



California State Board of Pharmacy

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

Legislation and Regulation Committee

Greg Lippe, CPA, Chair, Public Member
Ramón Castellblanch, PhD, Public Member
Randy Kajioka, PharmD, Professional Member
Amy Gutierrez, PharmD, Professional Member
Tappan Zee, Esq., Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee has not met in the past quarter.

PART I REGULATION

All section references are to the Business and Professions Code, or to Title 16 of the California Code of Regulations, unless otherwise stated.

a. Discussion and Possible Action to Adopt Text of Previously Noticed Regulations

ATTACHMENT 1

Combined Rulemaking: Amend Section 1745 – Partial Filling of Schedule II Controlled Substance Prescriptions; Add Section 1762 – Unprofessional Conduct; and Amend Section 1769 – Application Review / Criteria for Rehabilitation

The Board initiated a rulemaking to Amend Sections 1745 and 1769, and to Add Section 1762 to Title 16 of the California Code of Regulations. A summary of each proposal is provided below. The rulemaking was noticed on October 19, 2012, and the 45-day public comment period concluded on December 10. The board did not receive any comments related to this rulemaking during the public comment period.

Provided in **Attachment 1** is the proposed text as noticed on October 19th for the board's consideration and possible action to adopt, and further direct that the rulemaking be completed.

Summary of Proposals

Proposal to add Section 1762 – Unprofessional Conduct: Defined

In February 2011, the board moved to initiate a rulemaking to add Section 1762 to Title 16 California Code of Regulations to implement components of the Department of Consumer Affairs' Consumer Protection Enforcement Initiative (CPEI) relative to unprofessional conduct. The provisions would specify that unprofessional conduct include acts such as gag clauses in a

civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender.

Proposal to amend Section 1745 – Partial Fill of Schedule II Controlled Substance

Current regulation requires that when a pharmacist partially fills a prescription for a Schedule II controlled substance that specified information be recorded in a readily retrievable form and also on the original prescription document. The board approved draft language to allow a pharmacist to record specified information in a readily retrievable form **or** on the original prescription document.

Proposal to amend Section 1769 – Criteria for Rehabilitation

To implement components of the DCA's CPEI, the board directed that staff initiate a rulemaking that would authorize the board to request an applicant for licensure to undergo an examination, as specified, to determine if the applicant is safe to practice. The board further specified that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days, and that within 60 days of the evaluation, the report be received by the board.

b. Discussion and Possible Action Regarding 15-Day Comments and Possible Action to Adopt Text

Proposal to Add New Article 5.5 to Title 16 and Add Sections 1747 and 1747.1 – Pedigree Requirements

ATTACHMENT 2

At the December 13, 2012, Board Meeting, the board discussed the board's proposed regulations related to Pedigree Requirements (SNI / Grandfathering). At that time, the board voted to modify the language at proposed Section 1747 to incorporate a reference to subdivision (d) of Section 4034 of the Business and Professions Code, and to strike and/or modify dates specified in proposed Section 1747.1. In accordance with the board's motion, staff issued a Notice of Modified Text on December 21, 2012. A Second Notice of Modified Text was issued on January 11, to correct an error in the *placement of* the reference to Section 4034(d) in the first sentence of Proposed Section 1747. The Second Modified Text public comment period closed on January 28.

The board received one comment during the First Notice of Modified Text, but the comments were unrelated to the modifications authorized by the board. Thus, in accordance with the board's motion on December 13, the Executive Officer will adopt the language as noticed in the Modified Text Notice and staff will complete the rulemaking file. A copy of the First Modified Text, Second Modified Text, and the one comment received are provided in **Attachment 2**.

c. **Board Adopted Regulations – Undergoing Administrative Review**

1. **Amend Title 16, Section 1746 – Emergency Contraception Protocol**

ATTACHMENT 3

Provided in **Attachment 3** is the language Adopted by the board to modify its regulation at Title 16 CCR Section 1746 for the purpose of updating the Emergency Contraception Protocol, which has been approved by the Board of Pharmacy and the Medical Board of California (MBC).

This rulemaking was initiated on January 6, 2012. Modified Text was issued for a 15-day public comment period on October 30, during which time no comments to the rulemaking were received. In accordance with the motion of the board, the proposal was adopted, and the rulemaking file was completed. The Director of the Department of Consumer Affairs extended the one-year notice period, as authorized by Section 313.1(e)(1) of the Business and Professions Code.

The board received Agency approval, and delivered the rulemaking file to the Office of Administrative Law (OAL) on January 29 (Regulatory Action No. 2013-0129-04S). OAL has 30 business days in which to complete their review of the rulemaking.

Staff will keep the board apprised of the status of this rulemaking.

2. **Amend Title 16, Beginning with Section 1735.1 – Compounding Drug Products**

ATTACHMENT 4

This proposal was noticed for public comment on March 9, 2012. The 45-day comment period concluded on April 23, 2012, and the Board conducted a Regulation Hearing on May 1, 2012. On May 1, the board modified the language at Section 1735.3(a)(6) to incorporate by reference USP 797 related to “Redispensed CSPs”; and also to amend Section 1751.2(d) modifying the text of the special label used for cytotoxic agents. A Notice of Modified Text was issued on July 5, and the 15-day notice period concluded on July 20, 2012.

As reported at the October 2012 Board Meeting, and in accordance with the board’s motion at the July 2012 Board meeting, the Executive Officer adopted the proposed regulations and staff completed the rulemaking file. Following approval from the department and from Agency, the rulemaking was transmitted to the Office of Administrative Law (OAL) for final review on December 21, 2012 (Regulatory Action No. 2012-1221-01S). A copy of the Adopted Text is provided in **Attachment 4**. This text, and the Self-Assessment Form incorporated by reference are available on the board’s website.

OAL has 30 business days in which to complete its review. Board staff anticipates learning of the status of OAL’s review the week of February 4.

d. OTHER

Board Approved Regulations – Awaiting Formal Public Notice

ATTACHMENT 5

The following is provided for information only.

Below are four board-approved regulatory proposals that have not yet been noticed for public comment. A copy of the language approved for public notice is provided in **Attachment 5**, and a summary of each is provided below. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

Background

Proposal to Amend Section 1732.2 – Board Accredited Continuing Education

In January 2012, the board withdrew a pending regulation to Section 1732.2 which, at that time, was pending final review at the Office of Administrative Law. Thereafter, the Licensing Committee vetted revised language which, in May 2012, was approved by the board for public notice.

Proposal to Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas

In May 2012, the board approved a draft regulatory proposal for public comment to require continuing education in specific content areas. The proposed text would require six of the 30 units required of continuing education for a pharmacist renewal to be in specified content areas.

Proposal to Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education

In May 2012, the board approved a draft regulatory proposal to modify Section 1732.05(a)(2) and to initiate a rulemaking. This proposal was at the request of the California Pharmacists Association, to reflect the restructuring of the Pharmacy Foundation of California and its transference of duties related to the provision of continuing education to the California Pharmacists Association.

Proposal to Add Section 1751.9 – Standards for Agencies that Accredite Sterile Injectable Compounding Pharmacies

In May 2012, the board approved for public notice a draft regulatory proposal from the Licensing Committee to add Section 1751.9 to Title 16 of the CCR for the purpose of specifying standards for agencies that accredit licensed sterile injectable compounding pharmacies.

**AGENDA ITEM X
PART I**

ATTACHMENT 1

Title 16. Board of Pharmacy Proposed Language

(As Noticed for Public Comment on October 19, 2012)

To Amend Section 1745 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or

(2) The prescription is for a terminally ill patient. “Terminally ill” as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A “partially filled” prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The

remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4301, Business and Professions Code; and Sections 11055, 11153, 11154, 11166, 11200, Health and Safety Code.

To Add Section 1762 to Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

To Amend Section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1769. Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

- (1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.
- (2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.
- (3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).
- (4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.
- (5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.

ATTACHMENT 2

To Add a New Article 5.5 and Article Title, and
Add Sections 1747 and 1747.1 and Section Titles to Article 5.5

Section 1747 – Unique Identification Number

Section 1747.1 – Specification of Pedigreed Dangerous Drugs;
Specification of Existing Stock

First Modified Text (12/21/12 – 1/7/13)

Second Modified Text (1/11/13 – 1/28/13)

Comment Received during First Modified Text Comment Period

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

FIRST MODIFIED TEXT (Issued 12/21/12-1/7/13)

Proposal to Add a New Article 5.5 and Article Title, and Add Sections 1747 and 1747.1 and Section Titles to Article 5.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 5.5. Pedigree Requirements.

1747. Unique Identification Number.

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container by the manufacturer or repackager as defined in subdivision (d) of Section 4034 shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA's Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

Note: Authority cited: Sections 4005, 4034, and 4163.2, Business and Professions Code.
Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board, ~~by December 1, 2014,~~ **but** no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

Changes to the originally proposed language are shown as follows:

Deleted text is shown by double strike-through, thus: ~~deleted language~~.

New or added text is shown by double underline, thus: added language

(A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer's total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;

(B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;

(D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

(E) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board, ~~by December 1, 2015,~~ but no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.

(B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,

(D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

Changes to the originally proposed language are shown as follows:

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(b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than ~~August 1, 2016~~, July 31, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:

(1) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(2) a statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than ~~August 1, 2017~~, July 31, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(2) A statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

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1 Title 16. Board of Pharmacy
2 Second Modified Text (Issued 1/11/13-1/28/13)

3 Proposal to Add a New Article 5.5 and Article Title, and Add Sections 1747 and
4 1747.1 and Section Titles to Article 5.5 of Division 17 of Title 16 of the California
5 Code of Regulations to read as follows:

6 Article 5.5. Pedigree Requirements.

7 1747. Unique Identification Number.

8 For the purposes of Section 4034 of the Business and Professions Code, the "unique
9 identification number" that is to be established and applied to the smallest package or
10 immediate container as defined in subdivision (d) of Section 4034 by the manufacturer or
11 repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set
12 forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled
13 "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized
14 Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document),
15 hereby incorporated by reference. As stated therein, an SNI consists of a serialized National
16 Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial
17 number of no more than twenty (20) digits or characters. For dangerous drugs for which no
18 NDC product identifier is assigned or is in use, an equivalent serialized product identifier may
19 be used in place of the NDC consistent with the FDA's Guidance Document. This number
20 shall be combined with a unique numeric or alphanumeric serial number that is not more
21 than 20 digits or characters in length to establish the unique identification number.

22 This regulation shall become operative on January 1, 2015.

23 Note: Authority cited: Sections 4005, 4034, and 4163.2, Business and Professions Code.
24 Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and
25 Professions Code.

26
27 1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

28 (a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer
29 of a dangerous drug distributed in California shall submit to the board, ~~by December 1, 2014,~~
30 ~~but~~ no later than December 31, 2014, a declaration signed under penalty of perjury by an

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31 owner, officer, or employee with authority to bind the manufacturer, containing the
32 following:

33 (A) A list and quantity of dangerous drugs by name and product package (SKU) type
34 representing at least fifty (50) percent of the manufacturer's total that are ready for initial
35 implementation of the serialized electronic pedigree requirements as of January 1, 2015;

36 (B) A statement identifying which one of the following methods was used to measure
37 the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU)
38 type, or (iii) drug product family;

39 (C) A statement describing the calculation(s) used to arrive at the percentage figure of
40 dangerous drugs ready for serialized pedigree requirements;

41 (D) A list and quantity of dangerous drugs by name and product package (SKU) type that
42 are in the remaining percentage not yet ready to be serialized or subject to pedigree
43 requirements; and,

44 (E) a statement specifying the technology employed to meet the pedigree requirements,
45 including but not limited to any platform(s), vendor(s), hardware, software, and
46 communication technologies deployed.

47 (2) To comply with Business and Professions Code section 4163.5, each manufacturer of a
48 dangerous drug distributed in California shall also submit to the board, ~~by December 1, 2015,~~
49 ~~but~~ no later than December 31, 2015, a declaration signed under penalty of perjury by an
50 owner, officer, or employee with authority to bind the manufacturer, containing the
51 following:

52 (A) A list and quantity of its remaining dangerous drugs by name and product package
53 (SKU) type that are ready for implementation of serialized electronic pedigree requirements
54 as of January 1, 2016.

55 (B) A statement identifying which one of the following methods was used to measure
56 the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU)
57 type, or (iii) drug product family;

58 (C) A statement describing the calculation(s) used to arrive at the final percentage
59 figure; and,

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60 (D) A statement specifying the technology employed to meet the pedigree
61 requirements, including but not limited to any platform(s), vendor(s), hardware, software,
62 and communication technologies deployed.

63 (3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by
64 December 31, 2014, any failure to submit to the board a declaration compliant with
65 subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the
66 board in fully compliant form within ten (10) days after notice of deficiency by the board,
67 shall constitute a violation of the Pharmacy Law.

68 (b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any
69 manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses,
70 owns, or controls that are not subject to the serialized electronic pedigree requirements,
71 shall submit to the Board, by no later than ~~August 1, 2016,~~ July 31, 2016, a declaration signed
72 under penalty of perjury by an owner, officer, or employee with authority to bind the
73 manufacturer, wholesaler or repackager, containing the following:

74 (1) a list and quantity of dangerous drugs by name, product package (SKU) type and
75 National Drug Code (NDC) product identifier in the possession, ownership, or control of the
76 manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

77 (2) a statement that specifies the means and source of acquisition; and,

78 (3) a statement that specifies the anticipated means of any subsequent distribution or
79 disposition.

80 (c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any
81 pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses,
82 owns, or controls that are not subject to the serialized electronic pedigree requirements,
83 shall submit to the Board, by no later than ~~August 1, 2017,~~ July 31, 2017, a declaration signed
84 under penalty of perjury by an owner, officer, or employee with authority to bind the
85 pharmacy or pharmacy warehouse, containing the following:

86 (1) A list and quantity of dangerous drugs by name, product package (SKU) type and
87 National Drug Code (NDC) product identifier in the possession, ownership, or control of the
88 pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

89 (2) A statement that specifies the means and source of acquisition; and,

Changes to the originally proposed language (first modified text) are shown as follows:

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90 (3) a statement that specifies the anticipated means of any subsequent distribution or
91 disposition.

92 (d) The Board or its designee shall have sole discretion to determine whether any of the
93 declarations submitted pursuant to this Section are compliant, and to reject and require
94 re-submission of any non-compliant declaration(s) until determined to be fully compliant.

95 Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and
96 Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5,
97 Business and Professions Code.

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New or added text is shown by double underline italics, thus: added language.

Klein, Carolyn@DCA

From: Bill Connell <bconnell@maxiomgroup.com>
Sent: Monday, January 07, 2013 3:54 PM
To: Klein, Carolyn@DCA
Subject: RE: Comment on Proposed New Article 5.5 "Pedigree Requirements"

Hello Carolyn,

Comments pertaining to the Notice of Proposed Action to add a new Article 5.5, beginning with Sections 1747 of the California Code of Regulations related to Pedigree Requirements.

We have reviewed the proposed regulations, and have several comments and questions:

1. Will extensions be given for those companies that are unable to meet the deadlines? Specifically, if a company acquires a new pharmaceutical company in 2014, which has not made any effort to serialize their products, will there be an exclusion or extension for the acquiring company to allow additional time for them to get the new products compliant?
2. What is the policy for grandfathering inventory that was brought into the CA supply chain prior to January 1, 2015?
3. Regarding "drug product family" as a method of measuring the initial 50%: What does this mean exactly? Is drug product family defined as all products associated with a particular Active Pharmaceutical Ingredient (API) and covered under one commercial brand name? If this is correct, a manufacturer could serialize 50% of drug product families that represents less than 50% of unit volume.
4. What is the California Board of Pharmacy's definition of "dangerous drug"? Is it equivalent to the FDA's definition of "prescription drug"?
5. Is the violation and penalty for not complying with these regulations based on the default penalty defined in Article 20, sections 4320 and 4321 of the 2012 Lawbook for Pharmacy? Also, what is the definition of a single "offense"? Would each saleable unit that is not serialized and that goes against the manufacturer's 50% declaration be an individual offense?

Thank you for the opportunity to comment. I look forward to your response.

Best Regards,

Bill

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ATTACHMENT 3

Title 16, Section 1746 – Emergency Contraception

Adopted Text

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

To Amend § 1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section ~~4052(a)(8)~~ 4052.3(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

~~(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.~~

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication ~~within required limits~~ and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and state communicate the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of after unprotected intercourse. ~~EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.~~

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. For other options for EC, consult with your health care provider.

Please follow up with your health care provider after the use of EC.

(4) The pharmacist shall provide ~~the~~ a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in ~~the~~ this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Dedicated Emergency Contraception

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One-Dose Regimen				
Plan-B	Women's Capital Corporation	2 tablets	0	1.5
Two-Dose Regimens				
Plan-B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynetics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

<u>Brand</u>	<u>Dose</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	
<u>One Tablet Regimen</u>			
<u>Plan B™ One-Step</u>	<u>1 tablet</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<u>ella™</u>	<u>1 tablet</u>	<u>0</u>	<u>30mg ulipristal</u>
<u>Levonorgestrel</u>	<u>1 tablet</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>

<u>Two Tablet Regimens</u>			
<u>Next Choice™</u>	<u>2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later</u>	<u>0</u>	<u>Each tablet is 0.75 mg levonorgestrel</u>
<u>Levonorgestrel</u>	<u>2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later</u>	<u>0</u>	<u>Each tablet is 0.75 mg levonorgestrel</u>

Oral Contraceptive Pills

<u>Brand</u>	<u>Tablets per Dose (two doses 12 hours apart*)</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	<u>Levonorgestrel per dose (mg)*</u>
<u>Allesse</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Aviane</u>	<u>5 orange tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levlen</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Levlite</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levora</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Lo/Ovral</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.50</u>
<u>Low-Ogestrel</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Nordette</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Ogestrel</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Ovral</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Tri-Levlen</u>	<u>4 yellow tablets</u>	<u>100</u>	<u>0.50</u>
<u>Triphasil</u>	<u>4 yellow tablets</u>	<u>120</u>	<u>0.50</u>
<u>Trivora</u>	<u>4 pink tablets</u>	<u>120</u>	<u>0.50</u>
<u>Ovrette</u>	<u>20 yellow tablets</u>	<u>0</u>	<u>0.75</u>

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

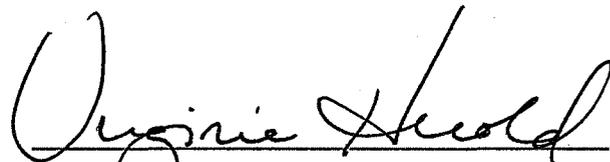
In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Anti-Nausea Treatment Options For Use With Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP EC dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.



Virginia Herold
Executive Officer
Board of Pharmacy

ATTACHMENT 4

Title 16, Beginning with Section 1735.1
Compounding Drug Products

Adopted Text

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

Amend Section 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.1. Compounding Definitions.

(a) "Equipment" means items that must be calibrated, maintained or periodically certified.

~~(a)~~ (b) "Integrity" means retention of potency until the expiration date noted on the label.

~~(b)~~ (c) "Potency" means active ingredient strength within +/- 10% of the labeled amount.

~~(c)~~ (d) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

~~(d)~~ (e) "Strength" means amount of active ingredient per unit of a compounded drug product.

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

Amend Section 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 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.

~~(2)~~ (4) Inactive ingredients to be used.

~~(3)~~ (5) Process and/or procedure used to prepare the drug.

~~(4)~~ (6) Quality reviews required at each step in preparation of the drug.

~~(5)~~ (7) Post-compounding process or procedures required, if any.

~~(6)~~ Expiration dating requirements.

(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. ~~01/11~~ 02/12.) 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.

To Amend Section 1735.3 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.3. Records of Compounded Drug Products.

(a) For each compounded drug product, the pharmacy records shall include:

- (1) The master formula record.
- (2) The date the drug product was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug product.
- (4) The identity of the pharmacist reviewing the final drug product.
- (5) The quantity of each component used in compounding the drug product.
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within ~~twenty-four~~ seventy-two (72) hours and stored in accordance with United States Pharmacopeia Standards for "REDISPENSED CSPs" in Chapter 797 (35th Revision, Effective May 1, 2012), which is hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
- ~~(7) The equipment used in compounding the drug product.~~
- ~~(8) (7)~~ A pharmacy assigned reference or lot number for the compounded drug product.
- ~~(9) (8)~~ The expiration date of the final compounded drug product.
- ~~(10) (9)~~ The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Note: Authority cited: Sections 4005, 4127 and 4169, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

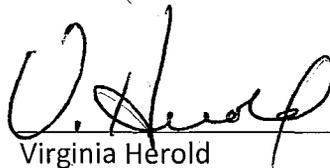
To Amend Section 1751.2 of Article 7 of Division 17 of Title 16 to read as follows:

§ 1751.2. Sterile Injectable Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

- (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- (b) Name and concentrations of ingredients contained in the sterile injectable product.
- (c) Instructions for storage and handling.
- (d) All cytotoxic agents shall bear a special label which states "Chemotherapy - Dispose of Properly." or "~~Cytotoxic Product~~ - Dispose of Properly."

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.



Virginia Herold
Executive Officer
Board of Pharmacy

ATTACHMENT 5

Awaiting Formal Public Notice

Proposals To

Amend Section 1732.2 – Board Accredited Continuing Education

*Amend 1732.5 – Specification of Continuing Education Credit in Specific
Content Areas*

*Amend Section 1732.05 – Update Accreditation Agencies for Continuing
Education*

*Add Section 1751.9 – Standards for Agencies that Accredite Sterile Injectable
Compounding Pharmacies*

1 **Title 16. Board of Pharmacy**
2 **Proposed Language**
3

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

6 **§ 1732.05. Accreditation Agencies for Continuing Education.**

7 (a) The following organizations are approved accreditation agencies:

8 (1) The Accreditation Council for Pharmacy Education.

9 (2) The ~~Pharmacy Foundation of California~~ [California Pharmacists Association](#).

10 (b) Accreditation agencies shall:

11 (1) Evaluate each continuing education provider seeking accreditation in accordance with the
12 provider's ability to comply with the requirements of section 1732.1 of this Division.

13 (2) Maintain a list of the name and address of the person responsible for the provider's continuing
14 education program. The accreditation agency shall require that any change in the responsible person's
15 identity shall be reported to the accreditation agency within 15 days of the effective date of the
16 change.

17 (3) Provide the board with the names, addresses and responsible party of each provider, upon request.

18 (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any
19 of its accredited providers or their coursework.

20 (5) Review at least one course per year offered by each provider accredited by the agency for
21 compliance with the agency's requirements and requirements of the board and, on request, report the
22 findings of such reviews to the board.

23 (6) Take such action as is necessary to assure that the continuing education coursework offered by its
24 providers meets the continuing education requirements of the board.

25 (7) Verify the completion of a specific continuing education course by an individual pharmacist upon
26 request of the board.

27 (c) Substantial failure of an approved accreditation agency to evaluate continuing education providers
28 as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation
29 agency by the board.

30
31 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232,
32 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 Pharmacists renewing their licenses which expire on or after July 1, 2015, shall be subject to the
82 requirements of this subdivision.

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

85

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

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100 **To Add § 1751.9 to Division 17 of Title 16 of the California Code of Regulations to read as follows:**

101

102 **§ 1751.9. Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products**

103 (a) An agency seeking to become an approved accrediting agency for pharmacies or nonresident
104 pharmacies that compound sterile injectable drug products pursuant to Business and Professions Code
105 sections 4127.1 or 4127.2 shall submit evidence satisfactory to the board as described in
106 subdivision (b) that:

107 (1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited
108 pharmacy at least annually. Site inspections shall be conducted to ensure compliance with Article 4.5
109 (commencing with Section 1735) and Article 7 (commencing with Section 1751) of Division 17 of
110 Title 16 of the California Code of Regulations governing the compounding of sterile injectable drug
111 products.

112 (2) The standards for granting accreditation shall reflect the Pharmacy Law.

113 (3) The surveyors who perform site inspections possess qualifications necessary to evaluate the
114 professional practices subject to accreditation. At least one member of the survey team must be a
115 licensed pharmacist. All health care practitioner surveyors must maintain current, active and
116 unrestricted licensure to practice their respective professions.

117 (4) The accrediting agency has sufficient personnel and resources to accredit California and non-
118 resident pharmacies.

119 (5) The accrediting agency has been operating for a minimum of two years with a history of
120 accrediting health care facilities.

121 (6) The accrediting agency shall provide the board access to an approved accrediting agency's report
122 on individual pharmacies for a three-year period following issuance of the report. Upon request of the
123 board, the agency shall provide the report within 10 business days.

124 (b) An agency seeking approval from the board must submit a formal written request to the board
125 signed by an authorized representative that includes the applicant owner's name, the company name,
126 address of record, and contact information along with the following information:

127 (1) A side-by-side comparison showing the agency's sterile compounding standards and describing
128 how each standard complies with each of the requirements of this Section.

129 (2) A list of employees performing survey inspections that also sets forth the name, title, license
130 number, license type, state of licensure and licensure status for each employee.

131 (3) A list of payers or organizations that the agency is recognized by, if applicable.

132 (4) A list of health care facility sites currently accredited by the agency including the name, location,
133 license type and license number of each site.

134 (5) A detailed description of the process used to evaluate health care facility sites seeking
135 accreditation or reaccreditation.

136 (6) Documentation of compliance with the requirements listed in the self-assessment form referenced
137 in section 1735.2(j) of Title 16 of the California of Code of Regulations in evaluating pharmacies and
138 non-resident pharmacies.

139 (7) Documentary or other evidence of a process to address non-compliance that may include any or
140 all of the following: (a) a requirement for correction of any identified deficiencies within a set
141 timeframe; (b) a requirement that failure to comply shall result in the accrediting agency issuing a
142 reprimand or suspending or revoking the accreditation; or, (c) a process for suspending or revoking the
143 licensed sterile injectable drug compounding pharmacy's accreditation.

144 (c) The Board of Pharmacy shall take action on a completed application at a scheduled board meeting,
145 as follows:

146 (1) If granted, the approval shall be valid for three years from the date of action by the board.

147 (2) If the approval is denied, the agency will be notified of the basis for the denial, including a
148 description of the standards that were not met. The agency may submit additional information to the
149 board for reconsideration of the denial within 30 days of the date of the notice of denial. The
150 reconsideration shall be considered at a scheduled board meeting and the accrediting agency may
151 show compliance with the standards set forth in this Section by producing new documentary evidence,
152 providing testimony or submitting other evidence demonstrating why the approval should be granted.

153 (d) After approval, an approved accreditation agency shall continue to meet the standards provided in
154 this Section and meet any conditions under which it is approved by the board. Failure to comply with
155 the standards set forth in this section or any conditions set by the board shall be grounds for rescission
156 of the board's approval.

157 (e) The accreditation agency shall, within 24 hours, report to the board any licensed sterile injectable
158 drug compounding pharmacy issued a reprimand or any licensed sterile injectable drug compounding
159 pharmacy whose accreditation has been suspended, revoked, or otherwise restricted by the
160 accrediting agency.

161 (f) On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a
162 report to the board listing all board-licensed pharmacies or nonresident pharmacies that are currently
163 accredited and have been accredited during the past 12 months with a notation of the outcome of
164 each inspection conducted by the accrediting agency.

165 (g) The board may conduct unannounced inspections of accredited sites to determine if the licensed
166 facility is in compliance with the Pharmacy Law. An accrediting agency shall cooperate with any board
167 investigation or inspection conducted by the board.

168 (h) Three months before the end of an approval or re-approval period, an approved accrediting
169 agency must submit a formal, written request for re-approval to the board or its designee for
170 continued recognition as an approved accrediting agency. The re-approval request shall provide the
171 information set forth in subdivision (b). If the re-approval application fails to demonstrate compliance
172 with this Section, or the board has evidence that the accrediting agency has failed to meet the
173 requirements of this section, the Board or its designee may issue and serve a notice of denial of re-
174 approval on the accrediting agency at its address of record with the board. The denial shall set forth
175 the factual and legal basis for the denial. Within 30 days of the date of the notice, the accrediting
176 agency may request an appeal of the decision to deny re-approval. If no appeal is requested, the
177 denial shall become final. If the board receives a request for an appeal of the notice, the request for an
178 appeal shall be considered a request for an informal hearing under the Administrative Procedure Act
179 (commencing with Section 11445.10 of the Government Code).

180 (i) Recognition of an approval shall continue pending the outcome of any appeal from a notice of
181 denial or rescission of any approval. However, if either a denial or rescission of an approval is upheld
182 after appeal, the accrediting agency shall notify all affected pharmacies or nonresident pharmacies of
183 the loss of the board's approval.

184 (j) The board may evaluate the performance of an approved accreditation agency and may rescind its
185 approval of the accreditation agency for failure to conform with the Pharmacy Law and standards
186 relating to sterile injectable drug compounding or any of the provisions of this section. The Board or its
187 designee may issue and serve a notice of rescission of approval on the accrediting agency at its address
188 of record with the board. The rescission notice shall set forth the factual and legal basis for the
189 rescission and set forth the process for appealing the notice. Within 30 days of the date of the notice,
190 the accrediting agency may request an appeal of the decision to rescind approval. If no appeal is
191 requested, the denial shall become final. If the board receives a request for an appeal of the notice,
192 the request for an appeal shall be considered a request for an informal hearing under the
193 Administrative Procedure Act (commencing with Section 11445.10 of the Government Code).

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195 Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:
196 Section 4127.1, Business and Professions Code.