32 program pursuant to this division shall establish written procedures
33 for, at a minimum, all of the following:

34 (1) Establishing eligibility for medically indigent patients who
35 may participate in the program.

36 (2) Ensuring that patients eligible for the program shall not be
37 charged for any medications provided under the program.

38 (3) Developing a formulary of medications appropriate for the
39 repository and distribution program.

1 (4) Ensuring proper safety and management of any medications
2 collected by and maintained under the authority of a participating
3 entity.

4 (5) Ensuring the privacy of individuals for whom the medication
5 was originally prescribed.

6 (c) Any medication donated to the repository and distribution
7 program shall comply with the requirements specified in this
8 division. Medication donated to the repository and distribution
9 program shall meet all of the following criteria:

10 (1) The medication shall not be a controlled substance.

11 (2) The medication shall not have been adulterated, misbranded,
12 or stored under conditions contrary to standards set by the United
13 States Pharmacopoeia (USP) or the product manufacturer.

14 (3) The medication shall not have been in the possession of a
15 patient or any individual member of the public, and in the case of
16 medications donated by a health or care facility, as described in
17 Section 150202, shall have been under the control of a staff
18 member of the health or care facility who is licensed in California
19 as a health care professional or has completed, at a minimum, the
20 training requirements specified in Section 1569.69.

21 (d) (1) Only medication that is donated in unopened,
22 tamper-evident packaging or modified unit dose containers that
23 meet USP standards is eligible for donation to the repository and
24 distribution program, provided lot numbers and expiration dates
25 are affixed. Medication donated in opened containers shall not be
26 dispensed by the repository and distribution program, and once
27 identified, shall be quarantined immediately and handled and
28 disposed of in accordance with the Medical Waste Management
29 Act (Part 14 (commencing with Section 117600) of Division 104).

30 (2) (A) A medication that is the subject of a United States Food
31 and Drug Administration managed risk evaluation and mitigation
32 strategy pursuant to Section 355-1 of Title 21 of the United States
33 Code shall not be donated if this inventory transfer is prohibited
34 by that strategy, or if the inventory transfer requires prior
35 authorization from the manufacturer of the medication.

36 (B) A medication that is the subject of a United States Food and
37 Drug Administration managed risk evaluation and mitigation
38 strategy pursuant to Section 355-1 of Title 21 of the United States
39 Code, the donation of which is not prohibited pursuant to

1 subparagraph (A), shall be managed and dispensed according to
2 the requirements of that strategy.

3 (e) A pharmacist or physician at a participating entity shall use
4 his or her professional judgment in determining whether donated
5 medication meets the standards of this division before accepting
6 or dispensing any medication under the repository and distribution
7 program.

8 (f) A pharmacist or physician shall adhere to standard pharmacy
9 practices, as required by state and federal law, when dispensing
10 all medications.

11 (g) Medication that is donated to the repository and distribution
12 program shall be handled in the following ways:

13 (1) Dispensed to an eligible patient.

14 (2) Destroyed.

15 (3) Returned to a reverse distributor or licensed waste hauler.

16 (4) (A) Transferred to another participating entity within the
17 county to be dispensed to eligible patients pursuant to this division.
18 Notwithstanding this paragraph, a ~~participating-county-owned~~
19 ~~pharmacy~~ *entity* may transfer eligible donated medication to a
20 ~~participating-county-owned pharmacy~~ *entity* within another county
21 that has adopted a program pursuant to this division, if the
22 ~~pharmacies participating entities~~ transferring the medication have
23 a written agreement ~~between the entities~~ that outlines protocols
24 and procedures for safe and appropriate drug transfer that are
25 consistent with this division. *A participating entity shall not*
26 *transfer more than 15 percent of its donated medications annually*
27 *unless the transfer is performed pursuant to Section 4126.5 of the*
28 *Business and Professions Code.*

29 (B) Medication donated under this division shall not be
30 transferred by any participating entity more than once, and after
31 it has been transferred, shall be dispensed to an eligible patient,
32 destroyed, or returned to a reverse distributor or licensed waste
33 hauler.

34 (C) Medication transferred pursuant to this paragraph shall be
35 transferred with documentation that identifies the drug name,
36 strength, and quantity of the medication, and the donation facility
37 from where the medication originated shall be identified on
38 medication packaging or in accompanying documentation. The
39 document shall include a statement that the medication may not
40 be transferred to another participating entity and must be handled

1 pursuant to subparagraph (B). A copy of this document shall be
2 kept by the participating entity transferring the medication and the
3 participating entity receiving the medication.

4 (h) Medication that is donated to the repository and distribution
5 program that does not meet the requirements of this division shall
6 not be distributed or transferred under this program and shall be
7 either destroyed or returned to a reverse distributor. Donated
8 medication that does not meet the requirements of this division
9 shall not be sold, dispensed, or otherwise transferred to any other
10 entity.

11 (i) (1) Medication donated to the repository and distribution
12 program shall be maintained in the donated packaging units or
13 new, properly labeled containers until dispensed to an eligible
14 patient under this program, who presents a valid prescription. When
15 dispensed to an eligible patient under this program, the medication
16 shall be in a new and properly labeled container, specific to the
17 eligible patient and ensuring the privacy of the individuals for
18 whom the medication was initially dispensed. Expired medication
19 shall not be dispensed. Donated medication shall not be repackaged
20 more than two times. Nothing in this section requires donated
21 medication to be repackaged two times.

22 (2) *All of the following requirements shall be satisfied when*
23 *repackaging donated medication:*

24 (A) *Medication shall be repackaged into a container that holds*
25 *an individual prescription for a supply of no more than 90 days.*

26 (B) *Repackaged medication shall be identifiable as donated*
27 *medication.*

28 (C) *Repackaged medication shall be labeled with all of the*
29 *following:*

30 (i) *All applicable lot numbers.*

31 (ii) *The earliest expiration date.*

32 (iii) *The number of times that the medication has been*
33 *repackaged.*

34 (j) Medication donated to the repository and distribution program
35 shall be segregated from the participating entity's other drug stock
36 by physical means, for purposes including, but not limited to,
37 inventory, accounting, and inspection.

38 (k) A participating entity shall keep complete records of the
39 acquisition and disposition of medication donated to, and
40 transferred, dispensed, and destroyed under, the repository and

1 distribution program. These records shall be kept separate from
2 the participating entity's other acquisition and disposition records
3 and shall conform to the Pharmacy Law (Chapter 9 (commencing
4 with Section 4000) of Division 2 of the Business and Professions
5 Code), including being readily retrievable.

6 (l) Local and county protocols established pursuant to this
7 division shall conform to the Pharmacy Law regarding packaging,
8 transporting, storing, and dispensing all medications.

9 (m) County protocols established for packaging, transporting,
10 storing, and dispensing medications that require refrigeration,
11 including, but not limited to, any biological product as defined in
12 Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262),
13 an intravenously injected drug, or an infused drug, shall include
14 specific procedures to ensure that these medications are packaged,
15 transported, stored, and dispensed at appropriate temperatures and
16 in accordance with USP standards and the Pharmacy Law.

17 (n) Notwithstanding any other provision of law, a participating
18 entity shall follow the same procedural drug pedigree requirements
19 for donated drugs as it would follow for drugs purchased from a
20 wholesaler or directly from a drug manufacturer.

Assembly Bill No. 679

CHAPTER 778

An act to amend Section 11165.1 of the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor October 11, 2015. Filed with
Secretary of State October 11, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 679, Travis Allen. Controlled substances.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Existing law authorizes the Department of Justice to provide the history of controlled substances dispensed to an individual to a licensed health care practitioner, pharmacist, or both, providing care or services to the individual. By January 1, 2016, or upon licensure in the case of a pharmacist, or upon receipt of a federal Drug Enforcement Administration registration in the case of another health care practitioner authorized to prescribe, order, administer, furnish, or dispense controlled substances, whichever respective event occurs later, existing law requires those persons to apply to the Department of Justice to obtain approval to access information contained in the CURES database regarding the controlled substance history of a patient under his or her care.

This bill would extend those January 1, 2016, deadlines to July 1, 2016.

This bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the

Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of

Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to ensure that health care practitioners and pharmacists are not out of compliance with the requirement to apply to access data contained in the Controlled Substance Utilization Review and Evaluation System Prescription Drug Monitoring Program on January 1, 2016, it is necessary that this act take effect immediately.

Legislation and Regulation Committee

Attachment 3

AMENDED IN SENATE AUGUST 19, 2015

AMENDED IN ASSEMBLY APRIL 22, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 12

Introduced by Assembly Member Cooley
(Coauthors: Assembly Members Chang, Daly, and Wilk)
(Coauthor: Senator Huff)

December 1, 2014

An act to add and repeal Chapter 3.6 (commencing with Section 11366) of Part 1 of Division 3 of Title 2 of the Government Code, relating to state agency regulations.

LEGISLATIVE COUNSEL'S DIGEST

AB 12, as amended, Cooley. State government: administrative regulations: review.

Existing law authorizes various state entities to adopt, amend, or repeal regulations for various specified purposes. The Administrative Procedure Act requires the Office of Administrative Law and a state agency proposing to adopt, amend, or repeal a regulation to review the proposed changes for, among other things, consistency with existing state regulations.

This bill would, until January 1, 2019, require each state agency to, on or before January 1, 2018, review that agency's regulations, identify any regulations that are duplicative, overlapping, inconsistent, or out of date, to revise those identified regulations, as provided, and report to the Legislature and Governor, as specified.

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

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

1 SECTION 1. Chapter 3.6 (commencing with Section 11366)
2 is added to Part 1 of Division 3 of Title 2 of the Government Code,
3 to read:

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CHAPTER 3.6. REGULATORY REFORM

Article 1. Findings and Declarations

9 11366. The Legislature finds and declares all of the following:

10 (a) The Administrative Procedure Act (Chapter 3.5 (commencing
11 with Section 11340), Chapter 4 (commencing with Section 11370),
12 Chapter 4.5 (commencing with Section 11400), and Chapter 5
13 (commencing with Section 11500)) requires agencies and the
14 Office of Administrative Law to review regulations to ensure their
15 consistency with law and to consider impacts on the state's
16 economy and businesses, including small businesses.

17 (b) However, the act does not require agencies to individually
18 review their regulations to identify overlapping, inconsistent,
19 duplicative, or out-of-date regulations that may exist.

20 (c) At a time when the state's economy is slowly recovering,
21 unemployment and underemployment continue to affect all
22 Californians, especially older workers and younger workers who
23 received college degrees in the last seven years but are still awaiting
24 their first great job, and with state government improving but in
25 need of continued fiscal discipline, it is important that state
26 agencies systematically undertake to identify, publicly review, and
27 eliminate overlapping, inconsistent, duplicative, or out-of-date
28 regulations, both to ensure they more efficiently implement and
29 enforce laws and to reduce unnecessary and outdated rules and
30 regulations.

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Article 2. Definitions

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34 11366.1. For the purposes of this chapter, the following
35 definitions shall apply:

36 (a) "State agency" means a state agency, as defined in Section
37 11000, except those state agencies or activities described in Section
38 11340.9.

1 (b) “Regulation” has the same meaning as provided in Section
2 11342.600.

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4 Article 3. State Agency Duties
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6 11366.2. On or before January 1, 2018, each state agency shall
7 do all of the following:

8 (a) Review all provisions of the California Code of Regulations
9 ~~applicable to, or adopted by,~~ *adopted by* that state agency.

10 (b) Identify any regulations that are duplicative, overlapping,
11 inconsistent, or out of date.

12 (c) Adopt, amend, or repeal regulations to reconcile or eliminate
13 any duplication, overlap, inconsistencies, or out-of-date provisions,
14 and shall comply with the process specified in Article 5
15 (commencing with Section 11346) of Chapter 3.5, unless the
16 addition, revision, or deletion is without regulatory effect and may
17 be done pursuant to Section 100 of Title 1 of the California Code
18 of Regulations.

19 (d) Hold at least one noticed public hearing, ~~that~~ *which* shall be
20 noticed on the Internet Web site of the state agency, for the
21 purposes of accepting public comment on proposed revisions to
22 its regulations.

23 (e) Notify the appropriate policy and fiscal committees of each
24 house of the Legislature of the revisions to regulations that the
25 state agency proposes to make at least 30 days prior to initiating
26 the process under Article 5 (commencing with Section 11346) of
27 Chapter 3.5 or Section 100 of Title 1 of the California Code of
28 Regulations.

29 (g) (1) Report to the Governor and the Legislature on the state
30 agency’s compliance with this chapter, including the number and
31 content of regulations the state agency identifies as duplicative,
32 overlapping, inconsistent, or out of date, and the state agency’s
33 actions to address those regulations.

34 (2) The report shall be submitted in compliance with Section
35 9795 of the Government Code.

36 11366.3. (a) On or before January 1, 2018, each agency listed
37 in Section 12800 shall notify a department, board, or other unit
38 within that agency of any existing regulations adopted by that
39 department, board, or other unit that the agency has determined
40 may be duplicative, overlapping, or inconsistent with a regulation

1 adopted by another department, board, or other unit within that
2 agency.

3 (b) A department, board, or other unit within an agency shall
4 notify that agency of revisions to regulations that it proposes to
5 make at least 90 days prior to a noticed public hearing pursuant to
6 subdivision (d) of Section 11366.2 and at least 90 days prior to
7 adoption, amendment, or repeal of the regulations pursuant to
8 subdivision (c) of Section 11366.2. The agency shall review the
9 proposed regulations and make recommendations to the
10 department, board, or other unit within 30 days of receiving the
11 notification regarding any duplicative, overlapping, or inconsistent
12 regulation of another department, board, or other unit within the
13 agency.

14 11366.4. An agency listed in Section 12800 shall notify a state
15 agency of any existing regulations adopted by that agency that
16 may duplicate, overlap, or be inconsistent with the state agency's
17 regulations.

18 11366.45. This chapter shall not be construed to weaken or
19 undermine in any manner any human health, public or worker
20 rights, public welfare, environmental, or other protection
21 established under statute. This chapter shall not be construed to
22 affect the authority or requirement for an agency to adopt
23 regulations as provided by statute. Rather, it is the intent of the
24 Legislature to ensure that state agencies focus more efficiently and
25 directly on their duties as prescribed by law so as to use scarce
26 public dollars more efficiently to implement the law, while
27 achieving equal or improved economic and public benefits.

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29 Article 4. Chapter Repeal
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31 11366.5. This chapter shall remain in effect only until January
32 1, 2019, and as of that date is repealed, unless a later enacted
33 statute, that is enacted before January 1, 2019, deletes or extends
34 that date.

AB 85 (Wilk)

Governor's Veto Message

To the Members of the California State Assembly:

I am returning Assembly Bill 85 without my signature.

This bill expands the Bagley-Keene Open Meeting Act to include state advisory bodies, regardless of their size.

My thinking on this matter has not changed from last year when I vetoed a similar measure, AB 2058. I believe strongly in transparency and openness but the more informal deliberation of advisory bodies is best left to current law.

Sincerely,

Edmund G. Brown Jr.

Assembly Bill No. 85

Passed the Assembly June 1, 2015

Chief Clerk of the Assembly

Passed the Senate August 31, 2015

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2015, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Section 11121 of the Government Code, relating to state government, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 85, Wilk. Open meetings.

The Bagley-Keene Open Meeting Act requires that all meetings of a state body, as defined, be open and public and that all persons be permitted to attend and participate in a meeting of a state body, subject to certain conditions and exceptions.

This bill would specify that the definition of “state body” includes an advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body that consists of 3 or more individuals, as prescribed, except a board, commission, committee, or similar multimember body on which a member of a body serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation.

This bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 11121 of the Government Code is amended to read:

11121. As used in this article, “state body” means each of the following:

(a) Every state board, or commission, or similar multimember body of the state that is created by statute or required by law to conduct official meetings and every commission created by executive order.

(b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body.

(c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body, and if the advisory body so created consists of three or more persons, except as in subdivision (d).

(d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to avoid unnecessary litigation and ensure the people's right to access the meetings of public bodies pursuant to Section 3 of Article 1 of the California Constitution, it is necessary that this act take effect immediately.

Approved _____, 2015

Governor

AB 1351 (Eggman)

Governor's Veto Message

To the Members of the California State Assembly:

I am returning Assembly Bill 1351 without my signature.

AB 1351 would transform the existing deferred entry of judgment program available to low level drug offenders to one that does not require a guilty plea. Instead, the offender would plead not guilty and when the program is completed, the charges would be dropped. If the offender fails to complete the program, the prosecutor would proceed with the charges at that time.

While I support the goal of giving low-level offenders a second chance, I am concerned that the bill eliminates the most powerful incentive to stay in treatment - the knowledge that judgment will be entered for failure to do so. The bill goes too far.

Sincerely,

Edmund G. Brown Jr.

Assembly Bill No. 1351

Passed the Assembly September 10, 2015

Chief Clerk of the Assembly

Passed the Senate September 9, 2015

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2015, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 1000, 1000.1, 1000.2, 1000.3, 1000.4, 1000.5, and 1000.6 of, and to add Section 1000.7 to, the Penal Code, relating to deferred entry of judgment.

LEGISLATIVE COUNSEL'S DIGEST

AB 1351, Eggman. Deferred entry of judgment: pretrial diversion.

Existing law allows individuals charged with specified crimes to qualify for deferred entry of judgment. A defendant qualifies if he or she has no conviction for any offense involving controlled substances, the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs other than a violation that qualifies for the program, the defendant's record does not indicate that probation or parole has ever been revoked without being completed, and the defendant's record does not indicate that he or she has been granted diversion, deferred entry of judgment, or was convicted of a felony within 5 years prior to the alleged commission of the charged offense.

Under the existing deferred entry of judgment program, an eligible defendant may have entry of judgment deferred, upon pleading guilty to the offenses charged and entering a drug treatment program for 18 months to 3 years. If the defendant does not perform satisfactorily in the program, does not benefit from the program, is convicted of specified crimes, or engages in criminal activity rendering him or her unsuitable for deferred entry of judgment, the defendant's guilty plea is entered and the court enters judgment and proceeds to schedule a sentencing hearing. If the defendant completes the program, the criminal charges are dismissed. Existing law allows the presiding judge of the superior court, with the district attorney and public defender, to establish a pretrial diversion drug program.

This bill would make the deferred entry of judgment program a pretrial diversion program. The bill would provide that a defendant qualifies for the pretrial diversion program if he or she has no prior conviction within 5 years prior to the alleged commission of the

charged offense for any offense involving controlled substances other than the offense that qualifies him or her for diversion, the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs other than a violation that qualifies for the program and the defendant has no prior conviction for a serious or violent felony within 5 years prior to the alleged commission of the charged offense.

Under the pretrial diversion program created by this bill, a qualifying defendant would enter a not guilty plea, and proceedings would be suspended in order for the defendant to enter a drug treatment program for 6 months to one year, or longer if requested by the defendant with good cause. The bill would require the court, if the defendant does not perform satisfactorily in the program or is convicted of specified crimes, to terminate the program and reinstate the criminal proceedings. The bill would require the criminal charges to be dismissed if the defendant completes the program.

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

SECTION 1. Section 1000 of the Penal Code is amended to read:

1000. (a) This chapter shall apply whenever a case is before any court upon an accusatory pleading for a violation of Section 11350, 11357, 11364, or 11365, paragraph (2) of subdivision (b) of Section 11375, Section 11377, or Section 11550 of the Health and Safety Code, or subdivision (b) of Section 23222 of the Vehicle Code, or Section 11358 of the Health and Safety Code if the marijuana planted, cultivated, harvested, dried, or processed is for personal use, or Section 11368 of the Health and Safety Code if the narcotic drug was secured by a fictitious prescription and is for the personal use of the defendant and was not sold or furnished to another, or subdivision (d) of Section 653f if the solicitation was for acts directed to personal use only, or Section 381 or subdivision (f) of Section 647 of the Penal Code, if for being under the influence of a controlled substance, or Section 4060 of the Business and Professions Code, and it appears to the prosecuting attorney that, except as provided in subdivision (b) of Section 11357 of the Health and Safety Code, all of the following apply to the defendant:

(1) The defendant has no prior conviction within five years prior to the alleged commission of the charged offense for any offense involving controlled substances other than the offenses listed in this subdivision.

(2) The offense charged did not involve a crime of violence or threatened violence.

(3) There is no evidence of a violation relating to narcotics or restricted dangerous drugs other than a violation of the sections listed in this subdivision.

(4) The defendant has no prior conviction within five years prior to the alleged commission of the charged offense for a serious felony, as defined in subdivision (c) of Section 1192.7, or a violent felony, as defined in subdivision (c) of Section 667.5.

(b) The prosecuting attorney shall review his or her file to determine whether or not paragraphs (1) to (4), inclusive, of subdivision (a) apply to the defendant. If the defendant is found eligible, the prosecuting attorney shall file with the court a declaration in writing or state for the record the grounds upon which the determination is based, and shall make this information available to the defendant and his or her attorney. This procedure is intended to allow the court to set the hearing for pretrial diversion at the arraignment. If the defendant is found ineligible for pretrial diversion, the prosecuting attorney shall file with the court a declaration in writing or state for the record the grounds upon which the determination is based, and shall make this information available to the defendant and his or her attorney. The sole remedy of a defendant who is found ineligible for pretrial diversion is a postconviction appeal.

(c) All referrals for pretrial diversion granted by the court pursuant to this chapter shall be made only to programs that have been certified by the county drug program administrator pursuant to Chapter 1.5 (commencing with Section 1211) of Title 8, or to programs that provide services at no cost to the participant and have been deemed by the court and the county drug program administrator to be credible and effective. The defendant may request to be referred to a program in any county, as long as that program meets the criteria set forth in this subdivision.

(d) Pretrial diversion for an alleged violation of Section 11368 of the Health and Safety Code shall not prohibit any administrative agency from taking disciplinary action against a licensee or from

denying a license. Nothing in this subdivision shall be construed to expand or restrict the provisions of Section 1000.4.

(e) Any defendant who is participating in a program referred to in this section may be required to undergo analysis of his or her urine for the purpose of testing for the presence of any drug as part of the program. However, urinalysis results shall not be admissible as a basis for any new criminal prosecution or proceeding.

SEC. 2. Section 1000.1 of the Penal Code is amended to read:

1000.1. (a) If the prosecuting attorney determines that this chapter may be applicable to the defendant, he or she shall advise the defendant and his or her attorney in writing of that determination. This notification shall include all of the following:

(1) A full description of the procedures for pretrial diversion.
(2) A general explanation of the roles and authorities of the probation department, the prosecuting attorney, the program, and the court in the process.

(3) A clear statement that the court may grant pretrial diversion with respect to any crime specified in subdivision (a) of Section 1000 that is charged, provided that the defendant pleads not guilty to the charge or charges, waives the right to a speedy trial and to a speedy preliminary hearing, if applicable, and that upon the defendant's successful completion of a program, as specified in subdivision (c) of Section 1000, the positive recommendation of the program authority and the motion of the defendant, prosecuting attorney, the court, or the probation department, but no sooner than six months and no later than one year from the date of the defendant's referral to the program, the court shall dismiss the charge or charges against the defendant.

(4) A clear statement that upon any failure of treatment or condition under the program, or any circumstance specified in Section 1000.3, the prosecuting attorney or the probation department or the court on its own may make a motion to the court to terminate pretrial diversion and schedule further proceedings as otherwise provided in this code.

(5) An explanation of criminal record retention and disposition resulting from participation in the pretrial diversion program and the defendant's rights relative to answering questions about his or her arrest and pretrial diversion following successful completion of the program.

(b) If the defendant consents and waives his or her right to a speedy trial and a speedy preliminary hearing, if applicable, the court may refer the case to the probation department or the court may summarily grant pretrial diversion. When directed by the court, the probation department shall make an investigation and take into consideration the defendant's age, employment and service records, educational background, community and family ties, prior controlled substance use, treatment history, if any, demonstrable motivation, and other mitigating factors in determining whether the defendant is a person who would be benefited by education, treatment, or rehabilitation. The probation department shall also determine which programs the defendant would benefit from and which programs would accept the defendant. The probation department shall report its findings and recommendations to the court. The court shall make the final determination regarding education, treatment, or rehabilitation for the defendant. If the court determines that it is appropriate, the court shall grant pretrial diversion if the defendant pleads not guilty to the charge or charges and waives the right to a speedy trial and to a speedy preliminary hearing, if applicable.

(c) (1) No statement, or any information procured therefrom, made by the defendant to any probation officer or drug treatment worker, that is made during the course of any investigation conducted by the probation department or treatment program pursuant to subdivision (b), and prior to the reporting of the probation department's findings and recommendations to the court, shall be admissible in any action or proceeding brought subsequent to the investigation.

(2) No statement, or any information procured therefrom, with respect to the specific offense with which the defendant is charged, that is made to any probation officer or drug program worker subsequent to the granting of pretrial diversion shall be admissible in any action or proceeding.

(d) A defendant's participation in pretrial diversion pursuant to this chapter shall not constitute a conviction or an admission of guilt for any purpose.

SEC. 3. Section 1000.2 of the Penal Code is amended to read:

1000.2. (a) The court shall hold a hearing and, after consideration of any information relevant to its decision, shall determine if the defendant consents to further proceedings under

this chapter and if the defendant should be granted pretrial diversion. If the defendant does not consent to participate in pretrial diversion the proceedings shall continue as in any other case.

(b) At the time that pretrial diversion is granted, any bail bond or undertaking, or deposit in lieu thereof, on file by or on behalf of the defendant shall be exonerated, and the court shall enter an order so directing.

(c) The period during which pretrial diversion is granted shall be for no less than six months nor longer than one year. However, the defendant may request, and the court shall grant, for good cause shown, an extension of time to complete a program specified in subdivision (c) of Section 1000. Progress reports shall be filed by the probation department with the court as directed by the court.

SEC. 4. Section 1000.3 of the Penal Code is amended to read:

1000.3. (a) If it appears to the prosecuting attorney, the court, or the probation department that the defendant is performing unsatisfactorily in the assigned program, or that the defendant is convicted of an offense that reflects the defendant's propensity for violence, or the defendant is convicted of a felony, the prosecuting attorney, the court on its own, or the probation department may make a motion for termination from pretrial diversion.

(b) After notice to the defendant, the court shall hold a hearing to determine whether pretrial diversion shall be terminated.

(c) If the court finds that the defendant is not performing satisfactorily in the assigned program, or the court finds that the defendant has been convicted of a crime as indicated in subdivision (a) the court shall schedule the matter for further proceedings as otherwise provided in this code.

(d) If the defendant has completed pretrial diversion, at the end of that period, the criminal charge or charges shall be dismissed.

(e) Prior to dismissing the charge or charges or terminating pretrial diversion, the court shall consider the defendant's ability to pay and whether the defendant has paid a diversion restitution fee pursuant to Section 1001.90, if ordered, and has met his or her financial obligation to the program, if any. As provided in Section 1203.1b, the defendant shall reimburse the probation department for the reasonable cost of any program investigation or progress report filed with the court as directed pursuant to Sections 1000.1 and 1000.2.

SEC. 5. Section 1000.4 of the Penal Code is amended to read:

1000.4. (a) Any record filed with the Department of Justice shall indicate the disposition in those cases referred to pretrial diversion pursuant to this chapter. Upon successful completion of a pretrial diversion program, the arrest upon which the defendant was diverted shall be deemed to have never occurred. The defendant may indicate in response to any question concerning his or her prior criminal record that he or she was not arrested or granted pretrial diversion for the offense, except as specified in subdivision (b). A record pertaining to an arrest resulting in successful completion of a pretrial diversion program shall not, without the defendant's consent, be used in any way that could result in the denial of any employment, benefit, license, or certificate.

(b) The defendant shall be advised that, regardless of his or her successful completion of the pretrial diversion program, the arrest upon which pretrial diversion was based may be disclosed by the Department of Justice in response to any peace officer application request and that, notwithstanding subdivision (a), this section does not relieve him or her of the obligation to disclose the arrest in response to any direct question contained in any questionnaire or application for a position as a peace officer, as defined in Section 830.

SEC. 6. Section 1000.5 of the Penal Code is amended to read:

1000.5. (a) The presiding judge of the superior court, or a judge designated by the presiding judge, together with the district attorney and the public defender, may agree in writing to establish and conduct a preguilty plea drug court program pursuant to the provisions of this chapter, wherein criminal proceedings are suspended without a plea of guilty for designated defendants. The drug court program shall include a regimen of graduated sanctions and rewards, individual and group therapy, urinalysis testing commensurate with treatment needs, close court monitoring and supervision of progress, educational or vocational counseling as appropriate, and other requirements as agreed to by the presiding judge or his or her designee, the district attorney, and the public defender. If there is no agreement in writing for a preguilty plea program by the presiding judge or his or her designee, the district attorney, and the public defender, the program shall be operated as a pretrial diversion program as provided in this chapter.

(b) The provisions of Section 1000.3 and Section 1000.4 regarding satisfactory and unsatisfactory performance in a program shall apply to preguilty plea programs. If the court finds that (1) the defendant is not performing satisfactorily in the assigned program, (2) the defendant is not benefiting from education, treatment, or rehabilitation, (3) the defendant has been convicted of a crime specified in Section 1000.3, or (4) the defendant has engaged in criminal conduct rendering him or her unsuitable for the preguilty plea program, the court shall reinstate the criminal charge or charges. If the defendant has performed satisfactorily during the period of the preguilty plea program, at the end of that period, the criminal charge or charges shall be dismissed and the provisions of Section 1000.4 shall apply.

SEC. 7. Section 1000.6 of the Penal Code is amended to read:

1000.6. (a) Where a person is participating in a pretrial diversion program or a preguilty plea program pursuant to this chapter, the person shall be allowed, under the direction of a licensed health care practitioner, to use medications including, but not limited to, methadone, buprenorphine, or levoalphacetylmethadol (LAAM) to treat substance use disorders if the participant allows release of his or her medical records to the court presiding over the participant's preguilty plea or pretrial diversion program for the limited purpose of determining whether or not the participant is using such medications under the direction of a licensed health care practitioner and is in compliance with the pretrial diversion or preguilty plea program rules.

(b) If the conditions specified in subdivision (a) are met, using medications to treat substance use disorders shall not be the sole reason for exclusion from a pretrial diversion or preguilty plea program. A patient who uses medications to treat substance use disorders and participates in a preguilty plea or pretrial diversion program shall comply with all court program rules.

(c) A person who is participating in a pretrial diversion program or preguilty plea program pursuant to this chapter who uses medications to treat substance use disorders shall present to the court a declaration from his or her health care practitioner, or his or her health care practitioner's authorized representative, that the person is currently under their care.

(d) Urinalysis results that only establish that a person described in this section has ingested medication duly prescribed to that

person by his or her physician or psychiatrist, or medications used to treat substance use disorders, shall not be considered a violation of the terms of the pretrial diversion or preguilty plea program under this chapter.

(e) Except as provided in subdivisions (a) to (d), inclusive, this section shall not be interpreted to amend any provisions governing diversion programs.

SEC. 8. Section 1000.7 is added to the Penal Code, immediately following Section 1000.6, to read:

1000.7. This chapter does not affect a pretrial diversion program provided pursuant to Chapter 2.7 (commencing with Section 1001).

Approved _____, 2015

Governor

Assembly Bill No. 1352

CHAPTER 646

An act to add Section 1203.43 to the Penal Code, relating to deferred entry of judgment.

[Approved by Governor October 8, 2015. Filed with
Secretary of State October 8, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1352, Eggman. Deferred entry of judgment: withdrawal of plea.

Existing law allows judgment to be deferred with respect to a defendant who is charged with certain crimes involving possession of controlled substances and who meets certain criteria, including that he or she has no prior convictions for any offense involving controlled substances and has had no felony convictions within the 5 years prior, as specified. Existing law prohibits the record pertaining to an arrest resulting in successful completion of a deferred entry of judgment program from being used in any way that could result in the denial of any employment, benefit, license, or certificate.

This bill would require a court to allow a defendant who was granted deferred entry of judgment on or after January 1, 1997, who has performed satisfactorily during the period in which deferred entry of judgment was granted, and for whom the criminal charge or charges were dismissed, as specified, to withdraw his or her plea and enter a plea of not guilty, and would require the court to dismiss the complaint or information against the defendant. If court records showing the case resolution are no longer available, the bill would require that the defendant's declaration, under penalty of perjury, that the charges were dismissed after he or she completed the requirements, be presumed to be true if the defendant submits a copy of his or her state summary criminal history information that either shows that the defendant successfully completed the deferred entry of judgment program or that the record does not show a final disposition. By expanding the application of the crime of perjury, the bill would impose a state-mandated local program.

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. Section 1203.43 is added to the Penal Code, to read:

1203.43. (a) (1) The Legislature finds and declares that the statement in Section 1000.4, that “successful completion of a deferred entry of judgment program shall not, without the defendant’s consent, be used in any way that could result in the denial of any employment, benefit, license, or certificate” constitutes misinformation about the actual consequences of making a plea in the case of some defendants, including all noncitizen defendants, because the disposition of the case may cause adverse consequences, including adverse immigration consequences.

(2) Accordingly, the Legislature finds and declares that based on this misinformation and the potential harm, the defendant’s prior plea is invalid.

(b) For the above-specified reason, in any case in which a defendant was granted deferred entry of judgment on or after January 1, 1997, has performed satisfactorily during the period in which deferred entry of judgment was granted, and for whom the criminal charge or charges were dismissed pursuant to Section 1000.3, the court shall, upon request of the defendant, permit the defendant to withdraw the plea of guilty or nolo contendere and enter a plea of not guilty, and the court shall dismiss the complaint or information against the defendant. If court records showing the case resolution are no longer available, the defendant’s declaration, under penalty of perjury, that the charges were dismissed after he or she completed the requirements for deferred entry of judgment, shall be presumed to be true if the defendant has submitted a copy of his or her state summary criminal history information maintained by the Department of Justice that either shows that the defendant successfully completed the deferred entry of judgment program or that the record is incomplete in that it does not show a final disposition. For purposes of this section, a final disposition means that the state summary criminal history information shows either a dismissal after completion of the program or a sentence after termination of the program.

SEC. 2. 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.

Attachment 4

Advanced Practice Pharmacist

Title 16. BOARD OF PHARMACY
Proposed Regulation

Proposal to add new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Proposal to add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

Title 16. BOARD OF PHARMACY

Proposed Regulation

Proposal to add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

For purposes of 4210 an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and area(s) of specialty.

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, and must be earned within four consecutive years. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, and discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

- (1) A written statement from the applicant attesting under penalty of perjury that he or she has:
- (A) Earned the clinical experience within the required time frame;
 - (B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210(a)(2)(C), which includes initiating, adjusting, and discontinuing drug therapy of patients; and
 - (i) The applicant shall provide a copy of the collaborative practice agreement or protocol.
 - (ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.
- (2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients.

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Section 4052.1, 4052.2, 4052.6, 4210 and 4400, Business and Professions Code.

Title 16. BOARD OF PHARMACY

Proposal to amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is two hundred seven dollars (\$207). The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195). The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

Advanced Practice Pharmacist – 45-day Comments

Code Section	Commenter	Comment
BP 4210	Sarah Loentz UCSD	<p>I wanted to get clarification regarding 2.B. and the meaning of the statement ³accredited postgraduate institution². Does that mean the the site where the resident received their training need to be accredited, or does the residency program need to be accredited by ASHP? There are many pharmacists who have competed excellent residency programs over the years which were not accredited by ASHP. Would those pharmacists not qualify based on that criteria?</p> <p>4210. Advanced Practice Pharmacist License</p> <p>(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:</p> <p>(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.</p> <p>(2) Satisfy any two of the following criteria:</p> <p>(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.</p>
1730	Brian Lawson Board of Pharmacy Specialties	<p>BPS appreciates efforts by the California State Board of Pharmacy to develop proposed regulations that address the creation of a new pharmacist licensure category. BPS is supportive of the Board's recognition of pharmacy patient care certification programs that are accredited by the National Commission for Certification Agencies (NCCA) as described in Section 1730 Acceptable Certification Programs. NCCA accreditation helps to ensure the health, welfare, and safety of the public through accreditation of a variety of certification programs/organizations that assess professional competence.</p> <p>The NCCA standards require demonstration of a valid and reliable process for development, implementation, maintenance, and governance of certification programs. NCCA uses a rigorous peer review process to establish accreditation standards; evaluate compliance with the standards; recognize organizations/programs which demonstrate compliance; and serve as a resource on quality certification. The NCCA Standards are comprehensive and cover all aspects of the certification program(s), including administration, assessment development and recertification. NCCA standards are consistent with The Standards for Educational and Psychological Testing (AERA, APA, & NCME,1999) and are applicable to all professions and industries.</p>

Code Section	Commenter	Comment
1730	Sarah Mcbane UCSD	<p>My comments center around the regulatory requirements to become an Advanced Practice Pharmacist. The currently language requires that a pharmacist have gained clinical experience within 10 years of submitting application to become an Advanced Practice Pharmacist, and that 1500 hours of that experience must be earned in four consecutive years. The ten year requirement would limit pharmacists who are seasoned experts in clinical pharmacy care – the pharmacists we look up to and seek expert advice from – who have now moved into supervisory roles where they oversee other pharmacy practitioners. These pharmacists are the individuals we would most want to become Advanced Practice Pharmacists, so they could continue to utilize that expertise in providing care to the people of California, while training other pharmacists to provide excellent clinical care. Additionally, there is no evidence to support that direct patient care experience is better if gained within a short period of time (ie – 4 years). In fact, Harvard has shown that occasional, repeated activity translates into better learning and we can extrapolate that to say that occasional but repeated direct patient care makes someone an excellent clinician.</p> <p>I would ask the board to strike the specific time requirements, and consider language such as: Demonstrate that experience earned under a collaborative practice agreement or protocol consists of no fewer than 1,500 hours of experience providing clinical services to patients.</p> <p>Additionally, I would ask the board to strike the requirement for a written statement from a supervisory or other individual at the facility attesting the pharmacist’s experience. Some pharmacists may have gained their experience at facilities which are now closed, or have merged with facilities, and there may not be someone who could attest to the pharmacist’s experience. The pharmacist should attest to his or her own experience (under penalty of perjury).</p> <p>Lastly, I would like to take this opportunity to remind the board that SB 493 was written and passed in the spirit of improving access to care for Californians. Would limiting the number of Advanced Practice Pharmacists – particularly experienced pharmacists – compromise the intent of the legislation, and the health of our state.</p>
1730	Tasneem Vazifdar	<p>A and C are unclear to me. Does A refer to BCPS certification Also, how many hours are needed for C and in what time frame?</p>

Code Section	Commenter	Comment
1730	Brian Warren California Pharmacist Association	<p>Acceptable Certification Program: The California Pharmacists Association (CPhA), California Retailers Association (CRA), and the National Association of Chain Drug Stores (NACDS) appreciate and support the Board of Pharmacy's (BOP) recognition of National Commission of Certifying Agencies (NCCA) accredited programs as one pathway for pharmacists to satisfy the requirements in Business and Professions Code section 4210(a)(2)(A).</p> <p>We also strongly encourage the Board of Pharmacy (BOP) not to limit the recognition of NCCA programs in the regulations. Rather, we believe the BOP is also required to recognize those programs that are statutorily authorized under Business and Professions Code section 4210(a)(2)(A) being offered "...from an organization recognized by the Accreditation Council for Pharmacy Education... ."</p> <p>Further, the BOP should include language in the draft regulations that requires all programs and/or providers seeking to offer certification of pharmacists to do so consistent with the clinical authorities of an Advanced Practice Pharmacist authorized under Section 4210. Specifically, these programs should be required to ensure that pharmacists are certified to deliver the following services: Patient Assessments; Ordering Tests; Patient Referrals; Collaborative Drug Therapy; Effective Communication; and Documentation. By articulating these services in the regulation the BOP is ensuring that any program seeking recognition by the BOP is required to align their certification programs with the authorized authorities.</p> <p>Ensuring multiple pathways and programs for pharmacists to achieve the certification criterion in section 4210(a)(2)(A) is critical for expanding quality patient care programs. We encourage the BOP is include these recommendations in the final regulations.</p>
1730.1	Brian Warren California Pharmacist Association	<p>CPhA, CSHP, and NACDS have strongly advocated for the full implementation of SB 493, including provisions relating to APPs. The public policy goal of SB 493 has always been to better utilize pharmacists' clinical knowledge and skills to improve patient care. This intent is carried out through ensuring that the greatest number of pharmacists who can practice under the bill's expanded authorities with a minimum level of competency are allowed to do so.</p> <p>Business and Professions Code Section 4210 establishes the application requirements for pharmacists seeking recognition as APPs. Among these requirements, applicants must meet two out of three prerequisite "pathways": certification, completion of a residency, or specified practice experience. Proposed Section 1730.1 establishes the specific elements that the Board intends to require for demonstration of each of these pathways.</p> <p>As you are aware, very few pharmacy resident openings are available to graduating pharmacists—less than 300 in the entire state. As a result, very few new graduate pharmacists applying for APP licensure will qualify using the residency pathway. Furthermore, pharmacists have practically no opportunity to enter a residency after beginning practice, essentially eliminating this pathway for experienced pharmacists who have not already completed a residency. It is therefore imperative that the requirements for satisfying the experiential and certification prerequisite pathways be carefully constructed so as to ensure that applicants for APP licensure meet minimum qualifications and levels of competency without creating unnecessary barriers to entry that would hinder the efficacy of the Legislature's intent in enacting SB 493.</p>

Code Section	Commenter	Comment
1730.1	<p>Brian Warren California Pharmacist Association</p>	<p>One of the three pathways for qualifying for APP licensure is to “have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.” Proposed Section 1730.1(c) outlines, in detail, what the Board believes should be required to demonstrate this one year of experience.</p> <p>We are concerned that some of the requirements that would be established by proposed Section 1730.1(c) would unintentionally limit the number of pharmacists who would be able to qualify for APP licensure. We therefore propose the following modifications to Section 1730.1 to ensure that the greatest number of competent pharmacists can obtain APP licensure.</p> <p>1. Remove the requirement in subsection (c) that the one year of experience be completed within 10 years of the time of application for APP licensure.</p> <p>This requirement unnecessarily excludes pharmacists with extensive clinical practice experience but who do not engage in clinical practice a majority of the time. This includes pharmacists who previously engaged in clinical practice on a regular basis but who have moved on to supervisory or managerial roles, as well as pharmacists who engage in clinical practice a minority of the time but over a long period of time. Ironically, this time limitation excludes some of the most experienced pharmacists and favors pharmacists with perhaps less experience</p>
1730.1	<p>Brian Warren California Pharmacist Association</p>	<p>2. Remove the requirement in subsection (c) that the one year of experience be completed within four consecutive years.</p> <p>Much like the above requirement, this unnecessarily excludes pharmacists who engage in clinical practice but not as a majority of their job. No evidence supports a specific timeframe for development and mastery of clinical skills. Establishing an arbitrary timeframe here would only serve to enact an unnecessary barrier to entry to APP licensure and would harm patient access to APP-licensed pharmacists.</p> <p>3. Modify the wording in subsection (c) and in subsection (c)(1)(B) of “initiating, adjusting, and discontinuing” to read “modifying, adjusting, or discontinuing.”</p> <p>Many pharmacists who engage in clinical practice actively manage drug therapy under a collaborative practice agreement or protocol but do not necessarily do all three of these authorities. In fact, prior to SB 493’s enactment, California’s collaborative drug therapy management statutes did not include the authority to discontinue medications (see B&P Code Sections 4052.1 and 4052.2, which authorize initiating and adjusting but not discontinuing). More importantly, the exercise of only some of these authorities does not indicate an absence of the ability to practice all three.</p> <p>4. Remove the requirement in subsection (c)(2) that a written statement be made by the supervising practitioner, program director, or health facility administrator overseeing the collaborative practice agreement or protocol.</p> <p>Depending on the duration of time passed since a pharmacist practiced under a given collaborative therapy agreement or protocol, that pharmacist may no longer have contact with the provider or facility. This requirement particularly affects pharmacists with a longer career. The requirement also seems duplicative of the requirements in subsection (c)(1) for the pharmacist to file the application under penalty of perjury and to provide a copy or description of the protocol.</p>

Code Section	Commenter	Comment
1730.1	Brian Warren California Pharmacist Association	<p>Among the above four areas of commentary, one overarching theme among these comments exists: that pharmacists should be trusted to use their professional judgment.</p> <p>It is well-known that the majority of pharmacists go underutilized; greater utilization of pharmacists is after all the central goal of SB 493. This underutilization means that despite expert knowledge and skills, many pharmacists spend the majority of their time in a strictly dispensing role. By only allowing those pharmacists who already practice to a significant extent in a clinical nature to qualify for APP licensure, these proposed regulations exclude precisely the pharmacists SB 493 was intended to better utilize</p>
1730.1	Brian Lawson Board of Pharmacy Specialties	<p>BPS Specialty Certification Programs in Ambulatory Care Pharmacy, Nuclear Pharmacy, Nutrition Support Pharmacy, Oncology Pharmacy, Pharmacotherapy and Psychiatric Pharmacy are recognized as accredited certification programs by the National Commission for Certifying Agencies, (NCCA). Per NCCA policies and procedures, the Critical Care Pharmacy and Pediatric Pharmacy specialty certification programs will be eligible for accreditation in 2016.</p> <p>BPS is also supportive of the documentation described in subsection (a) listed under Section 1730.1 Application Requirements for Advanced Practice Pharmacists Licensure. BPS is comfortable working with the California Board of Pharmacy to confirm the status of BPS Board Certified Pharmacists.</p>
1730.1	Douglas Barcon Barcon & Associates	<p>A certification is a single qualifying criteria. A post-graduation residency is a single qualifying criteria. Experience practicing under a collaborative practice agreement can be at the minimum level, or it can be at a level much greater than the minimum level and for a significant length of time, yet it is considered the same under the terms of the application for an Advanced Practice Pharmacist without regard for the length of that practice beyond the minimum. Some pharmacists gained more practical experience in their first year or two post graduation than in an ASHP PGY1 residency, yet that experience does not count toward licensure as an Advanced Practice Pharmacist without a time frame limitation.</p> <p>Depending on the experience and the duration of experience (perhaps more than 5 years) practicing under collaborative practice agreements, there should be a provision to allow pharmacists who have practiced under collaborative practice agreements to split that experience and petition the board to accept that experience both as a substitute for a residency and as qualifying experience practicing under a collaborative practice agreement.</p>

Code Section	Commenter	Comment
1730.1(b)	Douglas Barcon Barcon & Associates	<p>In 1730.1(b) and in SB 493, there is no time limitation placed upon the qualifying residency regardless of whether it was completed in 2015 or 30 years ago. An ASHP PGY1 residency is a one-year residency that is typically completed in the first post-graduation year following graduation from the school of pharmacy.</p> <p>However, in the proposed 1730.1 (c), experience in a collaborative practice agreement is not acceptable as a qualifying criteria if it occurred more than 10 years prior to filing the application as an Advanced Practice Pharmacist regardless of the length of time the pharmacist practiced under such an agreement.</p> <p>Why should an ASHP PGY1 residency completed 30 years ago, let alone more than 10 years ago, be an acceptable qualifying criteria, while the experience gained by a pharmacist who practiced under a collaborative practice agreement for more than one year not be acceptable if it occurred more than 10 years prior to the application? Many pharmacists have practiced under collaborative practice agreements for more than 10 years and do not have residencies.</p> <p>The board needs to reassess the time limitation, which is not even specified in SB 493, so as not to exclude pharmacists who have practiced under a collaborative practice agreement but do not have a residency.</p>
1730.1(c)	Steven Gray Kaiser Permanente	<p>contrary to the general intent and the explicit statutory language of the Legislature's passage of SB 493, in the 2013 session of the California Legislature.</p> <p>The intent of the legislation was to change the scope of practice and increase the number of California pharmacists providing specified medication management clinical services to alleviate the current and anticipated shortage of primary care providers as California residents seek more access to health care subsequent to the Affordable Care Act implementation in California, the expansion of Medi-Cal enrollment and the increases in population - especially the senior population.</p> <p>Specifically the Proposed regulation provision 1730.1(c) would narrow the eligibility specified in Business and Professions Code Section 4210(a)(2)(C) to clinical services experience performed only in the ten years prior to the application. Pharmacists in California have been performing such clinical service very successfully for over twenty years under the provisions of Business and Professions Code 4052.2. Many such pharmacists have gone on to train, supervise and manage pharmacists performing such clinical services. They perform the services personally as part of that training, supervision and management and are actually high performing models of competency, maturity and performance for the development of new APP pharmacists urgently needed to alleviate the shortage of Primary Care Providers by performing non-diagnostic medication therapy management and thus relieving physicians, nurse practitioners and other Primary Care Providers for diagnostic and other roles. However the proposed requirement that the 1500 hours of clinical experience must be earned in four consecutive years of a 10 year period prior to application is not realistic in their current roles as Professors in Schools of Pharmacy, trainers, supervisors and managers in clinical care organizations and other situations where they function in personal clinical experience on an intermittent basis.</p>

Code Section	Commenter	Comment
1730.1(c)	Steven Gray Kaiser Permanente	<p>Thus the Board of Pharmacy's proposed establishment of a 1500 hour requirement in 4 consecutive years in the past 10 years will inappropriately and unnecessarily limit the number of highly qualified and experienced pharmacists that would qualify for the new Advanced Practice Pharmacist licensed category and thus prevent their participation in alleviating the shortages of primary care providers. It will frustrate the Legislator's intent by adding restrictions without demonstration of any clinical care cases to support such restrictions.</p> <p>Recommended Changes</p> <p>We respectfully recommend the following changes to subsection "(c)":</p> <p>"(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of prior to the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, and must be earned within four consecutive years. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, and discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:"</p>
1730.1(c)	Joseph Woelfel University of the Pacific	<p>pharmacist and works in a part-time collaborative practice, the 10 year period would be very restrictive. This 10 year provision may favor recent graduates vs senior practicing consultant pharmacists with numerous years of experience. Same thing applies to the one year/1500 hours. This excludes those working part-time. Additionally, the four year requirement is very restrictive and favors those who have primary consulting as their full-time position or recent graduates with residencies.</p>
1730.1(c)	Douglas Barcon Barcon & Associates	<p>As in 1730.1(b), the 10-year limitation should be reconsidered and removed from the proposal. Such a limitation is not specified in SB 493. The 10-year limitation places an unfair burden on pharmacists who have practiced under collaborative practice agreements compared to pharmacists who completed an ASHP PGY1 or similar residency and can effectively preclude that pharmacist from becoming an Advanced Practice Pharmacist regardless of whether he or she completed a certification program and became certified in a specialty. For example, a pharmacist who practiced under collaborative practice agreements for 20 years but has not for the last 10 years would not qualify if he or she did not complete an ASHP PGY1 residency. That intent was not specified in SB 493.</p> <p>The duration of experience practicing under one or more collaborative practice agreements has more value than a date limitation.</p>

Code Section	Commenter	Comment
1730.1(c)(2)	Douglas Barcon Barcon & Associates	<p>In 1730.1(c)(1), the applicant pharmacist has already attested under penalty of perjury that he or she has complied with the clinical services and collaborative practice experience requirement.</p> <p>In 1730.1(c)(2), the applicant pharmacist is asked to prove what he or she attested to in 1730.1(c)(1) by providing a written statement by the supervising practitioner, program director or health facility administrator that the applicant has completed at least one year of providing clinical services to patients. It would appear that the board of pharmacy does not trust the applicant to answer truthfully by requiring (c)(2).</p> <p>What happens if the director of pharmacy is or was both the program director and the applicant?</p> <p>SB 493 became law in 2013. Pharmacists have been providing clinical services and collaborative practice in health-system pharmacy practice for many years. Requiring an Advanced Practice Pharmacist applicant to provide written statements as specified in 1730.1(c)(2) may not be possible because health facilities have closed, supervising practitioners may have passed away or are otherwise not able to be reached, or health facility administrators may have passed away or are otherwise not able to be reached.</p> <p>As written, the current proposal favors pharmacists with less than 10 years of experience and excludes others.</p>
Overall Comment	Daniel Robinson Western University	<p>A Sample Preamble to the Guidelines for Expanded Scope of Practice – Post-SB 493 including Advanced Practice Pharmacist Background</p> <p>Passage of SB 493 was an endorsement of the important role pharmacists can play in addressing the health care needs of the people of California. There is broad agreement that pharmacists are highly trained professionals who have been underutilized in providing team-based care. In the interest of public safety, it is incumbent on the Board of Pharmacy to work with the pharmacy profession to ensure that a critical number of pharmacists are fully engaged in providing services according to BPC Chapter 469 to have a meaningful impact on medication-related health care outcomes state-wide. Up to this point, the Board of Pharmacy has dealt with episodes of misconduct by pharmacists that are considered violations of pharmacy law. With the advent of Advanced Practice Pharmacists, pharmacists will be providing patient specific care that requires professional judgement that utilizes the full scope of pharmacy training and is in the best interest of the patient. In the event of a quality of care complaint, which may not be a violation of pharmacy law, the complaint should be reviewed by a pharmacy consultant with expertise in the area of consideration to determine if the pharmacist was acting within the acceptable standard of pharmacy care.</p> <p>SB 493 was signed into law by the Governor nearly two years ago and supported by a broad base of health care organizations and patient advocacy groups. In the interest of public safety we should do everything possible to provide immediate access to the additional services allowed under BPC Chapter 469. Our problem is not that we would qualify too many pharmacists, but that we would qualify too few.</p> <p>Daniel Robinson, September 2015</p>

Code Section	Commenter	Comment
Overall Comment	Daniel Robinson Western University	<p>Guidelines for Expanded Scope of Practice – Post SB 493 California Board of Pharmacy Sample Preamble</p> <p>Protection of the public is the highest priority for the California Board of Pharmacy (Board) in exercising its licensing, regulatory, and disciplinary functions. The Board recognizes that principles of high-quality pharmacy practice and California law dictate that the people of California have access to appropriate, safe, and effective pharmacist services. These guidelines are intended to help pharmacists improve outcomes of patient care through modifications to the BPC (Chapter 469) that improve access to pharmacist services with respect to travel health, immunizations, self-administered hormonal contraception, nicotine replacement products, ordering and interpreting tests for the purpose of monitoring and managing drug therapies, including improved access to services provided by the Advanced Practice Pharmacist.</p> <p>These guidelines are not intended to mandate the standard of care. The Board recognizes that deviation from guidelines will occur and may be appropriate depending upon the unique needs of individual patients. Pharmacy, like the other healing arts, is practiced one patient at a time and each patient has individual needs. Pharmacists are encouraged to document their rationale for each patient management decision. Pharmacists should understand that if one is ever the subject of a quality of care complaint, peer expert review will be sought by the Board that will consider the totality of circumstances surrounding the pharmacist’s practice decisions. Specifically, experts are instructed to define the standard of care in terms of the level of skill, knowledge, and care in pharmacy practice ordinarily possessed and exercised by other reasonably careful and prudent pharmacists in the same or similar circumstances at the time in question.</p> <p>These guidelines may be updated from time to time based on evolving knowledge, research and understanding of subject matter. It is the pharmacist’s responsibility to remain current with referenced standards, resources, and professional skills.</p>

**Advanced Practice
Pharmacist –
Modified Text**

Title 16. BOARD OF PHARMACY
Modified Text

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and bold and dashed underline for added language. (Additionally, the modified text is listed in red for color printers.)

Proposal to add new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Proposal to add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

Proposal to add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

For purposes of **Business and Professions Code section 4210** an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and area(s) of specialty. **For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).**

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, and must be earned within four consecutive years. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, **modifying or ~~and~~** discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(1) A written statement from the applicant attesting under penalty of perjury that he or she has:

(A) Earned the clinical experience within the required time frame;

(B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, and discontinuing drug therapy of patients; and

(i) The applicant shall provide a copy of the collaborative practice agreement or protocol.

(ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients. **For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).**

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Section 4052.1, 4052.2, 4052.6, 4210 and 4400, Business and Professions Code.

Proposal to amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, ~~4210~~, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is ~~two hundred seven dollars (\$207)~~ **one hundred ninety-five dollars (\$195)**. The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195). The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325) . The penalty for failure to renew is one hundred fifty dollars (\$150).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

Vaccinations

1746.4

Title 16. BOARD OF PHARMACY

Proposed Text

Proposal to add §1746.4 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.4 Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

(1) Completion of an approved immunization training program, and

(2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 30 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 30 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide

the patient with a vaccine administration record, which fully documents the initiation and administration of any vaccine. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

**Vaccinations –
45-day Comments
1746.4**

Code Section	Commenter	Comment
1746.4(d)	Karen Smith CDPH	<p>Change #1. (d) Add a requirement for the pharmacist to notify the prenatal care provider (if the patient is pregnant)</p> <p>Rationale. The Advisory Committee on Immunization Practices (ACIP) currently recommends all pregnant women receive an influenza vaccine during the flu season and Tdap (during the third trimester of every pregnancy). If prenatal care providers do not administer these vaccines in their offices and refer to pharmacists, the prenatal care providers need a routine mechanism to confirm immunization of their patients.</p>
1746.4(d)	Karen Smith CDPH	<p>Change #2. (d) Shorten the notification period to within 14 days of the administration of any vaccine.</p> <p>Acceptable Alternatives:</p> <p>... Notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine. Notification to the primary care provider must take place within 30 days of the administration of any vaccine.</p> <p>...Notification to the prenatal care provider and primary care providers of immunizations other than influenza vaccine must take place within 14 days of the administration of any vaccine. Notification to the primary care provider must take place within 30 days of the administration of influenza vaccine.</p> <p>Rationale. A longer interval of 30 days between immunization and notification may negatively impact patient care, especially for prenatal Tdap vaccine, which should be administered between 27 and 36 weeks of the pregnancy. A 30-day lag is too long for prenatal care providers to take timely action to follow up with women not yet vaccinated during the window. While a provider can call a pharmacist to request the fax of an immunization record, this is time consuming and inefficient. Timely notification from pharmacies to providers will optimize patient care.</p>

Code Section	Commenter	Comment
1746.4(d)	Karen Smith CDPH	<p>Change #3. (e) Enter vaccines into the Immunization Registry within 14 days of the administration of any vaccine.</p> <p>Acceptable Alternatives:</p> <p>A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any immunization given to a pregnant woman and within 30 days for all other immunizations.</p> <p>A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any immunization other than influenza vaccine and within 30 days for all influenza immunizations.</p> <p>Rationale. See Change #2 regarding the importance of timely notification for patient care. We understand that the 30 day time interval was a compromise developed during the public hearings. However, pharmacies in California are already using electronic systems to promptly report doses to California's immunization information system, the California Immunization Registry (CAIR). For example, CAIR receives messages from Walgreens within 24 hours of date of administration of the vaccine, and other pharmacy chains report at least weekly. The following additional pharmacies are already sharing their immunization data electronically with CAIR: Albertson's/Savon; SafewayNons/Pavilions; Walmart; and RiteAid. CVS is in process in sharing their immunization data.</p> <p>The California Board of Pharmacy reports that 60% of the state's 7000 community pharmacies are in large chains. Some of the remaining 40% of pharmacies (those that are a single site or less than eight stores in a chain) may also have electronic systems. Even for those that will manually enter into CAIR because they have no electronic upload yet, 14 days is reasonable given that data entry into CAIR takes only five minutes per patient</p>
1746.4(d)	Jeffrey Gunzenhauser LAC/DPH	<p>Recommendation 1: Require Pharmacists to Notify Prenatal Care Providers of Vaccine Doses Administered to Pregnant Women</p> <p>Pertussis and influenza vaccines are recommended for pregnant women to prevent complications during pregnancy and spread of disease to newborn infants, who are at high risk for complications. The CDC and American Congress of Obstetricians and Gynecologists encourage prenatal care providers to recommend, assess the need for, and/or offer vaccines to pregnant women. This requires access to a complete vaccination record, including vaccine doses administered in complementary settings. Thus, DPH recommends that the regulation be amended to require in situations where a woman's prenatal care provider is different from her primary care provider, that the pharmacist will also notify her prenatal care provider.</p>

Code Section	Commenter	Comment
1746.4(d) & (e)	Jeffrey Gunzenhauser LAC/DPH	<p>Recommendation 2: Require Notification and Reporting within 14 Days DPH recommends that the required timeframe for reporting vaccine doses to an immunization information system (Subsection e) and the provider (Subsection d) be shortened from 30 to 14 days.</p> <p>Timely reporting benefits patients, providers, and local health departments. A 14-day reporting period is better aligned with the CDC's immunization schedule, which allows some vaccine doses to be administered less than 30 days following a previous dose. If amended, providers will be better able to assess for minimal intervals between doses to ensure vaccine delivery according to recommended schedules and to avoid duplicate doses. Patients will also benefit from better access to vaccination records needed for employment, child care entry, or school entry. Local health department response during outbreak, case, and contact investigations will also be aided by having more complete vaccination records.</p> <p>Additionally, the proposed amendment is consistent with registry best practice standards. The American Immunization Registry Association, for example, recommends that vaccine records be submitted within 14 days of the encounter date, as a best practice for improving data quality. (Source: American Immunization Registry Association, Available at www.immregistries.org/resources/aira-mirow_dga_selected_aspects_best_practice_guide_05-17-2013.pdf)</p>
Overall Comment	Jeffrey Gunzenhauser LAC/DPH	<p>The LAC/DPH supports adoption of the proposed regulation on the basis of its potential to increase vaccine reporting and participation in the California Immunization Registry (CAIR), improve access to vaccinations, and encourage pharmacist adherence to recommended immunization practices.</p> <p>DPH also strongly supports the proposed requirement to report vaccination data to an immunization information system, such as CAIR. Systems like CAIR can improve patient care, as they allow providers to view, update, and store consolidated records of vaccines given in and outside of their clinic. They are recommended by the United States Task Force on Community Preventive Services based on strong evidence of effectiveness in increasing vaccination rates. At the point of clinical care, they provide decision support and help providers identify appropriate vaccinations, reduce missed opportunities to vaccinate, and prevent duplicate vaccine doses. Local health departments benefit from aggregate data for surveillance, program planning, and evaluation purposes and patient-level data during outbreaks. For these reasons, DPH supports the proposed reporting requirement.</p> <p>By establishing standards by which pharmacists can initiate and administer vaccines without a doctor's prescription, this regulation supports increased access to vaccinations and is supported by DPH.</p> <p>Vaccine storage, handling, and administration errors can lead to serious problems including patient harm, impotent or ineffective vaccines, and wasted vaccine doses. Formal immunization training may minimize vaccine errors and encourage adherence to the CDC's Advisory Committee on Immunization Practices' immunization schedule. Thus, DPH supports the proposed requirement for pharmacists to complete an accredited training program that includes hands-on injection technique, vaccine indications and contraindications, and vaccine reactions. This requirement is consistent with the National Vaccine Advisory Committee's Standards for Immunization Practices, which recommend that providers are knowledgeable about immunizations and receive ongoing immunization education.</p>

Code Section	Commenter	Comment
Overall Comment	San Diego County Pharmacists Assoc Board	<p>We fully support expanded access to routine vaccinations in pharmacies. However, we are concerned that requiring pharmacies to report to immunization registries may prohibit some pharmacies from participating. The pharmacy systems used by some of our local pharmacies do not support reporting. Without an electronic interface to facilitate efficient reporting, pharmacies will be unable to participate.</p> <p>Other health care providers who immunize are not required to report to immunization registries. While this should be a best practice recommendation to all immunizing health care providers, we ask that it be removed as a requirement. Registry reporting was not included in the senate bill text. To realize the full public benefit of this protocol, we request that this barrier be removed.</p>

**Vaccinations –
Modified Text
1746.4**

Title 16. BOARD OF PHARMACY

Modified Text

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and **dashed underline** for added language. (Additionally, the modified text is listed in red for color printers.)

Proposal to add §1746.4 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.4 Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

- (1) Completion of an approved immunization training program, and
- (2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within ~~30~~ **14** days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. **Notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.**

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within ~~30~~ **14** days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a vaccine administration record, which fully documents the initiation and administration of any vaccine. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

Travel Medications

1746.5

BOARD OF PHARMACY
Proposed Text

Add §1746.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.5 Pharmacists Furnishing Travel Medications.

(a) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), prescription medications “not requiring a diagnosis” means a prescription medication that is either:

(1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention’s (CDC) Health Information for International Travel (commonly called the Yellow Book), or

(2) A prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10) of the Business and Professions Code shall follow the requirements of this section.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an approved travel medicine training program, which must consist of at least 20 hours and cover each element of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine (2012),

(2) Completion of the CDC Yellow Fever Vaccine Course, and

(3) Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board’s website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of dispense, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required by title 42, section 300aa-25 of the United States Code and title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the Board's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052, Business and Professions Code.

Drug Warnings

1744

Title 16. Board of Pharmacy
Proposed Language

To Amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1744. Drug Warnings

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because ~~the~~ the following classes of drugs may impair a person's ability to ~~drive~~ operate a motor vehicle or vessel, ~~operate machinery when taken alone or in combination with alcohol~~ a pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel:

- (1) Muscle relaxants.
- (2) ~~Analgesics with central nervous system depressant effects.~~
- ~~(3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines~~
- (4) Antidepressants with central nervous system depressant effects.
- ~~(5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.~~
- (6) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~
- ~~(7) Anticholinergic agents and other drugs which~~ that may impair vision.
- (7) Any other drug which, based on the pharmacist's professional judgment, may impair a patient's ability to operate a vehicle or vessel.

(b) Because ~~the~~ the following ~~are examples~~ classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall provide a written warning notice on the label to alert the patient about possible potentiating effects: ~~which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle:~~

- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.
- (4) Cycloserine.
- (5) Antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).
- (6) Any other drug which, based upon a pharmacist's professional judgment, may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022, 4055 and 4074, Business and Professions Code.

**Reconciliation and
Inventory of Controlled
Substances**

1715.65

**Title 16. Board of Pharmacy
Proposed Text**

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Reconciliation and Inventory Report of Controlled Substances

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.
- (b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.
- (c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.
 - (1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.
 - (2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:
 - (A) A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.
 - (B) The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.
- (d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
- (e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
 - (1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.
 - (2) Likely causes of overages shall be identified in writing and retained.

- (3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.
- (f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.
- (1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.
- (2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.
- (3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.
- (g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.
- (h) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.

Attachment 5

Renewal Requirements 1702, 1702.1, 1702.2, and 1702.5

Board of Pharmacy

Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010.~~

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a)

either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. ~~omitting~~ ~~†~~ ~~Traffic~~ ~~infractions~~ ~~under~~ ~~\$300~~ ~~\$500~~ ~~not~~ ~~involving~~ ~~alcohol~~, ~~dangerous~~ ~~drugs~~, ~~or~~ ~~controlled~~ ~~substances~~ do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproof.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014. (1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision

(a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproof.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 2 Designated Representative Renewal Requirements

- (a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014. (1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.
- (2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).
- (3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).
- (4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
- (b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
- (c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproof.
- (c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority : Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, “disciplinary action” means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproval.

Authority: Section 4005, Business and Professions Code.

Reference: Sections 4112, 4161, 4300, and 4301, Business and Professions Code

Continuing Education
1732.05, 1732.2, and
1732.5

BOARD OF PHARMACY

Proposal to amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.05. Accreditation Agencies for Continuing Education

(a) The following organizations are approved accreditation agencies:

- (1) The Accreditation Council for Pharmacy Education.
- (2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

- (1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.
- (2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.
- (3) Provide the board with the names, addresses and responsible party of each provider, upon request.
- (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.
- (5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.
- (6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.
- (7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

Proposal to amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six (6) hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six (6) hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two (2) hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three (3) hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

Proposal to amend § 1732.5 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.5 Renewal Requirements for Pharmacists

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six (6) of the thirty (30) units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy's Drug Inventory
4. Ethics
5. Substance Abuse, Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility
6. Compounding

Pharmacists renewing their licenses which expire on or after July 1, 2016, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

Section 100
Requirements
1703

Board of Pharmacy

Proposal to Amend Section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; ~~and~~ issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; and make changes to its regulations without regulatory effect pursuant to Title, California Code of Regulations section 100 are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4311, Business and Professions Code.

**Third-Party Logistics
Providers
1780-1786**

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

1780. Minimum Standards for ~~Wholesalers~~

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

- (a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.
- (b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (1990, 22nd Revision).
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
 - (1) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
 - (3) The outside perimeter of the wholesaler premises shall be well-lighted.
- (d) All materials must be examined upon receipt or before shipment.
 - (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
- (e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
 - (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
 - (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
 - (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).
- (f) Policies and procedures must be written and made available upon request by the board.
 - (1) Wholesale and third-party logistics provider drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

- (2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.
 - (3) Wholesale ~~and third-party logistics provider~~ drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
 - (4) Each wholesaler ~~and third-party logistics provider~~ shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.
- (g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

1780.1. Minimum Standards for Veterinary Food-Animal Drug Retailers.

Not relevant to third-party logistics providers

1781. Exemption Certificate.

A registered pharmacist, ~~or an~~ designated representative or designated representative –3PL certified in accordance with Section 4053, 4053.1 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's ~~or~~ wholesaler's or a third-party logistics provider's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053, 4053.1 or 4054, Business and Professions Code.

1782. Reporting Sales of Drugs Subject to Abuse.

All manufacturers, ~~and~~ wholesalers and third-party logistics providers shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Section 4005, Business and Professions Code; and Section 26692, Health and Safety Code. Reference: Sections 4081 and 4332, Business and Professions Code; and Section 26692, Health and Safety Code.

1783. Manufacturer, ~~or~~ Wholesaler or Third-Party Logistics Provider Furnishing Drugs and Devices.

(a) A manufacturer, ~~or~~ wholesaler or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or~~ wholesaler or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to

furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler~~ or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or wholesaler~~ or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or wholesaler~~ if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or wholesaler~~ or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.

(d) A manufacturer, ~~or wholesaler~~ or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler~~ or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or wholesaler~~ or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

This section will be modified to also establish a self assessment process for the third-party logistics provider by the responsible manager. The changes have not been incorporated below

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

- (1) A new wholesaler permit is issued, or
- (2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.
- (3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 (Rev. 01/11) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

- (d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
- (e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4043, 4053, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.

**Patient-Centered
Labels: Requirements
1707.5**

Title 16. Board of Pharmacy

Proposed Regulations

To Amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
- (1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:
 - (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer's trade name of the drug, or the generic name and the statement “generic for _____” where the brand name is inserted into the parentheses. If it has been at least five years since the expiration of the brand name’s patent or, if in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, the name of the manufacturer.
 - (C) The directions for the use of the drug.
 - (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
 - (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
 - (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
 - (4) When applicable, directions for use shall use one of the following phrases:
 - (A) Take 1 [insert appropriate dosage form] at bedtime
 - (B) Take 2 [insert appropriate dosage form] at bedtime
 - (C) Take 3 [insert appropriate dosage form] at bedtime
 - (D) Take 1 [insert appropriate dosage form] in the morning
 - (E) Take 2 [insert appropriate dosage form] in the morning
 - (F) Take 3 [insert appropriate dosage form] in the morning
 - (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
 - (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

- (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
- (P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before taking again. Do not take more than ___ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

~~(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.~~

(f) (e) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.