



## California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR.

## LEGISLATION AND REGULATION COMMITTEE

Greg Lippe, CPA, Chairperson, Public Member  
Ryan Brooks, Public Member  
Deborah Veale, RPh, Professional Member  
Albert Wong, PharmD, Professional Member

### Part 1: LEGISLATION REPORT

#### a. Board Sponsored Legislation

#### Attachment 1

##### 1. Proposal to Amend Section 4209 of the Business and Professions Code

Existing law at Business and Professions Code section 4209 establishes parameters for pharmacy practice experience and how an applicant for a pharmacist license must comply with those requirements. Board regulation provides further specificity on pharmacy practice experience and in what settings the experience is to be obtained. In 2014 the board had various discussions and determined it should revise its current process for the reporting of pharmacy practice experience for individuals who graduate from an ACPE school of pharmacy.

In October 2014 the Licensing Committee brought to the board a proposal to amend Business and Professions Code section 4209 to implement the board's desire to accept the PharmD degree from an ACPE accredited school as documentation that an individual has completed the required pharmacy practice experience requirements. Board staff is working to identify possible authors to carry this legislation. A copy of the board-approved language to amend Section 4209 is provided in Attachment 1.

##### 2. Proposal to Repeal Section 11164.5 of the Health and Safety Code

Existing law at section 11164.5(a) of the Health and Safety Code requires the approval of the Board of Pharmacy and the California Department of Justice before a hospital or pharmacy may receive electronic data transmission prescriptions or computer entry prescriptions or orders. This provision was enacted in 2000 (Stats. 2000, Ch. 293). More recently, the US Drug Enforcement Administration adopted an Interim Final Rule for Electronic Prescriptions for Controlled Substances (21 CFR Parts 1300, 1304, 1036 and 1311 [Fed. Reg. 16236-16310]) which became effective on June 1, 2010.

At the October 2014 Board Meeting, the board discussed the necessity of retaining the Health and Safety Code provision and thereafter voted to recommend that

subdivision (a) of Section 11164.5 of the Health and Safety Code be repealed. A copy of Health and Safety Code section 11164.5 with this recommended change is provided in Attachment 1.

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

The Legislature reconvened in regular session on January 5. The last day that bills may be submitted to the Office of Legislative Counsel is January 30, and the last day that bills can be introduced is February 27.

Staff is daily monitoring bills to identify proposals that may impact the practice of pharmacy or the board's jurisdiction.

**c. Other Legislation Being Tracked by Board Staff**

**Attachment 2**

**1. AB 45 (Mullin) Household Hazardous Waste**

Introduced: December 1, 2014

As introduced, Assembly Bill 45 contains intent language to enact convenient household hazardous waste programs, to include curbside pickup, door-to-door collection and residential pick up services as a principal means of collecting household hazardous waste and diverting it from California's landfills and waterways. The measure is intended to include pharmaceutical waste. Board staff will maintain contact with Assembly Member Mullin's office and monitor the measure. A copy of AB 45 is provided in Attachment 2.

**2. SB 26 (Hernandez) California Health Care Cost and Quality Database**

Introduced: December 1, 2014

As introduced, Senate Bill 26 declares legislative intent to establish a system to provide valid, timely and comprehensive health care performance information that is publicly available and can be used to improve the safety, appropriateness, and medical effectiveness of health care, and to provide care that is safe, medically effective, patient-centered, timely, affordable and equitable. The bill would require the Secretary of California Health and Human Services Agency to, no later than January 1, 2017, enter into a contract with one or more independent, nonprofit organizations to administer the California Health Care Cost and Quality Database.

According to the author's office, the measure is designed to allow a consumer to access information in the database that will assist the consumer in making decisions about his or her health care.

A copy of SB 26 and the author's Fact Sheet is provided in Attachment 2.

**d. Discussion of Possible Legislative Proposals.**

**Part 2: Regulation Report**

**a. Recently Approved by the Office of Administrative Law – Update on Rulemaking to Amend Title 16 California Code of Regulations Section 1707.5 Regarding Patient-Centered Labeling Requirements**

**Attachment 3**

In 2013, the board voted to modify the board’s patient-centered prescription label requirements at 16 CCR Section 1707.5 (a) (1) to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label and to require these items to be printed in 12-point san serif typeface.

The rulemaking was noticed on April 14, 2014, and following the 45-day comment period, adopted by the board in June. Pursuant to the Administrative Procedure Act, following review and approval by Agency, the rulemaking was submitted to the Office of Administrative Law (OAL) for final review. OAL approved the rulemaking on January 8, 2015, and the regulation will become effective on April 1, 2015. Following approval by OAL, the board issued a Subscriber Alert announcing the approval of the regulation, and encouraged pharmacies to conform their prescription container labels to the new minimum font size requirement.

A copy of the adopted text is provided in **Attachment 3**.

**b. Board Approved – Awaiting Notice**

**Attachment 4**

**1. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements**

At the July 2013 Board Meeting, the board approved proposed text to amend Sections 1702 and 1702.5 and to add Sections 1702.1 and 1702.2 to Title 16 of the California Code of Regulations. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

**2. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations 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 16 California Code of Regulations 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. Staff is preparing the required notice documents and will be noticing these proposals as a combined rulemaking with other board-approved proposals.

**3. Proposal to Amend Title 16 California Code of Regulations Section 1703 Related to “Section 100” Regulatory Actions**

At the October 2013 Board Meeting, the board approved a proposal to amend Title 16 California Code of Regulations Section 1703 to delegate to the Executive Officer the authority to initiate a rulemaking to adopt “changes without regulatory effect.” Staff is preparing the required notice documents.

**4. Proposal to Amend Title 16 CCR 1793.5 Pharmacy Technician Application**

At the July 2014 Board Meeting, the board approved a proposal to amend Title 16 California Code of Regulations 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. Staff is preparing the required notice documents.

**5. Recommendation to Amend Title 16 California Code of Regulations Sections 1784 and 1751 to Update Self-Assessment Forms 17M-13, 17M-14, 17M-26 and 17M-35**

At the October 2014 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the text of 16 California Code of Regulations Sections 1715, 1735.2 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).

**Attachment 4** contains copies of each board-approved proposal.

# **Attachment 1**

#### **4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam**

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

(2) This pharmacy practice 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 experience shall include a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and must also include pharmacy practice experience in both the community and institutional pharmacy practice settings.

(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 such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. ~~Intern hours~~ 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 ~~intern experience~~ pharmacy practice, 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 the community and institutional pharmacy practice settings. 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 approved college of pharmacy or department of pharmacy of a university recognized by the board shall be deemed to have satisfied 1500 hours of pharmacy practice experience.

## Proposal to Amend Section 11164.5 of the California Health and Safety Code

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

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

~~(b)~~ ~~(e)~~ Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

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

# **Attachment 2**

**ASSEMBLY BILL**

**No. 45**

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**Introduced by Assembly Member Mullin**

December 1, 2014

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An act relating to hazardous waste.

LEGISLATIVE COUNSEL'S DIGEST

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

Existing law authorizes public agencies to operate curbside household hazardous waste collection facilities, door-to-door household hazardous waste collection programs, and household hazardous waste residential pickup services, and specifies conditions for the transportation of household hazardous waste.

This bill would express the Legislature's intent to enact legislation that would establish curbside household hazardous waste collection programs, door-to-door household hazardous waste collection programs, and household hazardous waste residential pickup services as the principal means of collecting household hazardous waste and diverting it from California's landfills and waterways.

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. (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

1 consumer items, effective and efficient disposal remains an  
2 extraordinary challenge.

3 (2) State and local efforts to address disposal of these items  
4 have been well intended, but ultimately these piecemeal and  
5 truncated approaches have not proved effective. These approaches  
6 fragment the collection of household hazardous waste and move  
7 collection away from the closest and most practical point of  
8 disposal: the consumer’s residence.

9 (3) A number of cities in California are already using curbside  
10 household hazardous waste collection programs, door-to-door  
11 household hazardous waste collection programs, and household  
12 hazardous waste residential pickup services as mechanisms for  
13 collecting and disposing of many commonly used household items  
14 for which disposal has been the subject of state legislation or local  
15 ordinances. The waste disposal companies and local governments  
16 that have implemented these programs and services have found  
17 them to be successful and inexpensive.

18 (b) It is the intent of the Legislature to enact legislation that  
19 would establish curbside household hazardous waste collection  
20 programs, door-to-door household hazardous waste collection  
21 programs, and household hazardous waste residential pickup  
22 services as the principal means of collecting household hazardous  
23 waste and diverting it from California’s landfills and waterways.

**Introduced by Senator Hernandez**December 1, 2014

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An act to add Chapter 8 (commencing with Section 127670) to Part 2 of Division 107 of, and to repeal the heading of Chapter 8 (formerly commencing with Section 127670) of Part 2 of Division 107 of, the Health and Safety Code, relating to health care.

## LEGISLATIVE COUNSEL'S DIGEST

SB 26, as introduced, Hernandez. California Health Care Cost and Quality Database.

Existing law establishes health care coverage programs to provide health care to segments of the population meeting specified criteria who are otherwise unable to afford health care coverage and provides for the licensure and regulation of health insurers and health care service plans.

This bill would state the intent of the Legislature to establish a system to provide valid, timely, and comprehensive health care performance information that is publicly available and can be used to improve the safety, appropriateness, and medical effectiveness of health care, and to provide care that is safe, medically effective, patient-centered, timely, affordable, and equitable. The bill would require the Secretary of California Health and Human Services to, no later than January 1, 2017, enter into a contract with one or more independent, nonprofit organizations to administer the California Health Care Cost and Quality Database. The bill would require the secretary to include specified terms in that contract or contracts, including, among others, that the nonprofit organization or organizations administering the California Health Care Cost and Quality Database develop methodologies relating to the submission of health care data by health care entities. The bill would

require certain health care entities, including health care service plans, to provide specified information to the nonprofit organization or organizations administering the California Health Care Cost and Quality Database. The bill would authorize the nonprofit organization or organizations to report a health care entity that fails to comply with that requirement to the health care entity's regulating agency, and would authorize the regulating agency to enforce that requirement using its existing enforcement procedures.

The bill would require all data disclosures made pursuant to these provisions to comply with all applicable state and federal laws for the protection of the privacy and security of data and would prohibit the public disclosure of any unaggregated, individually identifiable health information. The bill would require that certain confidentially negotiated contract terms be protected in data disclosures made pursuant to these provisions and would prohibit certain individually identifiable proprietary contract information from being disclosed in an unaggregated format. The bill would require the nonprofit organization or organizations administering the California Health Care Cost and Quality Database to receive, process, maintain, and analyze information from specified data sources, including, among others, disease and chronic condition registries. The bill would require, no later than January 1, 2019, the nonprofit organization or organizations administering the California Health Care Cost and Quality Database to publicly make available a web-based, searchable database and would require that database to be updated regularly. The bill would prohibit implementation and ongoing administration costs of the California Health Care Cost and Quality Database from being paid using General Fund moneys.

This bill would also require the secretary to convene a review committee composed of a broad spectrum of health care stakeholders and experts, as specified, to, among other things, develop the parameters for establishing, implementing, and administering the California Health Care Cost and Quality Database. The bill would require the secretary to arrange for the preparation of an annual report to the Legislature and the Governor that examines and addresses specified issues, including, among others, containing the cost of health care services and coverage. The bill would provide that the commission not be convened until the Director of Finance has determined that sufficient private or federal funds have been received and appropriated for that purpose, and that members of the committee not receive a per diem or travel expense reimbursement, or any other expense reimbursement.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

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. The heading of Chapter 8 (formerly commencing  
2 with Section 127670) of Part 2 of Division 107 of the Health and  
3 Safety Code, as amended by Section 230 of Chapter 183 of the  
4 Statutes of 2004, is repealed.

5 SEC. 2. Chapter 8 (commencing with Section 127670) is added  
6 to Part 2 of Division 107 of the Health and Safety Code, to read:

7  
8 CHAPTER 8. CALIFORNIA HEALTH CARE COST AND QUALITY  
9 DATABASE

10  
11 127670. (a) It is the intent of the Legislature to establish a  
12 system to provide valid, timely, and comprehensive health care  
13 performance information that is publicly available and can be used  
14 to improve the safety, appropriateness, and medical effectiveness  
15 of health care, and to provide care that is patient-centered, timely,  
16 affordable, and equitable. It is also the intent of the Legislature to  
17 grant access to provider performance information to consumers  
18 and purchasers in order for them to understand the potential  
19 financial consequences and liabilities and obtain maximum quality  
20 and value in health care services.

21 (b) It is the intent of the Legislature, by making cost and quality  
22 data available, to encourage health care service plans, health  
23 insurers, and providers to develop innovative approaches, services,  
24 and programs that may have the potential to deliver health care  
25 that is both cost effective and responsive to the needs of enrollees.

26 127671. (a) The Secretary of California Health and Human  
27 Services shall, no later than January 1, 2017, use a competitive  
28 process to contract with one or more independent, nonprofit  
29 organizations in order to administer the California Health Care

1 Cost and Quality Database. This competitive process and any  
2 requests for proposal shall be publicly posted on the agency's  
3 Internet Web site for a minimum of 30 days for public review and  
4 comment. A contract entered into pursuant to this section is exempt  
5 from Part 2 (commencing with Section 10100) of Division 2 of  
6 the Public Contract Code, and is exempt from review or approval  
7 by any division of the Department of General Services.

8 (b) The secretary shall include as a term in the contract or  
9 contracts entered into pursuant to subdivision (a) all of the  
10 following:

11 (1) A requirement that the nonprofit organization or  
12 organizations administering the California Health Care Cost and  
13 Quality Database do all of the following:

14 (A) Establish, implement, and administer the California Health  
15 Care Cost and Quality Database in accordance with parameters  
16 developed pursuant to subdivision (a) of Section 127672.

17 (B) Develop methodologies for the collection, validation,  
18 refinement, analysis, comparison, review, reporting, and  
19 improvement of health care data, including, but not limited to, data  
20 from fee-for-service, capitated, and other alternative, value-based,  
21 payment sources, submitted by health care entities that are  
22 validated, recognized as reliable, and meet industry and research  
23 standards.

24 (C) Receive information, as described in this section, from health  
25 care entities and report that information in a form that allows valid  
26 comparisons across care delivery systems.

27 (D) Comply with the requirements governing provider and  
28 supplier requests for error correction established pursuant to  
29 Section 401.717 of Title 42 of the Code of Federal Regulations  
30 for all claims data received, including, but not limited to, data from  
31 sources other than Medicare.

32 (2) A prohibition on the nonprofit organization or organizations  
33 administering the California Health Care Cost and Quality Database  
34 from doing either of the following:

35 (A) Using the data received during the execution of the contract  
36 for any purpose not specified in this chapter or in the contract.

37 (B) Receiving funding from any other source to accomplish the  
38 same purposes sought to be accomplished under this chapter unless  
39 funding is received from another nonprofit or government source  
40 and is for the purpose of research or education.

1 (3) A requirement that the nonprofit organization or  
2 organizations administering the California Health Care Cost and  
3 Quality Database identify, in accordance with this section, the type  
4 of data, purpose of use, and entities and individuals that are  
5 required to report to, or that may have access to, the California  
6 Health Care Cost and Quality Database. An entity or individual  
7 shall not be required to report to, and shall not have access to, the  
8 California Health Care Cost and Quality Database until the review  
9 committee established pursuant to Section 127672 has approved  
10 the nonprofit organization or organizations determination.

11 (c) (1) For the purpose of developing information for inclusion  
12 in the California Health Care Cost and Quality Database, a health  
13 care service plan, including a specialized health care service plan,  
14 an insurer licensed to provide health insurance, as defined in  
15 Section 106 of the Insurance Code, a self-insured employer, a  
16 supplier, as defined in paragraph (3) of subdivision (b) of Section  
17 1367.50, or a provider, as defined in paragraph (2) of subdivision  
18 (b) of Section 1367.50, shall, and a multiemployer self-insured  
19 plan that is responsible for paying for health care services provided  
20 to beneficiaries and the trust administrator for a multiemployer  
21 self-insured plan may, provide both of the following to the  
22 nonprofit organization or organizations administering the California  
23 Health Care Cost and Quality Database:

24 (A) Utilization data from the health care service plans' and  
25 insurers' medical, dental, and pharmacy claims or, in the case of  
26 entities that do not use claims data, including, but not limited to,  
27 integrated delivery systems, encounter data consistent with the  
28 core set of data elements for data submission proposed by the  
29 APCD Council, the University of New Hampshire, and the National  
30 Association of Health Data Organizations.

31 (B) Pricing information for health care items, services, and  
32 medical and surgical episodes of care gathered from allowed  
33 charges for covered health care items and services or, in the case  
34 of entities that do not use or produce individual claims, price  
35 information that is the best possible proxy to pricing information  
36 for health care items, services, and medical and surgical episodes  
37 of care available in lieu of actual cost data so to allow for  
38 meaningful comparisons of provider prices and treatment costs.

39 (2) (A) The nonprofit organization or organizations  
40 administering the California Health Care Cost and Quality Database

1 may report an entity's failure to comply with paragraph (1) to the  
2 entity's regulating agency.

3 (B) The regulating agency of an entity described in paragraph  
4 (1) may enforce paragraph (1) using its existing enforcement  
5 procedures. Notwithstanding any other law, moneys collected  
6 pursuant to this authorization shall be subject to appropriation by  
7 the Legislature, and the failure to comply with paragraph (1) shall  
8 not be a crime.

9 (d) (1) All uses and disclosures of data made pursuant to this  
10 section shall comply with all applicable state and federal laws for  
11 the protection of the privacy and security of data, including, but  
12 not limited to, the federal Health Insurance Portability and  
13 Accountability Act of 1996 (Public Law 104-191) and the federal  
14 Health Information Technology for Economic and Clinical Health  
15 Act, Title XIII of the federal American Recovery and Reinvestment  
16 Act of 2009 (Public Law 111-5), and implementing regulations.

17 (2) (A) All policies and protocols developed in the performance  
18 of the contract shall ensure that the privacy, security, and  
19 confidentiality of individually identifiable health information is  
20 protected. The nonprofit organization or organizations  
21 administering the California Health Care Cost and Quality Database  
22 shall not publicly disclose any unaggregated, individually  
23 identifiable health information and shall develop a protocol for  
24 assessing the risk of reidentification stemming from public  
25 disclosure of any health information that is aggregated, individually  
26 identifiable health information.

27 (B) For the purposes of this paragraph, "individually identifiable  
28 health information" has the same meaning as in Section 160.103  
29 of Title 45 of the Code of Federal Regulations.

30 (3) Confidentially negotiated contract terms contained in a  
31 contract between a health care service plan or insurer and a provider  
32 or supplier shall be protected in any public disclosure of data made  
33 pursuant to this section. Individually identifiable proprietary  
34 contract information included in a contract between a health care  
35 service plan or insurer and a provider or supplier shall not be  
36 disclosed in an unaggregated format.

37 (e) (1) The nonprofit organization or organizations  
38 administering the California Health Care Cost and Quality Database  
39 shall receive, process, maintain, and analyze information from  
40 data sources, including, but not limited to, data received pursuant

1 to subdivision (c), claims from private and public payers, disease  
2 and chronic condition registries, third-party surveys of quality and  
3 patient satisfaction, reviews by licensing and accrediting bodies,  
4 and local and regional public health data. Aggregated payer and  
5 provider performance on validated measures of clinical quality  
6 and patient experience, such as measures from the Healthcare  
7 Effectiveness Data and Information Set (HEDIS) and Consumer  
8 Assessment of Healthcare Providers and Systems (CAHPS), shall  
9 be collected from accrediting organizations, including, but not  
10 limited to, the National Committee for Quality Assurance (NCQA),  
11 URAC, and the Joint Commission.

12 (2) The nonprofit organization or organizations administering  
13 the California Health Care Cost and Quality Database shall include  
14 in an analysis performed pursuant to paragraph (1), but shall not  
15 be limited to, all of the following:

16 (A) Population-level data on prevention, screening, and wellness  
17 utilization.

18 (B) Population-level data on behavioral and medical risk factors,  
19 interventions, and outcomes.

20 (C) Population-level data on chronic conditions, management,  
21 and outcomes.

22 (D) Population-level data on trends in utilization of procedures  
23 for treatment of similar conditions to evaluate medical  
24 appropriateness.

25 (E) Facility and physician organization risk adjusted  
26 performance information on the quality, efficiency, and outcomes  
27 of care that are aligned with national efforts, including, but not  
28 limited to, those of the National Quality Forum, related to defining  
29 cost and quality measures.

30 (F) Data that permits consideration of socioeconomic status and  
31 disparities in care due to race, ethnicity, gender, sexual orientation,  
32 and gender identity.

33 (f) No later than January 1, 2019, the nonprofit organization or  
34 organizations administering the California Health Care Cost and  
35 Quality Database shall make publicly available a web-based,  
36 searchable database. The database shall include the information  
37 and analysis described in subdivision (e). The information and  
38 analysis included in the database shall be presented in a way that  
39 facilitates comparisons of cost, quality, and satisfaction across  
40 payers, provider organizations, and other suppliers of health care

1 services. This public database shall be regularly updated to reflect  
2 new data submissions.

3 (g) Implementation and ongoing administration costs of the  
4 California Health Care Cost and Quality Database shall not be  
5 paid using General Fund moneys.

6 127672. (a) The Secretary of California Health and Human  
7 Services shall convene a review committee, composed of a broad  
8 spectrum of health care stakeholders and experts, including, but  
9 not limited to, representatives of the entities that are required to  
10 provide information pursuant to subdivision (c) of Section 127671  
11 and representatives of purchasers, including, but not limited to,  
12 businesses, organized labor, and consumers, to develop the  
13 parameters for the establishment, implementation, and ongoing  
14 administration of the California Health Care Cost and Quality  
15 Database, including a business plan for sustainability without using  
16 moneys from the General Fund, and to approve the determinations  
17 described in paragraph (3) of subdivision (b) of Section 127671.  
18 The review committee shall hold public meetings with  
19 stakeholders, solicit input, and set its own meeting agendas.  
20 Meetings of the review committee are subject to the Bagley-Keene  
21 Open Meeting Act (Article 9 (commencing with Section 11120)  
22 of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government  
23 Code).

24 (b) The secretary shall arrange for the preparation of an annual  
25 report to the Legislature and the Governor, to be submitted in  
26 compliance with Section 9795 of the Government Code, based on  
27 the findings of the review committee, including input from the  
28 public meetings, that shall, at a minimum, examine and address  
29 the following issues:

30 (1) Assessing California health care needs and available  
31 resources.

32 (2) Containing the cost of health care services and coverage.

33 (3) Improving the quality and medical appropriateness of health  
34 care.

35 (4) Increasing the transparency of health care costs and the  
36 relative efficiency with which care is delivered.

37 (5) Use of disease management, wellness, prevention, and other  
38 innovative programs to keep people healthy and reduce disparities  
39 and costs and improving health outcomes for all populations.

40 (6) Efficient utilization of prescription drugs and technology.

1 (7) Reducing unnecessary, inappropriate, and wasteful health  
2 care.

3 (8) Educating consumers in the use of health care information.

4 (9) Using existing data sources to build the California Health  
5 Care Cost and Quality Database.

6 (c) The review committee established pursuant to this section  
7 shall not be convened until the Director of Finance has determined  
8 that sufficient private or federal funds have been received and that  
9 the funds have been appropriated for that purpose. The review  
10 committee shall continue to function for as long as the Department  
11 of Finance has determined that the California Health Care Cost  
12 and Quality Database is established and is being administered.

13 (d) Notwithstanding any other law, the members of the review  
14 committee shall receive no per diem or travel expense  
15 reimbursement, or any other expense reimbursement.

16 SEC. 3. The Legislature finds and declares that Section 2 of  
17 this act, which adds Section 127671 to the Health and Safety Code,  
18 imposes a limitation on the public's right of access to the meetings  
19 of public bodies or the writings of public officials and agencies  
20 within the meaning of Section 3 of Article I of the California  
21 Constitution. Pursuant to that constitutional provision, the  
22 Legislature makes the following findings to demonstrate the interest  
23 protected by this limitation and the need for protecting that interest:

24 In order to protect confidential and proprietary information  
25 submitted to the California Health Care Cost and Quality Database,  
26 it is necessary for that information to remain confidential.

# **Attachment 3**

**Order of Adoption  
Board of Pharmacy  
California Code of Regulations**

**To Amend Section 1707.5 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 ~~10-point sans serif typeface or, if requested by the consumer, 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 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.

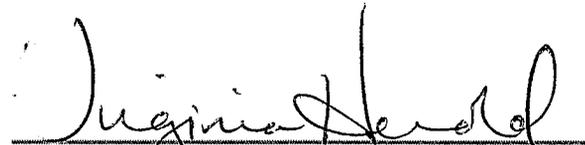
(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(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 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) 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.



Virginia Herold  
Executive Officer  
Board of Pharmacy

# **Attachment 4**

## Title 16. Board of Pharmacy Proposed Language

**To 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 reproval.

(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 cited: 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.

**To Add 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 reproval.

(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 cited: 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.

**To Amend 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 reproval.

(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 cited: 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.

## Title 16. Board of Pharmacy Proposed Language

**To Add 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 cited: Section 4005, Business and Professions Code. Reference: Sections 4112, 4161, 4300, 4301, Business and Professions Code

# Title 16. Board of Pharmacy

## Proposed Language

To Amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

### § 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.

34 **To Amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read**  
35 **as follows:**

36 **§ 1732.2. Board Accredited Continuing Education**  
37

38 (a) Individuals may petition the board to allow continuing education credit for specific coursework  
39 which is not offered by a provider but meets the standards of Section 1732.3.

40 (b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance  
41 to pharmacy practice and has been approved for continuing education by the Medical Board of  
42 California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the  
43 Dental Board of California shall, upon satisfactory completion, be considered approved continuing  
44 education for pharmacists.

45 (c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing  
46 the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to  
47 section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of  
48 continuing education for conducting a review of exam test questions. A subcommittee member shall  
49 not receive continuing education hours pursuant to this subdivision if that subcommittee member  
50 requests reimbursement from the board for time spent conducting a review of exam test questions.

51 (d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six  
52 hours of continuing education per renewal period. The board shall designate on its public agenda  
53 which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician  
54 requesting continuing education pursuant to this subdivision must sign in and out on an attendance  
55 sheet at the board meeting that requires the individual to provide his or her first and last name, license  
56 number, time of arrival and time of departure from the meeting.

57 (e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be  
58 awarded two hours of continuing education per renewal period. A pharmacist or pharmacy technician  
59 requesting continuing education hours pursuant to this subdivision must sign in and out on an  
60 attendance sheet at the committee meeting that requires the individual to provide his or her first and  
61 last name, license number, time of arrival and time of departure from the meeting.

62 (f) An individual may be awarded three hours of continuing education for successfully passing the  
63 examination administered by the Commission for Certification in Geriatric Pharmacy.  
64

65 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232,  
66 Business and Professions Code.

67 **To Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read**  
68 **as follows:**

69 **§ 1732.5. Renewal Requirements for Pharmacist.**

70

71 (a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this  
72 Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the  
73 board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

74 (b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or  
75 more of the following subject areas:

76 1. Emergency/Disaster Response

77 2. Patient Consultation

78 3. Maintaining Control of a Pharmacy's Drug Inventory

79 4. Ethics

80 5. Substance Abuse

81 6. Compounding

82 Pharmacists renewing their licenses which expire on or after July 1, 2015~~6~~, shall be subject to the  
83 requirements of this subdivision.

84 ~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four years following completion  
85 of a continuing education course.

86

87 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and  
88 4232, Business and Professions Code.

1 **Draft Proposed Text**

2 **Amend Title 16 California Code of Regulations Section 1703**  
3 **Related to Delegation of Certain Functions**  
4

5 **§ 1703. Delegation of Certain Functions.**

6 The power and discretion conferred by law upon the board to receive and file accusations; issue  
7 notices of hearing, statements to respondent and statements of issues; receive and file notices of  
8 defense; determine the time and place of hearings under Section 11508 of the Government Code; set  
9 and calendar cases for hearing and perform other functions necessary to the business-like dispatch of  
10 the business of the board in connection with proceedings under the provisions of Sections 11500  
11 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and  
12 delivery or mailing of copies of decisions under Section 11518 of said code; ~~and~~ issue summary  
13 suspension orders or notices of suspension under Section 4311 of the Business and Professions Code;  
14 and make changes to its regulations without regulatory effect pursuant to Title 1, California Code of  
15 Regulations section 100 are hereby delegated to and conferred upon the executive officer, or, in his or  
16 her absence from the office of the board, the acting executive officer.

17 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and  
18 4311, Business and Professions Code.

Proposed language to amend question number 7 on the pharmacy technician application and question number 19 on the pharmacist application.

**Proposed Question:**

Have you ever been convicted of, or pleaded guilty or nolo contendere/no contest to, any crime, in any state, the United States or its territories, a military court, or any foreign country? Include any offense felony or misdemeanor offense, and any infraction involving drugs or alcohol with a fine of \$500 or more. You must disclose a conviction even if it was (1) later dismissed or expunged pursuant to Penal Code section 1203.4 et seq., or an equivalent release from penalties and disabilities provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210 et seq., or an equivalent post-conviction drug treatment diversion dismissal provision or from a non-California jurisdiction. Failure to answer truthfully and completely may result in the denial of your application.

**NOTE:** You may answer "NO" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; and (3) convictions more than two years old on the date you submit your application for violations of California Health and Safety Code section 11357, subdivisions (b), (c), (d), or (e), or California Health and Safety Code section 11360, subdivision (b); and (4) infractions or traffic violations with a fine of less than \$500 that do not involve drugs or alcohol.

## BOARD OF PHARMACY

**Proposal to Amend Section 1715 in Article 2 of Division 17 of Title 16 to read:**

**§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.**

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy'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 pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) The components of this assessment shall be on Form 17M-13 (~~Rev. 01/11~~) ([Rev. 10/14](#)) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on Form 17M-14 (~~Rev. 01/11~~) ([Rev. 10/14](#)) entitled "Hospital Pharmacy Self-Assessment" which are 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 pharmacy for three years after it is performed.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: 4113, 4115, 4119, 4127, 4305, 4330, 4332 and 4333, Business and Professions Code.

**Proposal to Amend Section 1735.2 in Article 4.5 of Division 17 of Title 16 to read:**

**§ 1735.2. Compounding Limitations and Requirements; Self-Assessment**

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A “reasonable quantity” as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This “beyond use date” of the

compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "~~Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment~~" Form 17M-39 Rev. ~~02/12~~ [10/14](#).) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

**Proposal to Amend Section 1784 in Article 10 of Division 17 of Title 16 to read:**

**§ 1784. Self-Assessment of a Wholesaler by the Designated Representative-In-Charge.**

(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~~) ([Rev. 10/14](#)) 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.

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