California State Board of Pharmacy
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Phone (916) 574-7900
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www.pharmacy.ca.gov

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

Notice of Meeting and Agenda
Public Board Meeting
February 17, 2017

DATE(S) & TIME(S): February 17, 2017, at 9:00 a.m.

PLACE: Department of Consumer Affairs – First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

WEBCAST: http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml
(Webcast will be available earliest at 9:00 a.m. on February 17, 2017. See notices below.)

NOTE: Pharmacists and pharmacy technicians who attend in person may be awarded 6 hours of CE, in accordance with the Board's CE policy. Sign-in and sign-out on the day of the meeting will be required for the CE credit.

For questions or verification of the meeting, call Debbie Damoth at (916) 574-7935 or access the board's website at www.pharmacy.ca.gov.

Meeting materials should be available on the board's website at www.pharmacy.ca.gov by February 10, 2017.

Important Notices to the Public:

The meeting is open to the public and is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Debbie Damoth at (916) 574-7935, by emailing debbie.damoth@dca.ca.gov or sending a written request to the Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Discussion and action may be taken on any item on the agenda. The time and order of agenda items are subject to change at the discretion of the Board President. In accordance with the Bagley-Keene Open Meeting Act, all meetings of the Board are open to the public. The Board plans to webcast this meeting on its website at www.pharmacy.ca.gov. Webcast availability cannot, however, be guaranteed due to limited resources or technical difficulties. The meeting will not be cancelled if webcast is not available. If you wish to participate or to have a guaranteed opportunity to observe, please plan to attend at a physical location. Adjournment, if it is the only item that occurs after a closed session, may not be webcast.

Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by the Board or prior to the Board taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issues before the board, but the Board President may, at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before the Board to discuss items not on the agenda; however, the Board can neither discuss nor take official action on these items at the time of the same meeting (Government Code sections 11125, 11125.7(a)).

Agenda

Call to Order

I. Call to Order, Establishment of Quorum, and General Announcements

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

III. Comments from Senator Hernandez to the Board of Pharmacy

IV. Discussion and Consideration of the Proposed Regulation to Add Title 16 CCR Section 1746.5, Related to Travel Medications

V. Discussion and Consideration of the Proposed Regulation to Amend Title 16 CCR Section 1760, Related to Disciplinary Guidelines

VI. Automated Drug Delivery Systems (ADDS)
1. Presentation(s) Regarding Systems and Features Currently Available
2. Discussion of Current and Potential Circumstances Under which ADDS are Used and the Impact on Public Safety
3. Discussion and Consideration of Next Steps by the Board

Lunch
A lunch break will be taken at some point during each day's meeting.

VII. Closed Session
a. Pursuant to Government Code section 11126(c)(3), the Board may Convene in Closed Session to Deliberate on Disciplinary Matters, Including Petitions, Proposed Decisions, Stipulated Decisions, Defaults, and Any Other Disciplinary Matters.
b. Pursuant to Government Code section 11126(e), the Board may Convene in Closed Session to Discuss Pending Litigation

VIII. Reconvene Open Session

Adjournment **Upon conclusion of business**

1/31/2017

BOARD SETS SPECIAL MEETING ON AUTOMATED DRUG DELIVERY SYSTEMS

The California State Board of Pharmacy announces that it is holding a special meeting to discuss and consider possible changes in pharmacy laws to accommodate new technology and advances in the operation of automated drug delivery systems (ADDS) in a location that may be remote from the licensed pharmacy that provides oversight.

Background: Business and Professions Code sections 4105.5 and 4186, Health and Safety Code section 1261.6, and other provisions set specific requirements for pharmacies operating ADDS devices in licensed health facilities. Among other requirements, ADDS machines must "collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy and accountability." Key provisions specify who is responsible for stocking an ADDS machine with medication and how restocking may be done.

Because many ADDS devices today offer features not addressed in pharmacy law, the board is inviting vendors to present information about available technological features and how the devices are affected by existing laws.

The board is seeking ways to allow pharmacies to provide better quality care and service to patients while maintaining security and protecting the public from diversion of controlled substances and other prescription drugs. The board's focus during this meeting will be on reviewing ADDS technology that provides remote access to a health care professional (a nurse, anesthesiologist or other licensed provider).

Interested parties are invited to attend the board meeting at 9 a.m. Feb. 17, 2017, at 1625 N. Market Blvd., Sacramento, CA 95834. The meeting agenda is available on the board's website here.

Those wishing to present at the meeting will be invited to speak after a board review of a questionnaire to determine the relevancy of the ADDS device to the board's focus. If invited to speak, vendors will be advised to limit presentations to a brief demonstration or overview of their ADDS devices, focusing on inventory controls, security features and benefits to patient care. Vendors are asked to complete a questionnaire about their ADDS machines and to identify proposed changes to pharmacy law to more appropriately provide for use of such technology.

Vendors are asked to advise board staff no later than **5 p.m. Feb. 10** of their intent to present at the meeting; provide a copy of their presentation and responses to the ADDS questionnaire; and identify barriers that exist in current law. This will allow staff sufficient time to finalize the agenda and prepare materials for board members and the public.

To register or ask questions, please contact Debbie Damoth at (916) 574-7935 or debbie.damoth@dca.ca.gov.

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ADDS QUESTIONNAIRE

Vendor name _____

Contact information _____

1. In what specific patient care settings would this ADD be used? What are the security requirements for the remote location to ensure that medication access is limited only to authorized providers?

2. How will the pharmacist review medication orders? Is there an interface or other method that allows for prospective review, or is review only retrospective?

3. What specific features are available through the technology to ensure that the correct medication was removed per the provider's medication order?

4. What are the security features of the technology? How is user access maintained and by whom? Who has the ability to remove medications?

5. How are remote devices restocked? If the medication is transported after being checked by the pharmacist, what features are available that provide for detection of a tampered container?

6. Can controlled substances be stocked? If so, what additional security features are available?

7. How would patient consultation occur?

8. How would the ADDS remote user interact with the pharmacist? What technology options exist?

9. How would the pharmacist detect drug diversion for medications stocked in the ADDS? What reports are available to allow the pharmacist to monitor safe use of ADDS technology? Please provide an example of these reports.

10. What specific law changes are recommended to support the use of this remote ADDS technology?

Please submit completed questionnaire to Debbie Damoth by fax at (916) 574-8618 or by email at debbie.damoth@dca.ca.gov by **5 p.m. Feb. 10.**

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE

WORKGROUP ON COMPOUNDING

Ken Schell, Pharm.D.
John Tilley, R.Ph.

Hilton Oakland Airport
One Hegenberger Road
Oakland, CA 94621
(510) 635-5000

September 22, 2004
1:30 p.m. – 4:00 p.m.
Empire Room, Building 5

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 days prior to the meeting.

A. Call to Order **1:30 p.m.**

B. Introductions and Meeting Format

C. Discussion of Compounding Issues

- Law
  Manufacturing/Compounding
  Efficacy *Label on "unit of use" containers*
  Definition *Central Fill*
  Veterinary Anticipatory *OTC*
- Quality Standards
  Non-sterile (USP 795/1075)
  Equipment Quality/Process Validation
- Sterile Compounding
  USP797/Pending California Regulations
  Environmental Control
  Definition of inhalation drugs, otics, and ophthalmic
  Oils/suspensions
- *General Compounding Proposal*

D. Next Meeting – December 1, 2004

Adjournment **4:00 p.m.**

Meeting materials will be available on the board's Web site by September 17, 2004.

California State Board of Pharmacy
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Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Compounding Committee Report
July 11, 2019

Maria Serpa, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Greg Lippe, Public Member
Victor Law, Licensee Member

1. Call to Order and Establishment of Quorum

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings*
   **Note: The committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a)*

3. Discussion and Consideration of Proposed Amendments to Regulations Related to Pharmaceutical Compounding of Nonsterile Preparation

   Attachment 1

   Background
   During its February 20, 2019, meeting, members received a presentation on the proposed revisions to USP General Chapter 795, Pharmaceutical Compounding – Nonsterile Preparations. As part of that presentation, members were advised of USP's intended publication date of June 1, 2019, for the final chapter. Further, members were advised that December 1, 2019, is the intended official date for the revised chapter.

   USP has since released its final chapter, which is available for download from USP at www.USP.org.

   During this meeting
   During this meeting, members will have the opportunity to review proposed regulations intended to allow for the full implementation of USP 795 and provide clarity to members of the board's regulated public on the requirements that must be satisfied to prepare such products.

   The committee will have the opportunity to discuss the proposal and, if appropriate, make recommendations for the board's consideration during its July 2019 meeting.

   Attachment 1 includes two documents:
   1. Proposed regulation language to repeal and replace Article 4.5 related to Compounding.

2. Proposed regulation language that also includes a brief description of the necessity for the regulation provisions.

4. Approval of the April 16, 2019, Meeting Minutes

Attachment 2

Provided in **Attachment 2** for the committee's review and approval are the draft minutes from the February committee meeting.

5. Future Committee Meeting Dates

- August 28, 2019 – Staff is working to secure a location in Southern California. Once the location is finalized, the board's website will be updated and a subscriber alert will be sent.
- September 24, 2019
- October 16, 2019

6. Adjournment

Attachment 1

Proposal to Repeal Article 4.5 Compounding including Sections 1735-1735.8.

Proposal to Add Article 4.5 as proposed with the following:

Article 4.5 Nonsterile Compounding

1735. Compounding in Licensed Pharmacies

(a) "Compounding" as defined by United States Pharmacopeia in Pharmaceutical Compounding -Nonsterile Preparations Chapter 795 (USP Chapter <795>) occurs in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a patient specific prescription.

(b) Repackaging of a compounded nonsterile preparation (CNSP) shall be considered compounding and all requirements shall apply.

(c) Repackaging in accordance with directions which have not been FDA approved are still consider compounding and all requirements shall apply.

(d) No compounded non-sterile preparations (CNSPs) shall be compounded prior to receipt by a pharmacy of a valid patient specific prescription document where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription document prior to compounding. A signed and dated document between a prescriber and a pharmacy may serve as an understanding that all non-commercial available perpetrations will be compounded the identified patient.

(1) Except that a pharmacy may prepare and store a limited quantity of a CNSP in advance of receipt of a patient specific prescription document 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.

(e) No pharmacy or pharmacist shall compound a CNSP that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drug preparations have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, or the compounding of that CNSP is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(4) is made with any component not intended for use in a CNSP for the intended patient population.

(f) Prior to allowing any drug product preparation 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. XX/XX.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations.

(g) In addition to CCR 1707.2, consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of a CNSP and related supplies furnished by the pharmacy.

(h) Compounding with blood or blood components shall be done in compliance with Health and Safety Code section 1602.5.

(i)Weighing, measuring, compounding, and/or preforming other manipulation of an active pharmaceutical ingredient (API) or added substance deemed hazardous by Occupational Safety and Health (NIOSH) shall be done in compliance with CCR XXX and USP Chapter 800.

(j) Weighing, measuring, compounding, and/or preforming other manipulation of an antineoplastic under Occupational Safety and Health (NIOSH) shall be done in compliance with CCR XXX and USP chapter 800.

1735.1. INTRODUCTION AND SCOPE AND COMPOUNDING DEFINITIONS.
In addition to the definitions in the USP Chapter 795 and referenced chapters

(a) "Approved labeling" means the Food and Drug Administration's (FDA) approved labeling which contains FDA approved information for the diluent, the resultant strength, the container closure system, and storage time.

(b) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(c) "Diluent" is a liquid with no pharmacological activity used in reconstitution, such as water or sterile water for injection.

(e) "Integrity" means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.

(g) “Repackaging” means the act of removing a product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.

(h) “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

(i) “Product” means a commercially or conventionally manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(j) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(j) “Strength” means amount of active ingredient per unit of a compounded drug preparation.

1735.2 PERSONNEL TRAINING AND, EVALUATION
In addition to the requirements in USP Chapter 795 and referenced chapters.

(a) Training, evaluation, and requalification shall also contain at least the following:
(1) Quality assurance and quality control procedures,
(2) Container closure and equipment, selection and
(3) Component selection, and handling

(b) The pharmacist responsible for or directly supervising and controlling compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of CSNP.

(c) Personnel who fails any aspect of training or demonstrated competency, shall not be involved in the compounding process until after successfully passing reevaluations in the deficient area(s) as detailed in the SOPs.

(d) The pharmacist-in-charge shall be responsible for all activities and decisions made or approved by the designated person(s).

(e) Any person assigned to provide training must have documentation to show that they have obtained training and demonstrated competency an any area they will be providing training or observational review.

1735.3 PERSONAL HYGIENE AND GARBING
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Compounding personnel experiencing any of the following: rashes, recent tattoos or oozing

sores, conjunctivitis, active respiratory infection or and other conditions which could contaminate a CNSP or the environment shall not be allowed to enter the compounding area.

(b) Prior to entry into the compounding area all hand, wrist, and other exposed jewelry or piercing shall be removed.

(c) A gown and face mask shall be used whenever a closed system processing device is required.

(d) Disposable garb shall not be shared by staff and shall be discarded after each shift and when soiled. Garb removed during a shift must be maintained in the compounding area.

(e) Non-disposable garb shall be cleaned with a germicidal detergent and sanitized with 70% isopropyl alcohol before re-use.

(f) Eye glasses shall be cleaned as part of hand hygiene and garbing per a facility standard operating procedures (SOPs).

(g) Any gowning or garbing accommodation made by the designated person shall be documented and a full assessment of the risk to the CNSPs and environment shall be included. Documentation and assessment shall be done prior to accommodation taking place.

1735.4 BUILDING AND FACILITIES
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) The handwashing stations/scrub sink used for compounding and/or hand hygiene shall not be part of a restroom or water closet.

(b) Compounding personnel must monitor temperatures in storage area(s) and compounding areas either manually at least once daily on days that the facility is open or by a continuous temperature recording device to determine whether the temperature remains within the appropriate range for the CNSPs or components. This shall be documented.

(c) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.

(d) If compounding is performed daily, no activity other than compounding shall take place in the compounding area.

(e) No CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures or those required in USP chapter 795.

1735.5 CLEANING AND SANITIZING

In addition to the requirements in the USP Chapter 795 and reference chapters

(a) Cleaning and sanitizing of the compounding area must be documented each time it occurs. The personnel completing the cleaning and sanitizing shall be identified as well as the cleaning and sanitizing agents used.

(b) Decontamination, cleaning, disinfecting and sporicidal agents shall be used in accordance with manufacturers' specifications.

1735.6 EQUIPMENT AND COMPONENTS
In addition to the requirements in the USP Chapter 795 and referenced chapters
(a) Any equipment used to compound CNSP shall be used, in accordance with manufacturers' specifications.

(b) Any weighing, measuring, or other manipulation of a components in powder form shall occur inside a closed system processing device such as a ventilated enclosures (CVEs), or biological safety cabinets (BSCs).

(1) Closed system processing devices shall be certified according to current Controlled Environment Testing Association (CETA) guidelines.

(c) Any component used to compound a CNSP shall be used, stored, and dispensed, in accordance with all the following:

(1) United States Pharmacopeia (USP)- National formula (NF),

(2) Food Drug and Cosmetic Act (FD&CA),

(3) Food Drug Administration (FDA), and

(4) Manufacturers' specifications and requirements.

(d) Any API or added substance used to compound a CNSP shall be obtained from an FDA-registered supplier and shall be accompanied by a valid certificate of analysis (COA). This COA shall be in English and should all the requirements of Bulk Pharmaceutical Excipient-certificate of analysis, USP Chapter 1080. All COAs shall be readily retrievable for at least 3 years from last use in CNSP.

(e) Once removed from the original container, components not used in compounding (e.g., excess after weighing) shall be discarded and not returned to the original container to minimize the risk of contaminating the original container.

1735.7. MASTER FORMULATION AND COMPOUNDING RECORDS
In addition to the requirements in the USP Chapter 795 and referenced chapters.

(a)A CNSP shall not be compounded until the pharmacy has first prepared a written master formula document in compliance with USP Chapter 795 and the following:

(1) Active pharmaceutical ingredient (API) or added substances identities and amounts shall include at least salt form and purity grade.
(2) Container–closure systems shall include at least volume, and type for each container and closure to be used.
(3) The reference source of the BUD assignment; each reference shall be fully available at the time of compounding and 3 years from each dispense.
(4) Instructions for storage and handling of the compounded drug preparation.

(b) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself. This record shall be in compliance with USP 795 and 1735.7(a).

(c) A compounding log shall be a single document and shall include the requirements of USP chapters 795, and 800 as applicable, and the following:
(1) The date and time of preparation shall be the time when compounding started and when the assigned BUD starts.
(2) the assigned internal identification number shall be unique for each compounded drug preparation.
(3) the total quantity compounded shall include the number of units made and volume or weight of each unit.
(4) The identity of the compounder and pharmacist verifying the final drug preparation.

1735.8 RELEASE INSPECTIONS
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) The pharmacist performing, or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed once the preparation is dispensed.

1735.9 LABELING
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) A CNSP shall be labeled incompliance with USP Chapter 795 and the following:
(1) label shall also include:
(A) Route of intended administration
(B) Name of compounding pharmacy and dispensing pharmacy (if different)
(2) Labeling shall also include:
(A) Any special handling instructions
(B) Any warning statements that are applicable
(C) Name, address, and contact information of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded

(b)Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include

on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

1735.10 ESTABLISHING BEYOND-USE DATES
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Beyond use dates (BUDs) assigned with only a date shall expire at midnight on that date.

(b) No Beyond Use Date (BUDs) shall be assigned that exceeds:
(1) The limits defined in USP Chapter 795
(2) The chemical and physical properties of the drug and/or its formulation.
(3) The compatibility of the container–closure system with the finished preparation (e.g., leachables, interactions, and storage conditions)
(4) shortest remaining expiration date or BUD of any of the starting components.

(c) If the BUD of the CNSP is extended beyond the BUDs in USP Chapter 795, an aqueous CNSP, as defined by USP Chapter 795, shall be tested for antimicrobial effectiveness, in compliance with Antimicrobial Effectiveness Testing USP Chapter <51>.
(1) if a pharmacy chooses to use antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature sources the full reference, including the raw data and testing method suitability, and shall be fully available at the time of compounding and 3 years from each dispense.

1735.11 SOPs
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Standard operating procedures (SOPs) shall:
(1) Comply with Quality Assurance in Pharmaceutical Compounding USP Chapter 1163,
(2) Include at least the SOPs listed in Quality Assurance in Pharmaceutical Compounding USP Chapter 1163, and
(3) include the following:
(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdictional standards.

(C) The determination and approval, by a pharmacist, of the ingredients and the compounding process for each preparation before compounding begins

(b) Any pharmacy engaged in compounding non-sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(c) The policies and procedures shall be reviewed, and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented. Such changes shall be documented and disseminated to the appropriate staff prior to implementation.

1735.12 QUALITY ASSURANCE AND QUALITY CONTROL
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) The quality assurance program shall also include the following:

(1) a written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, potency, quality, or labeled strength.

(2) a written procedure for responding to out-of-range temperature variations within the medication storage areas where furnished drug is returned for redispensing

(3) compliance with Quality Assurance in Pharmaceutical Compounding USP chapter 1163 and shall include the integrated components and standard operating procedures.

(4) Quality assurance program shall be compliant with section CCR 1711.

1735.13 PACKAGING AND TRANSPORTING
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) There shall be a defined process and documented procedure to ensure heat/cold sensitive products will arrive at their desired destinations after transporting within the expected quality standards for integrity, potency, quality and labeled strength.

(b) Packaging materials shall protect CNSPs from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transport personnel.

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

1735. 14 COMPLAINT HANDLING AND ADVERSE EVENT REPORTING
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Recalls shall be carried out in compliance with Business and Professions Code section 4126.9,

(b) All complaints related to a potential quality problem with a compounded drug preparation

and all adverse events shall be reviewed by the pharmacist-in-charge, this review shall be documented and dated. All complaints shall be handled in compliance with Business and Professions Code section 4126.9.

1735.15 DOCUMENTATION
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Pharmacies shall maintain and retain all records required by this article and requirements in the USP chapters in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

(b) Records created shall be in an un-editable form. If edits are needed it must be tracked and the person making the edits along with date and time shall be documented. As used in the subdivision: Tracked is means the original documentation is readable and notes any changes made.

Proposal to Repeal Article 4.5 Compounding including Sections 1735-1735.8.

Proposal to Add Article 4.5 as proposed with the following:

Article 4.5 Nonsterile Compounding

1735. Compounding in Licensed Pharmacies

(a) "Compounding" as defined by United States Pharmacopeia in Pharmaceutical Compounding -Nonsterile Preparations Chapter 795 (USP Chapter <795>) occurs in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a patient specific prescription.

Necessity: Defines the locations for USP applicability to the board's regulated public.

(b) Repackaging of a compounded nonsterile preparation (CNSP) shall be considered compounding and all requirements shall apply.

Necessity: Provides clarity to the regulated public as the provisions USP related repackaging provisions speak only to conventionally manufactured products. Absent this provision, the board's regulated public would be unclear if the repackaging of a compounded nonsterile preparations was allowed and if so, under what conditions.

(c) Repackaging in accordance with directions which have not been FDA approved are still consider compounding and all requirements shall apply.

Necessity: This provide clarity because USP does not provide direction on what type of practice repackaging of a preparation is.

(d) No compounded non-sterile preparations (CNSPs) shall be compounded prior to receipt by a pharmacy of a valid patient specific prescription document where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription document prior to compounding. A signed and dated document between a prescriber and a pharmacy may serve as an understanding that all non-commercial available perpetrations will be compounded the identified patient.

(1) Except that a pharmacy may prepare and store a limited quantity of a CNSP in advance of receipt of a patient specific prescription document 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.

Necessity: Ensures consistency with 503A provisions.

(e) No pharmacy or pharmacist shall compound a CNSP that:

(1) Is classified by the FDA as demonstrably difficult to compound;
(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drug preparations have been found to be unsafe or not effective; or
(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, or the compounding of that CNSP is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.
(4) is made with any component not intended for use in a CNSP for the intended patient population.

Necessity: To ensure consistency with general provisions of federal law including 503A provisions SEC 503a (353a (b)(3)(A), SEC 503a (353a (b)(1) (C), CFR 216.24 and SEC 503a (353a (b)(1) (D), as well as o allow use of the specified ASHP list as necessary for patient care. Duplication with federal law provides for ease of use with the board's regulated public. Further proposed sections (e)(1) – (3) are consistent with current regulations. Further, (e)(4) ensures only appropriately graded (based on intended use, patient, etc.). Would prohibit inappropriate graded products from use in compounded products.

(f) Prior to allowing any drug product preparation 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. XX/XX.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations.

Necessity: This is consistent with current regulation and provides for consumer protection through self-education and assessment by licensee.

(g) In addition to CCR 1707.2, consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of a CNSP and related supplies furnished by the pharmacy.

Necessity: This is consistent with current requirements.

(h) Compounding with blood or blood components shall be done in compliance with Health and Safety Code section 1602.5.

Necessity: Provides clarity to the regulated public about the supplemental requirements established the HSC.

(i)Weighing, measuring, compounding, and/or preforming other manipulation of an active pharmaceutical ingredient (API) or added substance deemed hazardous by Occupational Safety and Health (NIOSH) shall be done in compliance with CCR XXX and USP Chapter 800.

Necessity: Provides clarity to the regulated public about the supplemental requirements that must be followed in USP 800.

(j) Weighing, measuring, compounding, and/or preforming other manipulation of an antineoplastic under Occupational Safety and Health (NIOSH) shall be done in compliance with CCR XXX and USP chapter 800.

Necessity: Provides clarity to the regulated public about the supplemental requirements that must be followed in USP 800.

1735.1. INTRODUCTION AND SCOPE AND COMPOUNDING DEFINITIONS.
In addition to the definitions in the USP Chapter 795 and referenced chapters

(a) "Approved labeling" means the Food and Drug Administration's (FDA) approved labeling which contains FDA approved information for the diluent, the resultant strength, the container closure system, and storage time.

Necessity: Provides clarity to the regulated public as to what is meant by Approved labeling in USP.

(b) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

Necessity: Ensures consistency with the provisions of 503A with the increase of the word "clinically' to eliminate abuse. Reference: SEC 503a (353a (b)(1) (D)(2)).

(c) "Diluent" is a liquid with no pharmacological activity used in reconstitution, such as water or sterile water for injection.

Necessity: Provides clarity to the board's regulated public about what a diluent is for purposes of compounding and its implications for FDA labeling. USP does not provide a definition.

(e) "Integrity" means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.

Necessity: Term is broadly used throughout the Chapter, but is not defined. Further, the definition is consistent with current legal definition.

(g) "Repackaging" means the act of removing a product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.

Necessity: Term is broadly used throughout the Chapter, but is not defined. This definition is drawn from from USP 797.

(h) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

Necessity: This provision is consistent with the board's current regulation. Further, the definition is necessary to ensure that the regulated public understands that a preparation refers to an item that is compounded versus a commercially available product. The term is broadly used throughout the Chapter, but is not defined.

(i) "Product" means a commercially or conventionally manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

Necessity: The term is broadly used throughout the Chapter, but is not defined.

(j) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

Necessity: Term is broadly used throughout the Chapter, but is not defined. Further, the language is consistent with current legal definition in regulation.

(j) "Strength" means amount of active ingredient per unit of a compounded drug preparation.

Necessity: Term is broadly used throughout the Chapter, but is not defined. Consistent with current legal definition in regulation.

1735.2 PERSONNEL TRAINING AND, EVALUATION
In addition to the requirements in USP Chapter 795 and referenced chapters.

(a) Training, evaluation, and requalification shall also contain at least the following:
- (1) Quality assurance and quality control procedures,
- (2) Container closure and equipment, selection and
- (3) Component selection, and handling

Necessity: Comprehensive training is essential to ensure the safety of California consumers dispensed or administered a CNSP.

(b) The pharmacist responsible for or directly supervising and controlling compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of CSNP.

Necessity: Because USP requires a facility to designate one or more individuals, a designated person, this needs to be clarified to ensure that the requirement applies to a pharmacist, who under pharmacy law, must be supervising or performing the compounding.

(c) Personnel who fails any aspect of training or demonstrated competency, shall not be involved in the compounding process until after successfully passing reevaluations in the deficient area(s) as detailed in the SOPs.

Necessity: Allowing an individual to compound inappropriately will compromise consumer protection, as such immediate remediation is necessary.

(d) The pharmacist-in-charge shall be responsible for all activities and decisions made or approved by the designated person(s).

Necessity: Remove any doubt about the role of the PIC in pharmacy law and his or her ultimate responsibility for compliance.

(e) Any person assigned to provide training must have documentation to show that they have obtained training and demonstrated competency an any area they will be providing training or observational review.

Necessity: Provides clarity to the regulated public that any person who has proper training may provide training to others, as long as the person can demonstrate appropriate competency to do so. Also, provides clarity that other staff besides the PIC can, if properly trained, may provide training or observational review.

1735.3 PERSONAL HYGIENE AND GARBING
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions which could contaminate a CNSP or the environment shall not be allowed to enter the compounding area.

Necessity: To eliminate the potential of contamination of CNSPs, such protections are mandatory, not discretionary. The list of conditions was developed based on the USP 795 requirements.

(b) Prior to entry into the compounding area all hand, wrist, and other exposed jewelry or piercing shall be removed.

Necessity: Provides clarity to the regulated public that such items must be removed for patient care. Further, proper fit of garb should not be subjective.

(c) A gown and face mask shall be used whenever a closed system processing device is required.

Necessity: To prevent the cross contamination and inadvertent inhalation of components when the component is a powder.

(d) Disposable garb shall not be shared by staff and shall be discarded after each shift and when soiled. Garb removed during a shift must be maintained in the compounding area.

Necessity: To prevent contamination of the garb used in compounding.

(e) Non-disposable garb shall be cleaned with a germicidal detergent and sanitized with 70% isopropyl alcohol before re-use.

Necessity: Although this is only a recommendation on the USP chapter, to prevent contamination, the cleaning of such garb must be mandatory. Failure to do so, can lead to product contamination.

(f) Eye glasses shall be cleaned as part of hand hygiene and garbing per a facility standard operating procedures (SOPs).

Necessity: To prevent product contamination, some level of cleaning must be performed.

(g) Any gowning or garbing accommodation made by the designated person shall be documented and a full assessment of the risk to the CNSPs and environment shall be included. Documentation and assessment shall be done prior to accommodation taking place.

Necessity: To provide accommodation and flexibility to staff after full assessment of the risk has been considered and determination has been made that preparation is not compromised.

1735.4 BUILDING AND FACILITIES
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) The handwashing stations/scrub sink used for compounding and/or hand hygiene shall not be part of a restroom or water closet.

Necessity: USP is silent on the location of a sink. Restroom sinks are a significant source of contamination and as such are not an appropriate location for such function to occur. This is

also consistent with current board regulation.

(b) Compounding personnel must monitor temperatures in storage area(s) and compounding areas either manually at least once daily on days that the facility is open or by a continuous temperature recording device to determine whether the temperature remains within the appropriate range for the CNSPs or components. This shall be documented.

Necessity: To ensure the appropriate temperature range of both the components and compounding areas, monitoring must be performed and documented.

(c) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.

Necessity: To ensure no product contamination results from the use of poor quality (tap water) water being used to wash the equipment used in compounding.

(d) If compounding is performed daily, no activity other than compounding shall take place in the compounding area.

Necessity: To provide clarity to the regulated public on what can and cannot occur in the compounding area.

(e) No CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures or those required in USP chapter 795.

Necessity: Requires the cessation of compounding in an environment found to be noncompliant to prevent the risk of contamination.

1735.5 CLEANING AND SANITIZING
In addition to the requirements in the USP Chapter 795 and reference chapters

(a) Cleaning and sanitizing of the compounding area must be documented each time it occurs. The personnel completing the cleaning and sanitizing shall be identified as well as the cleaning and sanitizing agents used.

Necessity: To ensure proper cleaning occurs and appropriate information documented to confirm compliance.

(b) Decontamination, cleaning, disinfecting and sporicidal agents shall be used in accordance with manufacturers' specifications.

Necessity: Only products used consistent with the manufacturers specification can be used

to perform decontamination, cleaning, disinfecting and sporicidal agent to ensure appropriate decontamination, cleaning and disinfecting is achieved.

1735.6 EQUIPMENT AND COMPONENTS

In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Any equipment used to compound CNSP shall be used, in accordance with manufacturers' specifications.

Necessity: Failure to use equipment according to manufacturer's specification can impact the safety and efficacy of the preparation.

(b) Any weighing, measuring, or other manipulation of a components in powder form shall occur inside a closed system processing device such as a ventilated enclosures (CVEs), or biological safety cabinets (BSCs).

(1) Closed system processing devices shall be certified according to current Controlled Environment Testing Association (CETA) guidelines.

Necessity: To ensure containment of any powder and avoid possible cross contamination and inadvertent inhalation of powders.

(c) Any component used to compound a CNSP shall be used, stored, and dispensed, in accordance with all the following:

(1) United States Pharmacopeia (USP)- National formula (NF),

(2) Food Drug and Cosmetic Act (FD&CA),

(3) Food Drug Administration (FDA), and

(4) Manufacturers' specifications and requirements.

Necessity: To ensure safe and appropriate component selection in CNSPs to avoid patient harm.

(d) Any API or added substance used to compound a CNSP shall be obtained from an FDA-registered supplier and shall be accompanied by a valid certificate of analysis (COA). This COA shall be in English and should all the requirements of Bulk Pharmaceutical Excipient-certificate of analysis, USP Chapter 1080. All COAs shall be readily retrievable for at least 3 years from last use in CNSP.

Necessity: The FD&C establishes that only APIs from a registered facility can be used. To ensure only proper added substances are used, the same threshold as required for APIs must be applied related to purchasing and COA requirements to avoid patient harm.

(e) Once removed from the original container, components not used in compounding (e.g., excess after weighing) shall be discarded and not returned to the original container to minimize the risk of contaminating the original container.

Necessity: To prevent contamination of components by reintroducing already removed product which may have been compromised.

1735.7. MASTER FORMULATION AND COMPOUNDING RECORDS
In addition to the requirements in the USP Chapter 795 and referenced chapters.

(a)A CNSP shall not be compounded until the pharmacy has first prepared a written master formula document in compliance with USP Chapter 795 and the following:

(1) Active pharmaceutical ingredient (API) or added substances identities and amounts shall include at least salt form and purity grade.
(2) Container–closure systems shall include at least volume, and type for each container and closure to be used.
(3) The reference source of the BUD assignment; each reference shall be fully available at the time of compounding and 3 years from each dispense.
(4) Instructions for storage and handling of the compounded drug preparation.

Necessity: Provides clarification regarding the expectation for documentation to ensure complete records. Note: this does not expand upon USP requirements regarding master formulas.

(b) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself. This record shall be in compliance with USP 795 and 1735.7(a).

Necessity: This will allow the current practice for such documentation to continue for those products not routinely compounded.

(c) A compounding log shall be a single document and shall include the requirements of USP chapters 795, and 800 as applicable, and the following:

(1) The date and time of preparation shall be the time when compounding started and when the assigned BUD starts.
(2) the assigned internal identification number shall be unique for each compounded drug preparation.
(3) the total quantity compounded shall include the number of units made and volume or weight of each unit.
(4) The identity of the compounder and pharmacist verifying the final drug preparation.

Necessity: Provides clarification as what is expected in the documentation to ensure complete records and establishes a requirement to document the staff involved in the compounding on the log, including the pharmacist performing verification of the final drug preparation. Such documentation ensures a complete record and allows for identification and remediation of staff if necessary.

1735.8 RELEASE INSPECTIONS
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) The pharmacist performing, or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed once the preparation is dispensed.

Necessity: This is current law. USP does not establish the responsibility of the pharmacist involvement in compounding as the USP Chapter applies to all settings where compounding occurs. Clarification is necessary to ensure the board's regulated public has a clear understanding of his or her responsibility.

1735.9 LABELING
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) A CNSP shall be labeled incompliance with USP Chapter 795 and the following:
(1) label shall also include:
(A) Route of intended administration
(B) Name of compounding pharmacy and dispensing pharmacy (if different)
(2) Labeling shall also include:
(A) Any special handling instructions
(B) Any warning statements that are applicable
(C) Name, address, and contact information of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded

Necessity: It is imperative that any CNSP leaving a facility shall be properly labeled for patient safety and to avoid patient harm, USP provisions make these items recommendations only. Patients must have a clear understanding of how to take their medications as well as how to contact the compounding pharmacy.

(b)Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

Necessity: This is current law and requires patient specific labeling on a compounded product.

1735.10 ESTABLISHING BEYOND-USE DATES
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Beyond use dates (BUDs) assigned with only a date shall expire at midnight on that date.

Necessity: To provide clarity to the regulated public on the board's expectation regarding

determination of a BUD.

(b) No Beyond Use Date (BUDs) shall be assigned that exceeds:
(1) The limits defined in USP Chapter 795
(2) The chemical and physical properties of the drug and/or its formulation.
(3) The compatibility of the container–closure system with the finished preparation (e.g., leachables, interactions, and storage conditions)
(4) shortest remaining expiration date or BUD of any of the starting components.

Necessity: To avoid patient harm the above parameters shall be used to assign the BUD. Under USP section 10 the above items may be optional in establishment of a BUD. To ensure the integrity, potency, quality and labeled strength of a preparation the above parameters shall be used to limit the BUD.

(c) If the BUD of the CNSP is extended beyond the BUDs in USP Chapter 795, an aqueous CNSP, as defined by USP Chapter 795, shall be tested for antimicrobial effectiveness, in compliance with Antimicrobial Effectiveness Testing USP Chapter <51>.
(1) if a pharmacy chooses to use antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature sources the full reference, including the raw data and testing method suitability, and shall be fully available at the time of compounding and 3 years from each dispense.

Necessity: Ensures compliance with relevant USP Chapters and establishes the timeframe for documentation. Further, this provides clarity to the board's regulated public on the board's expectations.

1735.11 SOPs
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Standard operating procedures (SOPs) shall:
(1) Comply with Quality Assurance in Pharmaceutical Compounding USP Chapter 1163,
(2) Include at least the SOPs listed in Quality Assurance in Pharmaceutical Compounding USP Chapter 1163, and
(3) include the following:
(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdictional standards.

(C) The determination and approval, by a pharmacist, of the ingredients and the compounding process for each preparation before compounding begins

Necessity: Ensures compliance with relevant USP Chapters and provides clarity to the board's regulated public on the board's expectation.

(b) Any pharmacy engaged in compounding non-sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

Necessity: The above language is in current law in the under CCR 1735.3(a) and 1735.5(a) and provides clarity to the regulated public on the board's expectations and enforceability.

(c) The policies and procedures shall be reviewed, and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented. Such changes shall be documented and disseminated to the appropriate staff prior to implementation.

Necessity: The above language is in current law and clarifies the need to document any changes in the policy prior to implementation. CCR 1735.5(b)

1735.12 QUALITY ASSURANCE AND QUALITY CONTROL
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) The quality assurance program shall also include the following:

(1) a written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, potency, quality, or labeled strength.

(2) a written procedure for responding to out-of-range temperature variations within the medication storage areas where furnished drug is returned for redispensing

(3) compliance with Quality Assurance in Pharmaceutical Compounding USP chapter 1163 and shall include the integrated components and standard operating procedures.

(4) Quality assurance program shall be compliant with section CCR 1711.

Necessity: A robust QA program is essential for consumer protection. The proposed language is consistent with current legal requirements in board regulation (e.g. 1735.8(d) and CCR 1735.8(e). USP established separate sections for Quality Assurance and Quality Control (Section 12) and Complaint Handling and Adverse Event Reporting (Section 14.) Further, a comprehensive QA program must include the process to follow in the event of a recall and procedures to follow in the event of a temperature excursion. This section also provides cross reference to relevant USP chapters to assist with full compliance with USP and to ensure consistency within the practice.

1735.13 PACKAGING AND TRANSPORTING
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) There shall be a defined process and documented procedure to ensure heat/cold sensitive products will arrive at their desired destinations after transporting within the expected quality standards for integrity, potency, quality and labeled strength.

Necessity: A process and procedure is necessary to ensure the product arrives with the same integrity, potency, quality and labeled strength as labeled. USP provides general requirements but lacks sufficient specificity on the minimum requirements.

(b) Packaging materials shall protect CNSPs from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transport personnel.

Necessity: USP provides this as a recommendation only, however to ensure proper packaging of a CNSP to ensure patient safety it must be a requirement.

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

Necessity: This provision is consistent with current board regulation. Further, because USP is applicable in all settings where compounding can occur, clarification to board licensees on the board's requirements and board jurisdiction is necessary.

1735. 14 COMPLAINT HANDLING AND ADVERSE EVENT REPORTING
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Recalls shall be carried out in compliance with Business and Professions Code section 4126.9,

Necessity: Establishes a cross-reference to the underlying statute regarding recall provisions for nonsterile compounded drug products.

(b) All complaints related to a potential quality problem with a compounded drug preparation and all adverse events shall be reviewed by the pharmacist-in-charge, this review shall be documented and dated. All complaints shall be handled in compliance with Business and Professions Code section 4126.9.

Necessity: As USP requirements apply to all settings where compounding can occur, clarification on the board's expectation regarding the responsibility of the PIC is necessary to ensure a common understanding of the applicability of the requirement for board licensees.

1735.15 DOCUMENTATION
In addition to the requirements in the USP Chapter 795 and referenced chapters

(a) Pharmacies shall maintain and retain all records required by this article and requirements in the USP chapters in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Necessity: The above language is in current law (CCR 1735.3(b) and clarifies the board's expectation for compliance.

(b) Records created shall be in an un-editable form. If edits are needed it must be tracked and the person making the edits along with date and time shall be documented. As used in the subdivision: Tracked is means the original documentation is readable and notes any changes made.

Necessity: Records should not editable to ensure proper tracking and compliance. This is needed to ensure the original document is correct and appropriate audit of changes is maintained.

Attachment 2

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

DRAFT

COMPOUNDING COMMITTEE MEETING MINUTES

DATE: April 16, 2019

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chairperson
Stan Weisser, Licensee Member, Vice Chairperson
Victor Law, Licensee Member
Allen Schaad, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Shirley Kim, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Julia Ansel, Chief of Enforcement
Christine Acosta, Supervising Inspector
Laura Hendricks, Staff Analyst
Laura Freedman, DCA Staff Counsel
Kelsey Pruden, DCA Staff Counsel

1. **Call to Order and Establishment of Quorum and General Announcements**

   Chairperson Serpa called the meeting to order at 10:05 am. Board members present: Allen Schaad, Maria Serpa, Stan Weisser and Victor Law. A quorum was established.

2. **Public Comment on Items not on the Agenda/Agenda Items for Future Meetings**

   There were no comments from the committee or the public.

3. **Presentation on the Proposed USP Chapter 800 – Hazardous Drugs – Handling in Healthcare Settings**

   The committee heard a presentation on the current proposed revisions to USP General Chapter 800 regarding the handling of hazardous drugs by Supervising Inspector Christine Acosta.

Supervising Inspector Acosta provided an overview of the United States Pharmacopeia (USP) 2015-2020 Council of Experts including Healthcare Quality Standards Collaborative Group which includes compounding. USP maintains resolutions to work with stakeholders in the development and maintenance of practice and quality standards in sterile and nonsterile compounding. USP includes General Chapters: <795> – Pharmaceutical Compounding – Nonsterile Products; <797> – Pharmaceutical Compounding – Sterile Preparations; <800> – Hazardous Drugs – Handling in Healthcare Settings; and <825> – Radiopharmaceutical Preparation, Compounding, Dispensing, and Repackaging. Dr. Acosta updated the committee on the status of USP revising Chapter <797> and subsequent revisions. The committee was provided with a summary of the changes made in draft Chapter <797> based on the 18 sections.

Dr. Acosta stated that the National Institute for Occupational Safety and Health (NIOSH) is a division of Center for Disease Control and Prevention (CDC). She explained that NIOSH developed a list of antineoplastic and other hazardous drugs in healthcare settings. Dr. Acosta noted that the list has not been updated in 2018, but an updated list is expected to be released soon (typically it is updated every two years).

Dr. Acosta reviewed the following six characteristics that are used by NIOSH to determine if a drug is hazardous in humans or animals.

- Carcinogenicity
- Teratogenicity or fertility impairment
- Reproductive toxicity
- Organ toxicity
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous

Dr. Acosta explained that NIOSH organizes hazardous drugs into categories which are commonly referred to as "tables." Dr. Acosta summarized the characteristics of each of the tables as provided below.

Table 1. Group 1: Antineoplastic drugs

- One or more of the NIOSH criteria for a hazardous drug.
- Many of these drugs are cytotoxic.
- Represent an occupational hazard to healthcare workers and should ***always*** be handled with use of recommended engineering controls and personal protective equipment (PPE), regardless of their formulation.

Table 2. Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug

- Some of these drugs may represent an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.
- Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation.

Table 3. Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

- NIOSH criteria for reproductive hazards.
- Represent a potential occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, as they may be present in breast milk.
- Unopened, intact tablets and capsules may not pose the same degree of occupational risk as injectable drugs that usually require extensive preparation.

Table 4

- Contains drugs that were deleted from the 2014 NIOSH hazardous drug list for the 2016 update; however, there are no deletions to report.

Table 5

- Provides general guidance for some of the possible scenarios that may be encountered in healthcare settings where hazardous drugs are handled.

Dr. Acosta explained that NIOSH defines the criteria and identifies hazardous drugs (HD), while USP develops the standards for handling these HDs to minimize the risk to public health. Dr. Acosta stated that the goals of the USP standards are to help increase awareness, provide uniform guidance to reduce the risk of managing HD, and help reduce the risk posed to patients and the healthcare workforce. Dr. Acosta noted that healthcare workers will become patients if they are exposed to these HDs without the proper precautions.

Dr. Acosta stated that there has been a delay in enforceable date for USP 800 due to the number of comments and stakeholders involved; however, it is expected to become enforceable on December 1, 2019.

Dr. Acosta recommended that interested parties visit the frequently asked questions section of USP's website because it contains a wealth of information broken down in an easy to search format.

Dr. Acosta reported that USP 800 is broken down into the following 18 sections. She noted that her presentation would also be broken down into these sections.

1. Introduction and Scope
2. List of Hazardous Drugs
3. Types of Exposure
4. Responsibilities of Personnel Handling Hazardous Drugs
5. Facilities and Engineering Controls
6. Environmental Quality and Control
7. Personal Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, and Disposal
12. Dispensing Final Dosage Forms
13. Compounding

14. Administering
15. Deactivating, Decontaminating, Cleaning, and Disinfecting
16. Spill Control
17. Documentation and Standard Operating Procedures
18. Medical Surveillance

Section 2. List of Hazardous Drugs

Dr. Acosta explained that NIOSH maintains a list of antineoplastic and other HDs used in healthcare. The entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. Dr. Acosta added that the list must be reviewed at least every 12 months and whenever a new agent or dosage form is used.

Dr. Acosta explained that section two contains the criteria that can be used by pharmacists to determine if containment requirements in USP 800 must be followed or when an "assessment of risk" can be conducted to determine alternative containment strategies.

Dr. Acosta explained that any HD active pharmaceutical ingredient (API) must follow the requirements in the chapter. She also provided the following definition of API: "any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body." Dr. Acosta stated that any antineoplastic requiring HD manipulation must also follow all of the requirements of the chapter.

Dr. Acosta explained that drugs on the NIOSH list that do not have to follow all of the containment requirements of this chapter if an assessment of risk (AOR) is performed and implemented include: final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer). Dr. Acosta stated that for dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and work practices.

Dr. Acosta reported that an AOR must document what alternative containment strategies and/or work practices are being employed for dosage forms to minimize occupational exposure. She added that it must be reviewed at least every 12 months and the review must be documented. Dr. Acosta also stated that the AOR must, at a minimum, consider the following:

- Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
- Dosage form
- Risk of exposure
- Packaging
- Manipulation

Dr. Acosta explained that an assessment of risk (AOR) may be performed for dosage forms to determine alternative containment strategies and/or work practices.

Section 3. Types of Exposure

Dr. Acosta highlighted the potential opportunities of exposure based on activity as provided in Section 3. For example, the risk of exposure that can occur while transporting HDs within a healthcare setting. Dr. Acosta provide Table 1 further examples.

Section 4. Responsibility of Personnel Handling Hazardous Drugs

Dr. Acosta explained that each facility must have a designated person who:

- is qualified and trained to be responsible for developing and implementing appropriate procedures;
- oversees compliance with this chapter and other applicable laws, regulations, and standards;
- ensures competency of personnel;
- ensures environmental control of the storage and compounding areas.
- thoroughly understands:
  - rationale for risk-prevention policies,
  - risks to themselves and others,
  - risks of noncompliance that may compromise safety,
  - the responsibility to report potentially hazardous situations to the management team.
- Is responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities and acting on the results.

Section 5. Facilities and Engineering Controls

Dr. Acosta stated that HDs must be handled under conditions that promote patient safety, worker safety, and environmental protection. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. She explained that access to areas where HDs are handled must be restricted to authorized personnel to protect persons not involved in HD handling.

Dr. Acosta also reported that HD handling areas must be located away from breakrooms and refreshment areas for personnel, patients, or visitors to reduce risk of exposure. There must be designated areas available for: receipt and unpacking, storage of HDs, nonsterile HD compounding, and sterile HD compounding. Dr. Acosta reviewed the following criterial for the designated areas.

- Designated areas:
  - Receipt and unpacking: (Antineoplastic HDs and all HD APIs)
    - neutral/normal or negative pressure relative to the surrounding areas.
- Storage of HDs:
  - Not on floor
  - Antineoplastic HDs (requiring manipulation) and all HD APIs:
    - stored separately from non-HDs
    - stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).

- Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs:
  - may be stored with other inventory if permitted by entity policy.
- Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH.

Dr. Acosta explained that a containment primary engineering control (C-PEC) is a ventilated device to minimize worker and environmental HD exposure and it must operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding.

Dr. Acosta stated that a containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed and must:

- be externally vented,
- be physically separated (a different room from other areas),
- have an appropriate air exchange (ACPH); and
- have a negative pressure **between** 0.01 and 0.03 inches of water column relative to all adjacent areas.

Dr. Acosta reported that supplemental engineering controls (closed-system drug-transfer device (CSTD)) are adjunct controls to offer additional levels of protection.

Dr. Acosta noted that a sink must be available for hand washing and the water source and drain must be located at least one-meter way from the C-PEC.

Dr. Acosta explained that C-PECs must be placed in separate rooms, unless the C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. She added that if they are in the same room they must be placed at least one-meter apart and particle-generating activity must not be performed when sterile compounding is in process.

Dr. Acosta stated that nonsterile HD compounding must be performed in a C-PEC within a C-SEC. she added that the C-SEC surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.

Dr. Acosta reviewed the following requirements for C-PECs (Class II or III Biological Safety cabinet or compounding aseptic containment isolator):

- must be externally vented
- must provide an ISO Class 5 or better air quality
- must not be used for the preparation of a non-HD unless:
  - non-HD is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.
- must be located in a C-SEC

Dr. Acosta explained that in the HD cleanroom suite the C-SEC (clean/buffer room) must have:

- fixed walls,
- minimum of 30 ACPH of HEPA-filtered supply air,
- air quality of ISO Class 7 or better; and
- negative pressure **between** 0.01 and 0.03 inches of water column relative to all adjacent areas

Dr. Acosta also explained that the C-SEC (Anteroom) must have:

- Fixed walls,
- Minimum of 30 ACPH of HEPA-filtered supply air
- Positive pressure of at **least** 0.02 inches of water column relative to all adjacent unclassified areas
- Air quality of ISO Class 7 or better
- Hand-washing sink **must** be placed in the ante-room at least 1 meter from the entrance to the HD buffer room

Dr. Acosta stated that if the HD buffer room is entered through the positive-pressure non-HD buffer room, the following is also required: (Not a recommended facility design)

- Line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE
- Method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination.
  - If using a pass-through chamber (buffer area and adjacent space).
    - must be included in the facility's certification (particles and pressure)
    - refrigerator pass-through must not be used.

Dr. Acosta reported that containment segregated compounding areas (C-SCA) must have:

- Fixed walls,
- Negative pressure **between** 0.01 and 0.03 inches of water column relative to all adjacent areas,
- 12 ACPH
- Externally vented
- hand-washing sink must be placed at least 1 meter from C-PEC
  - either inside the C-SCA or directly outside the C-SCA.
- Only low-and medium-risk HD CSPs may be prepared in a C-SCA.

Dr. Acosta explained that a closed-system drug-transfer device (CSTD) may limit the potential of generating aerosols during compounding. She also stated that it must not be used as a substitute for a C-PEC when compounding. Dr. Acosta explained that a CSTD should be used when compounding HDs when the dosage form allows and when administering antineoplastic HDs when the dosage form allows.

Section 6. Environmental Quality and Control

Dr. Acosta stated that environmental wipe sampling for HD surface residue should be performed routinely.

Dr. Acosta explained that surface wipe sampling should include:

- Interior of the C-PEC and equipment contained in it
- Pass-through chambers
- Surfaces in staging or work areas near C-PEC
- Areas adjacent to C-PECs (floors, staging, and dispensing area)
- Areas immediately outside the HD buffer room or the C-SCA
- Patient administration areas

Dr. Acosta stated that if any measurable contamination is found, the designated person **must** identify, document, and contain the cause of contamination.

Section 7. Personal Protective Equipment (PPE)

Dr. Acosta reviewed the types of personal protective equipment must be used by the staff.

- Gloves:
  - Must meet American Society for Testing and Materials (ASTM) standard D6978
  - worn for handling all HDs
  - must be powder-free
  - must be inspected for physical defects before use.
  - for sterile compounding: two pairs required
    - the outer chemotherapy gloves must be sterile
    - changed every 30 minutes
    - must be changed when torn, punctured, or contaminated
- Gowns:
  - must be disposable and shown to resist permeability by HDs
  - must be selected based on the HDs handled
  - must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit
  - must not have seams or closures
  - must be changed per the manufacturer's information for permeation of the gown. If none every 2–3 hours
  - must not be worn to other areas

- Respiratory Protection:
  - Surgical masks must not be used when respiratory protection is required.
  - For most activities, a fit-tested NIOSH-certified N95 or more is sufficient to protect against airborne particles.
    - no protection against gases and vapors and little protection against direct liquid splashes
  - Appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) should be worn when there is a risk of respiratory exposure to HDs, including when:
    - Attending to HD spills larger than what can be contained with a spill kit
    - Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
    - There is a known or suspected airborne exposure to powders or vapors

- Disposal of Used Personal Protective Equipment:
  - All PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs.
  - All PPE worn be disposed of in the proper waste container before leaving the C-SEC.
  - Chemotherapy gloves and sleeve covers worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.

Section 8. Hazard Communication Program

Dr. Acosta reviewed the requirements for hazard communication programs as provided below.

- Required to establish P&Ps that ensure worker safety during all aspects of HD handling.
- Must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
- Elements of the hazard communication program plan must include:
  - Written plan that describes how the standard will be implemented
  - All containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings
  - must have an SDS for each hazardous chemical they use (29 CFR 1910.1200)
  - must ensure that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas
  - Personnel who may be exposed to hazardous chemicals when working must be provided information and training before the initial assignment to work with a hazardous chemical, and also whenever the hazard changes
  - Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs

Section 9. Personnel Training

Dr. Acosta informed the committee that all personnel must be trained based on their job functions. She added that the training must occur before the employee handles any HDs and each employee must demonstrate the effectiveness of the training. Dr. Acosta stated that the training must include at least the following:

- Overview of entity's list of HDs and their risks
- Review of the entity's SOPs related to handling of HDs
- Proper use of PPE
- Proper use of equipment and devices (e.g., engineering controls)
- Response to known or suspected HD exposure
- Spill management
- Proper disposal of HDs and trace-contaminated materials

Dr. Acosta explained that all training must be documented and must be reassessed every 12 months.

Section 10. Receiving

Dr. Acosta provided the following requirements for receiving of HD products.

- HD products should be received from the supplier in impervious plastic to segregate them from other drugs.
- HD products must be delivered to the HD storage area immediately after unpacking.
- PPE, including chemotherapy gloves, must be worn when unpacking HDs.
- A spill kit must be accessible in the receiving area.
- The entity must enforce policies that include a tiered approach, starting with visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass).
- Damaged shipping containers: transported to a C-PEC designated for nonsterile compounding.
    - Damaged containers are considered spills and must be reported to the designated person and managed.

Section 11. Labeling, Packaging, Transport and Disposal

Dr. Acosta provided a summary of each section as provided below.

- Labeling
    - HDs identified must be clearly labeled at all times during their transport.
    - Personnel must ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas.
- Packaging
    - must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport.
    - must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs.
    - must have written SOPs to describe appropriate shipping containers and insulating materials.
- Transport
    - must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations.
    - must be in containers that minimize the risk of breakage or leakage.
    - must ensure that labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.
- Disposal
    - All personnel performing custodial waste removal and cleaning activities must be trained in appropriate procedures.
    - Disposal of all HD waste, including, but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations.

Section 12. Dispensing Final Dosage Forms

Dr. Acosta explained that HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g., HD dust or leakage). She added that clean equipment should be dedicated for use with HDs and should be decontaminated after every use. Dr. Acosta also noted that tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines.

Section 13. Compounding

Dr. Acosta stated that all compounding must be compliant with the appropriate USP standards for compounding including <795> and <797> and must be done in proper engineering controls.

Dr. Acosta explained that when compounding HD preparations in a C-PEC, a plastic-backed preparation mat should be placed on the work surface of the C-PEC and the back should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity.

Dr. Acosta reported that bulk containers of liquid and API HD must be handled carefully to avoid spills. She also explained that APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities

Section 14. Administering

Dr. Acosta explained that HDs must be administered safely using protective medical devices and techniques and appropriate PPE must be worn. She added that PPE must be removed and disposed of in a waste container approved for trace contaminated HD waste at the site of drug administration.

Dr. Acosta stated that equipment (such as tubing and needles) and packaging materials must be disposed of properly, such as in HD waste containers, after administration.

Dr. Acosta explained that If HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) for a single dose, personnel **must** don appropriate PPE and use a plastic pouch to contain any dust or particles generated.

Section 15. Deactivating, Decontaminating, Cleaning and Disinfecting

Dr. Acosta explained that all areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. She noted that sterile compounding areas and devices must be subsequently disinfected.

Dr. Acosta stated that policies and procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements.

Dr. Acosta described appropriate PPE as follows:

- resistant to the cleaning agents used,
- two pairs of chemotherapy gloves
- impermeable disposable gowns
- eye protection and face shields must if splashing is likely
- respiratory protection must be used, if warranted

Dr. Acosta explained that agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and all disposable materials must be discarded to meet EPA regulations and the entity's policies.

Dr. Acosta also reminded that committee that all cleaning must be performed in areas that are sufficiently ventilated.

Dr. Acosta provided the committee with the following definitions of deactivating, decontaminating, cleaning and disinfecting.

- Deactivation
  - renders a compound inert or inactive.
  - Residue must be removed by decontaminating the surface.
  - There is no one proven method for deactivating all compounds. (EPA-registered oxidizing agents that are appropriate for the intended use
- Decontamination
  - inactivating, neutralizing, or physically removing HD residue and transferring it to absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area being cleaned.
  - The work surface of the C-PEC must be decontaminated between compounding of different HDs.
  - The C-PEC must be decontaminated at least daily, any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved.
    - areas under the work tray must be deactivated, decontaminated, and cleaned at least monthly
- Cleaning
  - a process that results in the removal of contaminants (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergents, surfactants, solvents, and/or other chemicals.
  - Cleaning agents used on compounding equipment should not introduce microbial contamination.
- Disinfection
  - a process of inhibiting or destroying microorganisms.
  - must be done for areas intended to be sterile, including the sterile compounding areas.

Section 16. Spill Control

Dr. Acosta provided the committee with the following information regarding spill control.

- personnel must receive proper training in spill management and the use of PPE and NIOSH-certified respirators

- Spills must be contained and cleaned immediately by qualified personnel with appropriate PPE.
- Qualified personnel must be available at all times while HDs are being handled.
- Signs must be available for restricting access to the spill area.
- Spill kits must be readily available in all areas where HDs are handled.
- All spill materials must be disposed of as hazardous waste.
- The circumstances and management of spills must be documented.
- Personnel potentially exposed during the spill or spill cleanup or who have direct skin or eye contact with HDs require immediate evaluation.
- Non-employees exposed to an HD spill should follow entity policy, which may include reporting to the designated emergency service for initial evaluation and completion of an incident report or exposure form.
- SOPs must:
    - be developed to prevent spills and to direct the cleanup of HD spills.
    - address the size and scope of the spill and specify who is responsible for spill management and the type of PPE required.
    - address the location of spill kits and clean-up materials as well as the capacity of the spill kit.

Section 17. Documentation and Standard Operating Procedures (SOP)

Dr. Acosta explained that standard operating procedures must be reviewed (and documented) at least every 12 months and should include:

- Hazard communication program
- Occupational safety program
- Designation of HD areas
- Receipt
- Storage
- Compounding
- Use and maintenance of proper engineering controls
- Hand hygiene and use of PPE based on activity
- Deactivation, decontamination, cleaning, and disinfection
- Dispensing
- Transport
- Administering
- Environmental monitoring
- Disposal
- Spill control
- Medical surveillance

Dr. Acosta stated that personnel who transport, compound, or administer HDs must document their training according to OSHA standards (OSHA Standard 1910.120) and other applicable laws and regulations.

Section 18. Medical Surveillance

Dr. Acosta explained that Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE. She added that healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program.

The committee thanked Dr. Acosta for her presentation and asked for public comments.

A pharmacist that compounds exclusively for veterinary practices asked if the board would be creating an exception that would allow certain veterinary HD products to be handled in a room that is not USP 800 complaint. Dr. Acosta recommended contacting the CDC as they create the NIOSH list which is used to determine how HD products must be handled.

A member of the public asked if the committee could make Dr. Acosta's slides available in an electronic format or in larger printed sizes. Chairperson Serpa reminded the public that the it is the responsibility of the PIC and designated staff to review the USP standards, the slides are only a high-level review of the standards. Slides will soon be added to website.

A compounding pharmacist asked if a pharmacy what provides patient specific HDs to a hospital is responsible to make sure that the HDs are handled appropriately by hospital staff when it is administered (i.e. wearing proper PPE and proper disposal). Chairperson Serpa responded that in some healthcare systems the pharmacy is responsible to oversee the HDs from compounding to administration; however, an independent pharmacy would have different requirements. DCA legal counsel Laura Freedman stated that this question goes beyond the agenda item and should be placed on a future agenda for future discussion.

Interim Executive Officer Anne Sodergren reminded the committee that there is pending legislation that will set the relevant USP chapters as the floor for the board's compounding regulations. After the floor is set the board will have the opportunity to develop additional regulations if nessecary.

4. Approval of the February 20, 2019 Meeting Minutes

Chairperson Serpa noted that in both the February and March minutes on page 2 the term "<825> – Preparation" should be corrected to read "<825> – Radiopharmaceuticals Preparation."

The committee agreed with the changes to both minutes.

Motion: Approve the February 20, 2019, committee meeting minutes with the correction noted by Chairperson Serpa.

M/S: Weisser/Law

Support: 4 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law	x			
Schaad	x			

Board Member	Support	Oppose	Abstain	Not Present
Serpa	x			
Weisser	x			

5. Approval of the March 13, 2019 Meeting Minutes

Motion: Approve the March 13, 2019, committee meeting minutes with the correction noted by Chairperson Serpa.

M/S: Schaad/Weisser

Support: 4 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law	x			
Schaad	x			
Serpa	x			
Weisser	x			

6. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for June 4, 2019, in Sacramento. She added that the July meeting has been rescheduled to July 11, 2019, in Sacramento. Chairperson Serpa noted that the board's website has been updated to reflect the new meeting date.

7. Adjournment

Chairperson Serpa adjourned the meeting at 11:25 a.m.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE
WORKGROUP ON COMPOUNDING
Meeting Summary

DATE: September 22, 2004

TIME: 1:30 p.m. – 4:00 p.m.

LOCATION: Hilton Oakland Airport
One Hegenberger Road
Oakland, CA 94621

Workgroup Members: Ken Schell, Pharm.D., Chair
John Tilley, R.Ph.

Staff Present: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Dennis Ming, Supervising Inspector
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General

Call to Order/Introductions

Chair of the workgroup, Dr. Schell, called the meeting to order at 1:30 p.m. Individuals attending the meeting were all invited to participate and were asked to introduce themselves.

Dr. Schell stated that this is the third meeting of the workgroup. He acknowledged and thanked the participants for their commitment and involvement. While the workgroup was initially formed in part to respond to a request from the Department of Health Services to identify the criteria used by the board to determine when a compounding pharmacy should be considered a manufacturer, it is the board's goal to work with the compounding profession in trying to respond to the request from DHS as well as to identify "gaps" in pharmacy law related to pharmacy compounding, and to address them.

General Compounding Proposal

Board Supervising Inspector Dennis Ming and Chief of Legislation and Regulation Paul Riches presented a concept proposal on general compounding. Dr. Ming explained that the concept draft was developed by he and Mr. Riches using documents prepared by the law subcommittee formed from this workgroup, compounding guidelines from the National Association of Boards

of Pharmacy (NABP), compounding requirements developed by the Texas State Board of Pharmacy, and California pharmacy law(s).

The workgroup discussed the concept draft and provided suggestions to clarify various provisions. Mr. Riches requested that any additional comments be provided by November 1st.

Subcommittee on Law - *Compounding versus Manufacturing*

The subcommittee on law presented their draft revisions of compounding guidelines that the Board of Pharmacy adopted in 1995. These guidelines were developed using the FDA Compliance Policy Guides in effect at the time and their original purpose was to provide the factors to be considered by board inspectors that may suggest that a pharmacy that claims to be compounding may actually be engaged in manufacturing.

The workgroup reviewed the subcommittee's revisions to the factors. It was noted that the general concept draft developed by Dr. Ming and Mr. Riches includes a definition of compounding, which currently is not defined in pharmacy law. The concept draft also requires that the pharmacist have a professional relationship with both the prescriber and the patient. Moreover, the general compounding draft addresses the issues of central fill (where a pharmacy may contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), recordkeeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug, and requirements for facilities and equipment. The concept draft also specifies that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications. There also was discussion regarding the compounding of OTC products and whether a prescription is required. It is the board's position that a prescription would be required whenever a pharmacy compounds a drug product. A drug product is defined broadly enough to include OTC compounding.

In response to questions about the relative roles of the Board of Pharmacy, the federal Food and Drug Administration and its California counterpart(s), it was explained to the workgroup that the Board of Pharmacy regulates the practice of pharmacy, which includes compounding. It is, however, ultimately within the authority of the federal and state FDA to license and regulate manufacturers and it is within their purview to determine when an entity must be licensed as a manufacturer. It was noted that compounding is included in the definition of manufacturing but a pharmacy that engages in compounding is not required to be registered as a manufacturer so long as the compounding is done within the pharmacy practice (upon prescription from a practitioner for a patient who is under the care of that practitioner). Because the FDA is concerned with public safety, it is reassessing pharmacy compounding.

The board is seeking to establish guidelines that provide uniformity in compounding in California. Better definition and regulation of the practice of compounding is primarily for the purpose of public safety. It may also solidify the role of compounding in pharmacy practice, and thereby diminish the likelihood that pharmacies compounding within their practice of pharmacy will be required to register as manufacturers. However, the board can offer no such guarantee.

Moreover, counsel advised that the proposed "factors" for distinguishing compounding from manufacturing would at best be considered "guidelines," and as such, do not have the force of law. Absent adoption by regulation, they may also be underground regulations.

It was reiterated during the meeting that the Board of Pharmacy's priority mandate is to protect the public and this mandate extends to the compounding of prescription drugs. It would appear that the general compounding draft provides the regulation necessary to guarantee that those pharmacies that compound prescription drugs meet specific standards to assure patient safety.

Next Meeting Date

Dr. Schell stated that the next meeting date for the Workgroup on Compounding is December 1, 2004, in Burbank.

Adjournment

Dr. Schell thanked the participants for attending and adjourned the meeting at 4:00 p.m.

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

COMPOUNDING COMMITTEE
MEETING MINUTES

DATE: July 11, 2019

LOCATION: Department of Consumer Affairs
California State Board of Pharmacy – Building Two
1747 N. Market Blvd., Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chairperson
Greg Lippe, Public Member
Allen Schaad, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Victor Law, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Julia Ansel, Chief of Enforcement
Christine Acosta, Supervising Inspector
Debbie Damoth, Staff Services Manger
Laura Freedman, DCA Staff Counsel
Kelsey Pruden, DCA Staff Counsel

1. **Call to Order and Establishment of Quorum**

   Chairperson Serpa called the meeting to order at 10:01 am. Board members present: Maria Serpa, Allen Schaad and Greg Lippe. A quorum was established.

2. **Public Comment on Items not on the Agenda/Agenda Items for Future Meetings**
   Chairperson Maria Serpa invited public comment.

   Seth DePaquale of BET Pharm, Lexington, Kentucky suggested the following items be considered:
   - Extension of Beyond Use Dating for sterile preparations
   - Office use for veterinary compounding for sterile preparations

3. **Discussion and Consideration of Proposed Amendments to Regulations Related to Pharmaceutical Compounding of Nonsterile Preparations**

   CCR 1735 Compounding in Licensed Pharmacies

Chairperson Serpa began the discussion by recommending to the committee and the full board to promulgate regulations as necessary to mirror structure of United States Pharmacopeia (USP) chapters. She recommended that as regulations for the respective chapters are finalized that the board initiate the rulemaking process one chapter at a time to allow for more immediate transition to the new regulations. Draft regulations as prepared by staff, were presented to the committee to be considered. Chairperson Serpa stated the draft regulations are to repeal Article 4.5 and replace it with an entirely new Article 4.5, nonsterile compounding.

DCA Counsel, Laura Freedman suggested, with board approval, there may be some non-substantive edits that can be addressed outside of the meeting that can be handled organizationally.

Mr. Lippe asked if the public should be afforded the opportunity to comment on non-substantive changes.

Ms. Freedman stated any changes made whether substantive or non-substantive would go to the full board for review.

Dr. Serpa advised everyone present that as the committee moved forward with its discussion, each section would be discussed one at a time. Further, Dr. Serpa would provide opportunity for board member comments followed by public comment. Dr. Serpa noted that the proposed language would be projected and during the discussion live edits would be made and documented through consensus.

The committee initiate its review with Section 1735, entitled, "Compounding in Licensed Pharmacies"

As part of public comment on this section, Danny Martinez, CPhA, asked if CCR 1735(b) and (c) are necessary. Business and Professions Code (BPC) 4052.7 addresses repackaging. Mr. Martinez suggest striking these two sections as he believes they are duplicative and unnecessary, particularly in a hospital setting. Dr. Serpa asked for clarification on why this would be more problematic in a hospital setting. Mr. Martinez stated he would provide further clarification at a later date.

Mr. Martinez referenced CCR 1735 (d), noting that that obtaining further documentation that a prescription from a prescriber has approved use of a compounded drug preparation will be laborious for compounders. He stated patient care will be delayed by this section and asked that it be stricken. He recommended if the board is unwilling to strike this, he is suggested to add the following after the first sentence, "If it is unclear whether a compounded preparation was intended, approval shall be obtained orally or in writing." Mr. Martinez commented if the prescription is written for a compounded product, there should not be a need to call the prescriber back to verify.

Christine Versichele, Dynalabs, under CCR 1735(c) , suggested that the word "repackaging" be corrected to read "reconstitution."

Marie Cottman, Pacific Compounding Pharmacy, suggested an allowance for a delay in the implementation of these regulations as some of the suggested language is an undue burden.

Dr. Cottman commented that under CCR 1735(a) USP describes compounding to include "all places but not limited to pharmacies". Dr. Serpa explained the purview of the board is limited to what occurs in a pharmacy, thus the limitation. Dr. Cottman suggested 1735(d) to replacing "perpetrations" with "preparations" and replace "noncommercial" with "noncommercially". Dr. Cottman referred to the

word disposal under CCR 1735(g) and stated under CCR 1707.2 disposal is not referenced. She suggested the board consider adding the word disposal under Duty to Consult language.

Dr. Serpa responded that any discussion on the delay of implementation needs to be related to language the board drafts in the regulation that goes above USP guidance.

Ranel Larsen, compounding pharmacist, commented that under BPC 4037(a), compounding is defined and is unclear why we are restating the definition under 1735(a). Dr. Larsen noted that she did not see reference to this definition in USP 795 and suggested it should be removed from this regulation entirely. Dr. Larsen mentioned under 1735(e)(3), "documented medical need" is not defined and as such should be defined or removed. She requested that discussion should be had on delay on implementation of of 1735(i) and (j) and suggested they be combined as they are very similar. Dr. Larsen asked for clarification on CCR 1735(b), specifically why it references repackaging for nonsterile compounding when USP 795 is silent on repackaging when it comes to nonsterile drug preparations. She stated repackaging needs to be addressed for sterile preparations but not nonsterile.

Lorri Walmsley, Walgreens, explained that the proposed regulations could prevent community pharmacies from potentially flavoring antibiotics if they are not USP 795 compliant. Inspector Christine Acosta stated the USP 795 committee intended for the inclusion of a flavoring agent to be considered compounding and she will contact USP for further clarification.

Joe Grasela, University Compounding Pharmacy, referred to 1735(d) and stated contacting a doctor every time to confirm a compound is overwhelming and unnecessary. He agreed with Mr. Martinez's statement regarding the conditions under which such documentation would be appropriate if it is unclear whether a compounded product is necessary. Mr. Grasela asked that this section be stricken from the draft regulation. Dr. Acosta responded that the expectation is not to be documented on every prescription. Dr. Serpa added part of the intent is to make the patient aware a product they are receiving is compounded and not manufactured, but it is certainly not intended for each and every compounded product.

Board staff noted their belief that the proposed regulation provision is consistent with federal law governing 503A facilities, but staff would confirm.

Nichole DiLoretta, Dynalabs, commented that with respect to repackaging, many pharmacists are making compounded kits and they would appreciate guidance on these products. She asked if it would be possible for a pharmacist to perform an assessment of risk when making compounding kits. Dr. Acosta stated 1735(c) is attempting to clarify compounding kits. Dr. Acosta clarified that if the kit does not have FDA approved labeling then reconstitution is compounding. Dr. Serpa stated the board and staff is considering drafting FAQs to provide additional education on the regulation.

Dr. Serpa reviewed the proposed edits offered through public comment for section 1735 and asked the committee members if they agree with said changes. The committee reached consensus on proposed changes to the drafted language.

1735.1 Introduction and Scope and Compounding Definitions

The committee continued its review and proceeded to Section 1735.1 including public comment.

Ask part of public comment, Marie Cottman commented there is no definition of potency in the new language and requested it be added. She stated section (f) is missing from the document and quality

and strength are both listed as section (k). Dr. Cottman stated that in 1735.1(g), repackaging sounds like dispensing and asked for clarification on the differences between the two. Dr. Acosta stated that definition is taken from USP 797 and the regulation is attempting to explain what is meant by repackaging. Dr. Serpa asked if adding words at the end of that section to read, "that is not pursuant to a patient prescription", would make the section clearer. Mr. Lippe agreed the section clearer with that edit.

Dr. Acosta suggested under (j) to have it read "potency means an active ingredient strength typically within +/-10% (or range specified in USP) of the labeled amount". Ms. Freedman suggested cross referencing USP to be clear. Ms. Sodergren wanted to make clear that potency will be defined with the language of "+/-10% of the labeled amount".

Dr. Larsen suggested under 1735.1(a) to add "approved mixing directions" for continuity. She recommended under (b) that the word clinically be removed for clarity. Ms. Sodergren stated it was a deliberate deviation. Dr. Acosta said there is a distinct difference between a "clinically significant" and "significant" noting that wanting to decrease the cost of producing a product could fall under the latter. Dr. Acosta stated clinically significant could mean the patient cannot take this drug because he will have an allergic reaction versus cost savings. Dr. Larsen requested to add back the words "sterile product" under section (g) for the definition of repackaging. Dr. Serpa stated that was not the intent of this section and that this regulation is for nonsterile and specifically sterile was removed.

The discussion continued regarding 1735(a) regarding adding "mixing directions". Dr. Acosta requested that Dr. Larsen provide more information on this section.

Public comment suggested that referring to potency with a +/- 10% range is not appropriate. It was suggested that a USP monograph be used instead.

Mr. Grasela suggested using FDA guidelines under section (b) to make the section clearer.

Dr. Cottman, suggested to simplify section (g) add a comma after manipulation so the section reads: "manipulation, not pursuant to a prescription." She suggested to add potency to the definitions or remove it from 1735.8.

Jacqueline Sitack, Dignity Health, suggested that for strength and potency, to revise the term to reference "labeled strength". Dr. Serpa stated concern with limiting this to labeled strength because a compounder could have strength in the master formula and the definition would not apply.

Dr. Serpa reviewed the proposed edits for CCR 1735.1(a) – (j) and asked the committee members if they agree with said changes. The committee reached consensus on proposed changes to the drafted language. A definition of potency will be added and under (g) repackaging – the words "that is not pursuant to a prescription" will be added.

1735.2 Personnel Training and Evaluation

Having reached consensus on section 1735.1, the committee moved to review and consideration of proposed section 1735.1. Mr. Lippe asked that CSNP be changed to CNSP in section (b). The committee then received public comment.

As part of public comment, Mr. Martinez stated that CCR 1735.2 (a),(b), and (e) in that the proposed regulation restates information in USP on training and is duplicative. Dr. Serpa stated it may be appropriate to provide an FAQ for clarity on this section.

Dr. Cottman suggested changing section (b) to read "in all skills as listed in USP 795". Dr. Acosta stated the intent of the requirement is for the pharmacist to have documented skills for anything they oversee. Dr. Serpa noted that everyone involved in the compounding process should have the necessary skills and demonstrate proficiency. The committee decided to keep the language as written.

Dr. Serpa asked if the committee or board staff had any concerns about the changes suggested in CCR 1735.2 and stated these changes will be presented in the motion at the end of the meeting. The committee reached consensus on the section.

CCR 1735.3 Personal Hygiene and Garbing

With no comments being made from members, the committee heard public comments related to Section 1735.3

Dr. Cottman suggested changing the phrasing "shall not be allowed" to "should not allow" in section (a). She stated that she would like to exercise professional judgment to determine if compounding personnel with specified conditions should be prohibited from entering the compounding area because of potential risk of contamination. Dr. Cottman suggested if you be appropriate to allow the supervising pharmacist to make the decision whether to allow personnel into the compounding area. Dr. Serpa suggested the section be more specific and suggested a brief break to allow for drafting of possible revision to the language for consideration.

After the break the following language was drafted by staff 1735.3(a):
"The supervising pharmacist shall evaluate compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection and or any other conditions to determine if such condition could contaminate a CNSP or the environment. The supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area."

Dr. Serpa asked the public if this section satisfied the publics concerns. Dr. Cottman stated the language is good and acceptable, but these conditions are already stated in USP 795. She suggested the following alternative language "The designated person or pharmacist supervisor shall document evaluation of individuals posing a possible contamination risk prior to allowing the individuals to enter the compounding area." Dr. Cottman agreed to the statement as drafted by board staff.

Dr. Cottman stated section (b) indicates any exposed piercing must be removed noting she believes including ear piercings in this instance or nose piercings that are covered by a hair or face mask is excessive and unnecessary. She mentioned under section (f), having to wash glasses multiple times a day is excessive. Dr. Acosta clarified that section (f) states the facility can determine through their SOPs how and when they want to wash glasses.

Dr. Larsen noted her concurrence with Dr. Cottman on the jewelry removal issue, indicating that a compounding professional should be able to determine whether jewelry will interfere. Dr. Larsen agreed that hand and wrist jewelry should be removed, as that would be the most problematic in compounding, but that not all jewelry should be included in the removal requirement under section (f).

Mr. Martinez stated CPhA will be submitting a full letter with all the suggested changes they have from its members. He mentioned that if you are a CPhA member and have suggested changes that are not voiced today they will incorporate those suggestions in their letter to the board. Mr. Martinez noted that he will submit the letter in a timely matter, so it is available for review at the full board meeting.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.3 and stated these changes will be presented in the motion at the end of the meeting.

1735.4 Building and Facilities

Having no committee discussion on section 1735.4, the committee entertained public comment on section 1735.4.

As part of public comment, Mr. Martinez commented that under section (d), the proposed regulation is very vague and open to interpretation regarding the compounding area. He stated many activities other than compounding occur during the compounding operations. Mr. Martinez suggested adding the phrase "when compounding is performed no other activity shall take place in the adjacent area without adequate controls to prevent contamination of the compounding area and preparations". Dr. Serpa requested clarification on what "adjacent area" means, as it is very broad. She stated the board was attempting to provide some flexibility in this instance. Mr. Martinez stated they will work on this issue in the document they will be presenting to the board.

Dr. Cottman, suggested alternative language to section (d): "If compounding is performed daily, activities not related to the preparation of CNSPs shall not take place in the compounding area." Dr. Serpa noted the challenge with the language as there are different compounding environments and the board's goal is to not limit compounding but to assure that compounding occurs in a safe environment. Ms. Sodergren and Dr. Acosta suggested removing this section. Dr. Serpa noted that removing the section doesn't impact patient safety, but it does impact practice environment.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.4 including removing (d) relating to the compounding area. She stated these changes will be presented in the motion at the end of the meeting.

CCR 1735.5 Cleaning and Sanitizing

The committee did not have comments on section 1735.5 and requested public comments.

As part of public comment, Dr. Cottman commented under 1735.5(a) that cleaning is done all the time as part of the practice. Dr. Cottman noted her belief that compounding staff will just write it down, that cleaning occurred, even when it has not. She questioned the value of such documentation and how it was related to consumer protection. Dr. Serpa explained there has to be minimum amount of documentation. Dr. Cottman encourage documentation at least once a day, but not every time and suggested it may be a training issue, that an SOP needs to be written, it needs to be monitored and a daily documentation of what agents were used is appropriate.

Dr. Acosta stated the intention is to capture documentation of the cleaning and sanitizing of the compounding area to include the personnel who are performing this task and the agents used.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.5. She stated these changes will be presented in the motion at the end of the meeting.

CCR 1735.6 Equipment and Components

Dr. Serpa stated section 1735.6 discusses new technology, which will require new equipment to be purchased and that the committee and board may want to consider a delay in implementation. She encouraged the public to provide comments specific to delayed implementation and timelines.

As part of public comment, Dr. Walmsley, Walgreens, and Michael Cuellar, Manager of Walgreens compounding center, suggested striking 1735(b) relating to the required use of a closed system processing device for any weighing, measuring, or other manipulations of components in powder form. She stated in the current version of USP 795 it references that an assessment of whether powder should be handled in a BSC or CVE and would like this USP guidance to stand. Dr. Cuellar mentioned the requirement of an assessment being captured in an SOP as to whether or not a hood is required for a nonsterile preparation is appropriate. Dr. Walmsley commented the would have a significant cost component for pharmacies and believes an enforcement delay would be appropriate as powder hood would need to be purchased and there have been significant delays for 800 compliant hoods of up to 8 to 16 weeks.

Public comments under section (b) included adding the word "containment" before "ventilated enclosures" to reflect the CVE as the enclosure.

Tim Frost, CVS Health, suggested removing section (b) as he is concerned on how this would affect access and patient safety (particularly patients who cannot swallow pills). Dr. Frost stated if this is not stricken then he would like the board to consider and amendment to include single use containment glove bags as a third option.

Dr. Cottman agrees with section (d), but in existing law 1735.3(c) or (e) compounders use commercially made FDA approved products and crush them to make smaller strengths. She explained this requires a Certificate of Analysis (CofA) for any API or added substance, but there is no CofA for tablets. In our current language we do have that a CofA is not required for FDA approved products. She would like to see this added to section (d). Dr. Acosta stated API is a bulk substance not a manufactured product and suggested to reference USP 800. Dr. Serpa suggested to address this issue in a FAQ.

Dr. Cottman added she would like to see FAQ information on section (e) regarding when components not used in compounded can be returned to the original container versus when such components must be discarded. She asked for clarification on where to you draw the line on what has been removed from the original container and are you able to add product back into a container if removed by a single use disposable spoon? Dr. Cottman suggested "should be discarded" instead of "shall be discarded". Ms. Freedman suggested changing the language to "shall be discarded if the returning to the original container could result in contamination". Dr. Cottman suggested the following "Once removed form the original container, components that have been contaminated and not used in compounding shall be discarded." Dr. Acosta responded that such an approach could create challenges with enforcement of the requirement. Dr. Cottman noted that the requirement as written would increase cost, decrease access and increase waste. Dr. Acosta stated USP is written as "should" versus "shall" and suggested to eliminate section (e).

Mr. Martinez asked for clarification on (b)(1) in that for CVEs there are no guidelines. Dr. Acosta said currently there are no guidelines for CVEs, but that they are under way in a new revision of CETA. Dr. Acosta noted that vendors know to certify to CETA guidelines and are specific to each unit.

Dr. Larsen stated under (c)(1), relating to requirements for components used, that a National Formula (NF) doesn't exist for everything and suggested adding the phrase "if one exists" as without this phrase there is confusion. Dr. Acosta stated this is much broader than a monograph and doesn't change the context. Dr. Serpa noted that the regulation is referring to the concepts in USP not drug specific information in USP. She noted that Dr. Larsen and Dr. Acosta are both correct. Dr. Acosta stated this is not referencing a specific product, it is a specific component, noting this section is not referring to the end product.

Dr. Serpa noted that section 1735.6 is probably the most significant of regulations as it will change how pharmacy is practiced in facilities where powders are being used. She asked how to implement this section in a manner that does not limit access to patients. Mr. Schaad questioned the value of requiring a CVE for nonsterile compounding, but noted the need for hazardous compounded preparations.

Dr. Acosta noted that one of the challenges with the assessment approach is determining the standard for such an assessment. Dr. Serpa stated safety of patient, personnel and environment should drive the decision.

The committee considered the requirement of the CVE and significant public comment, both in support of and opposed to the mandated requirement. Ultimately the committee reached consensus and removed the requirement but agreed to readdress the issue at a later time.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.6. She stated these changes will be presented in the motion at the end of the meeting.

1735.7 Master Formula and Compounding Records
The committee did not have comments on section 1735.7 but heard public comment.

As part of public comment, Dr. Cottman stated that in USP 795, already reference to "API or added substance identities and amounts must include at least a salt form and purity grade". Dr. Acosta stated yes, but after that phrase USP states, if applicable and makes this optional. Dr. Cottman agreed with (a)(2) regarding container closure but she believes the "at least volume" is not practical and excessive, particularly in the veterinary world based on the size of an animal. Dr. Acosta noted the difference between making a 10ml vial and a 1ml vial and the master formula should tell you how much and how many you are making.

Dr. Cottman requested that under 1735.7(c) the board can change the word "log" to "record", so it is congruent with USP 795.

Mr. Martinez asked in 1735.7(a)(3) how does a pharmacy make the reference fully available for an inspector and was advised that the pharmacy must have the article fully available and it does not say printed.

Dr. Larsen requested under section (a)(1) to add "if applicable" in congruence with USP, because not every single substance has a salt form and requested that the language be stricken.

Dr. Larsen stated her agreement with Dr. Cottman's comments regarding the container-closure system indicating the proposed language is restrictive and should not include the volume. Public comment noted the difference between CNSPs and CSP and the significance the volume for each.

Dr. Sitack suggested changing, under 1735.7 (a)(b), the wording “master formula document” and “master formula record” to “master formulation record” in congruence with USP.

Dr. Serpa asked if the committee has consensus on the language in CCR 1735.7. She stated these changes will be presented in the motion at the end of the meeting.

CCR 1735.8 Release Inspections
No committee discussion.

No public comment.

CCR 1735.9 Labeling
There were not comments by the committee however the committee heard public comments.

As part of public comment, Dr. Cottman inquired about the provisions under (a)(1)(A) and requiring inclusion of the “route of intended administration” on the prescription label. Dr. Serpa stated that the intent is to have the label requirement in the future to be the same across all prescriptions. Dr. Cottman also asked why (a)(2)(B) (regarding labeling) is necessary to provide “any warning statements that are applicable” and was advised that DMSO, and other things that are specific to your product.

CCR 1735.10 Establishing Beyond-Use Dates
There were not comments by the committee however the committee received public comments.

As part of public comment, Mr. Martinez commented that stability studies are left out of the regulation. Ms. Sodergren commented that it was left out because it is referenced in USP 795. Dr. Serpa stated the regulation is addressing items that go above and beyond USP guidelines and USP has written an informative FAQ on this topic.

CCR 1735.11 SOPs
Having no committee comments, the committee entertained public comments.

As part of public comment, Dr. Cottman asked for clarification of what is meant by “procedures for handling, compounding and disposal of infectious materials” and was advised the language is consistent with current law.

CCR 1735.12 Quality Assurance and Quality Controls
No committee discussion.

No public comment.

CCR 1735.13 Packaging and Transporting
There were not comments by the committee however the committee received public comments.

As part of public comment, Dr. Cottman asked under CCR 1735.13 (c) to consider changing the term “delivery” to dispensing.

The committee reached consensus on the section.

CCR 1735.14 Complaint Handling and Adverse Event Reporting
No committee discussion.

No public comment.

CCR 1735.15 Documentation
There were not comments by the committee however the committee received public comments.

As part of public comment, a member of the public asked about documentation in general regarding master formulas if there is an audit trail in the batch record is that satisfactory. Dr. Acosta responded that several vendors have software that allows for edits in the electronic system and the board cannot tell if edits were made. She stated if the compounder is making an edit in the log or the master formula the board wants to be able to see the original record and the edit itself. Dr. Acosta commented that systems need to provide some type of audit trail and not all software has an audit trail. Dr. Acosta noted that a dispensing record can be deleted but a hard copy prescription cannot be deleted.

Dr. Cottman stated when edits are made to master formulas, they are dated and signed and questioned the value of documenting the time an edit occurs. Dr. Acosta stated time is important to documented.

Having reached consensus, the committee concluded its review of the regulation proposal.

Motion: Recommend to the board the approval of the proposal to repeal and replace Article 4.5 related to compounding and propose a new Article 4.5 related to Nonsterile Preparations, including sections CCR 1735 through 1735.15, as reviewed and edited today.

No public comment on the motion.

M/S: Allen/Greg

Support: 3 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law				x
Schaad	x			
Serpa	x			
Lippe	x			

4. Approval of the April 16, 2019 Meeting Minutes

Motion: Approve the April 16, 2019, committee meeting minutes.

M/S: Allen/Maria

Support: 2 Oppose: 0 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law				x
Schaad	x			
Serpa	x			
Lippe			x	

5. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for August 28, 2019, in Irvine, California.

6. Adjournment

Chairperson Serpa adjourned the meeting at 3:23p.m.

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NOTICE OF PUBLIC BOARD MEETING

Thursday, December 12, 2019, 9:00 a.m. – 1:00 p.m. (or until the conclusion of business)
Contractors State License Board
John C. Hall Hearing Room
9821 Business Park Drive, Sacramento, CA 95827

Meetings are open to the public except when specifically noticed otherwise in accordance with the Open Meeting Act. All times when stated are approximate and subject to change without prior notice at the discretion of the board, unless listed as "time certain." Items may be taken out of order to maintain a quorum, accommodate a speaker, or for convenience. Action may be taken on any item listed on this agenda, including information-only items. The meeting may be canceled without notice.

Members of the public can address the board during the public comment session. Public comments will also be taken on agenda items at the time the agenda item is heard and prior to CSLB taking any action on said items. Total time allocated for public comment may be limited at the discretion of the board chair.

MEETING AGENDA

A. Call to Order, Roll Call, Establishment of Quorum and Chair's Introduction

B. Presentation of Certificates of Recognition – May Include Oral Presentations Commemorating Achievements and Service of CSLB Staff

C. Public Comment Session for Items Not on the Agenda and Future Agenda Item Requests
(*Note: Individuals may appear before the board to discuss items not on the agenda; however, CSLB's board can neither discuss nor take official action on these items at the time of the same meeting (Government Code sections 11125, 11125.7(a)).*

D. Enforcement
1. Review and Possible Approval of November 7, 2019 Enforcement Committee Meeting Summary Report

2. Enforcement Program Update
    a. Internal Policy and Procedure Changes to Address Budget Deficit
    b. CSLB Disaster Response
        i. Presentation of Video on CSLB Disaster Response
    c. Staff Vacancy Update
    d. Consumer Investigation Highlights
    e. General Complaint-Handling Statistics
    f. Statewide Investigative Fraud Team Highlights and Statistics
    g. Joint Enforcement Strike Force Update

3. Review, Discussion, and Possible Action to Pursue Legislation to Amend Business and Professions Code Section 7099.2

4. Review and Discussion Regarding Strategies to Address Unlicensed Contracting

5. Review and Discussion of Enforcement 2019-21 Strategic Plan Objectives

E. Licensing
    1. Review and Possible Approval of November 7, 2019 Licensing Committee Meeting Summary Report

    2. Licensing Program Update
        a. Internal Policy and Procedure Changes Related to License Application Review
        b. Application Processing Statistics
        c. Renewal Processing Statistics
        d. Workers' Compensation Recertification Statistics
        e. Fingerprinting/Criminal Background Unit Statistics
        f. Experience Verification Statistics
        g. Licensing Information Center Statistics
        h. Judgment Unit Statistics

    3. Testing Program Update
        a. Examination Administration Unit Update
        b. Examination Development Unit Update

    4. Update, Discussion, and Possible Action Regarding Outsourcing CSLB Exam Administration and Possible Legislative Change to Grant CSLB Authority to Outsource Exam Administration

    5. Review, Discussion, and Possible Action Regarding Feasibility of Creating a CSLB License Applicant Satisfaction Survey

    6. Update on Distribution of Construction Management Education Funds

    7. Review, Discussion, and Possible Action to Amend Licensing 2019-21 Strategic Plan Objectives

F. Public Affairs
    1. Review and Possible Approval of November 7, 2019 Public Affairs Committee Meeting Summary Report

    2. Public Affairs Program Update
        a. Online Highlights
        b. Video/Digital Services
        c. Social Media Highlights
        d. Media Relations Highlights
        e. Publications/Graphic Design Highlights
        f. Industry/Licensee Outreach Highlights
        g. Consumer/Community Outreach Highlights
        h. Intranet/Employee Relations

    3. Review, Discussion, and Possible Action on 2020-22 Communications Plan

    4. Update, Discussion, and Possible Action to Amend Public Affairs 2019-21 Strategic Plan Objectives

G. Legislation
    1. Review and Possible Approval of November 7, 2019 Legislative Committee Meeting Summary Report
    2. Review, Discussion, and Possible Action to Replace Paper Bill Text with a Website Link in Future Committee and Board Packets

3. Update on Action to Initiate an Emergency Rulemaking, Adopt a Finding of Emergency, and Possibly Initiate a Regular Rulemaking to Amend Title 16, California Code of Regulations (CCR) Section 811 Regarding Increasing Renewal Fees

4. Review, Discussion and Possible Action Regarding CSLB's 2019-20 Legislative Proposals

5. Discussion and Possible Action on Staff Recommendations for Legislative Proposals to Make Minor, Technical, or Non-Substantive Changes to the Contractors State License Law (Omnibus Bill, Clean-Up Request)

6. Update, Discussion, and Possible Action on 2019-21 Legislative Strategic Plan Objectives

H. Executive
   1. Review and Possible Approval of September 24, 2019 Board Meeting Minutes

   2. Budget Update
      a. CSLB Budget Update and Statistics Summary
      b. Disaster Response Funding

   3. Information Technology Update
      a. Update and Discussion of Information Technology 2019-21 Strategic Plan Objectives

   4. Administration Update Regarding Personnel and Facilities
      a. Update and Discussion of Administration 2019-21 Strategic Plan Objectives

   5. Registrar's Report
      a. Tentative Board Meeting Schedule

   6. Update and Discussion on Outreach and Enforcement Strategies to Address Consumer Solar Complaints
      a. Consumer Protection Government Taskforce – Department of Business Oversight, California Public Utilities Commission, and CSLB
      b. Discussion Regarding Proposed California Public Utilities Commission Rulemaking 14-07-002/Application Number 16-07-015 (enhance consumer protection for solar energy customers)
      c. CSLB Solar Taskforce, Investigations, and Prioritizing Property Assessed Clean Energy (PACE) Administrator Cases
      d. CSLB Lead Generator and Solar Brokers Industry Bulletin

   7. Review, Discussion, and Possible Action to Direct Staff to Identify and Retain an Outside Consultant or Expert to Study Energy Storage System (ESS) Information Received and ESS Installation Issues Including Safety Concerns and Appropriate Contractor Classifications to Install ESS and Provide General Guidance about the Scope of the Report and Estimated Cost Parameters
      a. Discussion regarding state contracting process
      b. Timeline for possible rulemaking to effectuate proposed changes to license classification(s)

I. Adjournment

Note: The board intends to provide a live webcast of the meeting. The webcast can be located at www.cslb.ca.gov. Webcast availability cannot, however, be guaranteed due to limitations on resources or technical difficulties. The meeting will continue even if the webcast is unavailable. If you wish to participate or have a guaranteed opportunity to observe, please plan to attend the physical meeting location.

The meeting is accessible to those needing special accommodation. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Phyliz Jones at (916) 255-4000, or phyliz.jones@cslb.ca.gov, or Phyliz Jones, 9821 Business Park Drive, Sacramento, CA, 95827. Providing your request at least five business days prior to the meeting will help ensure availability of the requested accommodation.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
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CEMETERY AND FUNERAL BUREAU

NOTICE OF PUBLIC STAKEHOLDER WORKSHOP VIA WEBEX

MONDAY, JUNE 21, 2021 FROM 10:00 a.m. to 12:00 p.m. (or until the conclusion of business)

NOTE: This meeting will be held telephonically only. Access will be provided to the public as set forth in this notice. No physical address or public location for the meeting will be provided.

Meeting Agenda

- Newly Proposed Regulatory Language (Add a New Article 3.5 and Title and Sections 2334, 2334.1, 2334.2, 2334.3, 2334.4, and amend Section 2350 in Article 5 of Division 23 of Title 16 of the California Code of Regulations relating to Endowment Care Funds and the Unitrust Distribution Method)
- Newly Proposed Unitrust Conversion Application (23-UCA (New 7/21)

Summary

On June 21, 2021, the Cemetery and Funeral Bureau (Bureau) will host a workshop to discuss a possible new regulatory action for licensed cemeteries, its board of trustees or its corporate trustee seeking Bureau approval to convert its endowment care fund (ECF) from a net income distribution method to a unitrust distribution method. The text of the proposal is available on the Bureau's web site at:
https://www.cfb.ca.gov/laws_regs/proposed_regs.shtml

Public Participation Information

WebEx - Observation and Public Comment
Members of the public may participate or join the meeting and provide public comment by accessing the WebEx event information provided below.

Teleconference Information to Register/Join/Access the WebEx Event for Members of the Public via WebEx, attendees will need to click the following link and enter their first name, last name, email, and the event password listed below:

https://dca-meetings.webex.com/dca-meetings/onstage/g.php?MTID=e6bdb2070078466014cf6792d58c40792

Event number: 187 772 0702
Event password: CFB06212021
Audio Conference: US Toll -1-415-655-0001
Access code:187 772 0702

Members of the public may but are not obligated to provide their names or personal information as a condition of observing or participating in the meeting. When joining the WebEx platform, participants may be asked for their name and email address.

Participants who choose not to provide their names will need to provide a unique identifier such as their initials or another alternative, so that the meeting moderator can identify individuals who wish to make public comment; participants who choose not to provide their email address may utilize a fictitious email address in the following sample format: XXXXX@mailinator.com.

The meeting is open to the public and is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Carolina Sammons by phone at (916) 574-7876, or by email at Carolina.Sammons@dca.ca.gov or by sending a written request to the Cemetery and Funeral Bureau, 1625 North Market Blvd., Suite S-208 Sacramento, CA 95834. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Please contact Carolina Sammons by phone at (916) 574-7876, or by email at Carolina.Sammons@dca.ca.gov for additional information concerning this workshop.

DEPARTMENT OF CONSUMER AFFAIRS
CALIFORNIA BOARD OF ACCOUNTANCY
2000 EVERGREEN STREET, SUITE 250
SACRAMENTO, CA 95815-3832
TELEPHONE: (916) 263-3680
FACSIMILE: (916) 263-3675
WEB ADDRESS: *http://www.cba.ca.gov*

CBA Item VI.A.
January 26-27, 2012

Regulation Hearing Regarding Title 16, California Code of Regulations Sections 15, 15.1, 15.2, 15.3, 15.4, 70, 71 and 87.1- Retired Status

Presented by: Kari O'Connor, Special Projects Analyst
Date: January 3, 2012

Purpose of the Item

Staff are providing the materials pertinent to the public hearing for the proposed rulemaking. The public hearing for this proposal will be held at the California Board of Accountancy's (CBA) January 2012 meeting.

Action(s) Needed

No specific action is required on this agenda item.

Background

At its November 2011 meeting, the CBA directed staff to initiate the rulemaking process for retired status.

The Notice of Proposed Action was filed with the Office of Administrative Law (OAL) on November 29, 2011 and published on December 9, 2011 , thus initiating the required 45-day public comment period. January 23, 2012 will mark the end of the public comment period, and on January 27, 2012, a public hearing will be conducted on the proposed regulation. The following attachments will aid in your preparation for the hearing:

- Notice of Proposed Action **(Attachment 1)**
- Text of Proposal **(Attachment 2)**
- Initial Statement of Reasons **(Attachment 3)**
- Public Comments **(Attachment 4)**

Comments

During the public hearing, CBA members may hear oral testimony and receive written comments. If any changes are made as a result of these comments, a 15-day Re-Notice will be required. Staff have not received any public comment related to this regulatory package. Any comments received after the CBA mail out date will be supplied to CBA members at the meeting. The CBA may act to adopt the proposed regulations under **CBA Agenda Item VI.A.1**. Prior to submitting the final regulation

package to the OAL, staff will draft responses to any comments and prepare the Final Statement of Reasons for distribution to all persons who provided comments.

Recommendation
None

Attachments
Notice of Proposed Action
Text of Proposal
Initial Statement of Reasons
Public Comment Letter

Attachment 1

TITLE 16. CALIFORNIA BOARD OF ACCOUNTANCY

NOTICE IS HEREBY GIVEN that the California Board of Accountancy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at Crowne Plaza Irvine, 17941 Von Karman Avenue, Irvine, CA 92614, at 9:10 a.m. on January 27, 2012. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the California Board of Accountancy at its office not later than 5:00 p.m. on January 23, 2012 or must be received by the California Board of Accountancy at the hearing. The California Board of Accountancy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 5010, 5018, 5027, 5070.1 and 5134 of the Business and Professions Code; and to implement, interpret or make specific Sections 122, 163, 5010, 5028, 5058.3, 5070.1, 5096, 5109, and 5134 of the Business and Professions Code; the California Board of Accountancy is considering changes to Division 1 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Legislation enacted in 2011 (Stats 2011, ch. 395 (AB 431)) added Section 5070.1 to the Business and Professions Code effective January 1, 2012 allowing the Board to establish, by regulation, a system for placing a license in a retired status for certified public accountants and public accountants who are not actively engaged in the practice of public accountancy or any activity which requires them to be licensed by the Board. This proposal would implement the requirements for obtaining and maintaining such a license in a retired status. The regulatory proposal is as follows:

1. Adopt New Article 2.5 in Division 1 of Title 16 of the California Code of Regulations.

This proposal would add a new Article 2.5 to Division 1 in the California Board of Accountancy's regulations that would be entitled "Retired Status."

2. Adopt Section 15 in Title 16 of the California Code of Regulations.

This proposal would adopt Section 15 in a newly created Article 2.5 regarding retired status. This proposal would allow a licensee to apply to have their license placed in a

retired status. This new article would not prohibit a holder of a license in a retired status from receiving compensation or profits from a public accounting firm provided the licensee does not engage in the practice of public accountancy.

In addition, this proposal states that failure to maintain compliance with this new Article and Sections 5058.3 or 5070.1 of the Business and Professions Code is grounds for discipline of the retired license.

3. Adopt Section 15.1 in Title 16 of the California Code of Regulations.

This proposal would require a licensee to apply for placing their license in a retired status using Form 11R-48 (11/11) which is incorporated by reference. Form 11R-48 (11-11) would include the following:

(1) Require disclosure of the name, address of record, license number, email address (optional), personal and business telephone number;
(2) Require disclosure of whether the applicant intends to practice public accountancy with a license in retired status;
(3) Require disclosure of whether the applicant is aware of any pending or current enforcement action against his or her license;
(4) Require disclosure of whether the applicant has held a license as a CPA or PA in the U.S. or its territories for a minimum of 20 total years and then require the applicant to provide the state or territory in which the license was held, the license number and the number of years the license was held;
(5) Require disclosure of whether the applicant held a CPA or PA license in an active status for a minimum of five years;
(6) Provide a notice regarding collection and use of personal information given on the application; and,
(7) Require the applicant to certify his or her statements under penalty of perjury.

The proposal would require a licensee to have held a license as a certified public accountant (CPA) or public accountant (PA) in the United States or its territories for a minimum of twenty years, and that five of those years must have been in an active status as a California licensee. Failure to meet the requirements of this new Article and Section 5070.1 of the Business and Professions Code is grounds for denying the application.

The proposal would also require the applicant to pay the application fee set forth in newly proposed Section 70(i)(1).

4. Adopt Section 15.2 in Title 16 of the California Code of Regulations.

This proposal would require the holder of a license in a retired status to continue to renew their license on the same renewal schedule they were on prior to being granted retired status as described in Section 5070.5 of the Business and Professions Code. It exempts a licensee with a license in a retired status from the regular renewal fee and the regular continuing education (CE) requirements.

5. Adopt Section 15.3 in Title 16 of the California Code of Regulations.

This proposal would allow the holder of a license in a retired status to restore that license to an active status at the time of renewal by paying the fee set forth in newly proposed Section 70(i)(2) and complying with the CE requirements of existing Section 87 with a minimum of 20 hours of CE in the year prior to renewal and 12 hours in specific subject areas prescribed in existing Section 88(a)(1).

This proposal would allow the holder of a license in a retired status to restore that license to an active status prior to their next renewal date by paying the fee described in Section 70(i)(2) and completing the CE requirements set forth in existing Section 87.1.

6. Adopt Section 15.4 in Title 16 of the California Code of Regulations.

This proposal limits the number of times a licensee may be granted retired status to two.

7. Amend Section 70 in Title 16 of the California Code of Regulations.

This proposal would set the fee for application for a license to be placed in a retired status at $100.

This proposal would set the fee for restoring a license in a retired status to an active status on a scale based on the time that has elapsed between the retired status being granted and the time the Board receives a written request for restoration and the restoration fee. The restoration fee begins at $200 and increases by $200 for every two years up to the maximum of $1000.

8. Amend Section 71 in Title 16 of the California Code of Regulations.

This proposal would add an application for retired status to the list of applications that can be abandoned if the applicant fails to complete the application within two years of its original submission or within one year of notification by the Board of any deficiency in the application.

9. Amend Section 87.1 in Title 16 of the California Code of Regulations.

This proposal would ensure that the CE requirements for restoring a license in a retired status to active status prior to renewal are the same as those for converting a license in an inactive status to an active status prior to renewal.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:

This bill will create an absorbable fiscal impact to the California Board of Accountancy (CBA).

The CBA will experience a loss in renewal revenue through implementation of the retired status due to the large population of older licensees that will pursue the new option. Much of this loss in revenue will be offset by the same population paying for the $100 retirement fees as well as delinquent licensees providing revenue in the first year when they wouldn't otherwise have done so. It is estimated that the CBA will lose approximately $6 million in revenues during this initial 6 year period. The ongoing annual fiscal impact after this initial wave of retirements is projected to be a loss in revenues of approximately $1 million.

Assumptions:

1. A "start date" of January 1, 2013.
2. The temporary renewal fee reduction of $120 reverts to its original $200 amount on July 1, 2015.
3. A licensee must have been practicing a minimum of 20 years to be eligible for the retired status.
4. Licensees who are 62 years of age or older are the population that will apply for the retired status. 50% of CBA licensees will retire upon reaching 62.
5. For each additional year of age, an additional 10% of the group will retire (or 20% of the remaining licensees who did not retire). For example, 60% of licensees 63 years of age will be retired. 70% of licensees 64 years of age will be retired.
6. All delinquent licensees age 62 or older (licensees that have no practice rights and do not pay renewal fees or complete continuing education) will opt for the retired status within the first year of implementation. The law has provisions which allow delinquent licensees to forgo paying any past renewal or delinquency fees if they opt for the retired status within the first year of implementation. Because this provision is only available for the first year, it is not expected that any delinquent licensees will opt for the retired status in subsequent years.
7. The retired status application fee will be a one-time fee of $100.
8. Licensees who opt for the retired status would have paid renewal fees for 3 renewal cycles (6 years) had there not been an option for the retired status.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500-17630 Require Reimbursement: None

Business Impact:

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

AND

The following studies/relevant data were relied upon in making the above determination: The only possibility of the proposal impacting businesses is if the application or restoration fees are paid for by a business. The CBA assumes that this will be an infrequent occurrence as this is not a normal cost of doing business.

Impact on Jobs/New Businesses:

The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action and that are known to the Board are insignificant.

The population of licensees choosing to apply for retired status must have been in practice for at least 20 years or more. The licensee will need to pay a one-time $100 fee to apply for “retired” status. Should the licensee desire to practice again, payment of fees up to a maximum of $1,000 would need to be paid. The regulation permits a licensee to retire/restore twice, however once the licensee restores for the second time, a third retirement is not permitted. It is not expected that many retired licensees will restore their license to an active status and even less would be assumed for a second restoration. Any estimate of restoration fees will be statistically insignificant.

It is assumed that the population of licensees that will be eligible for retirement will be 62 years of age or older. The CBA anticipates a huge influx of individuals to opt for the retired status; in the first year (2013), the CBA projects over 14,000 licensees will retire.

After the initial wave of retirements, it is expected that the population of licensees opting for the retired status will stabilize to approximately 2,000 annually. The one-time retirement fees of $100 will be offset by the individuals no longer having to pay biennial renewal fees which will be $120 in 2013, and are expected to be $200 every two years by the time this stabilization period occurs.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations may affect small businesses if the application or restoration fees are paid for by a business. The CBA is assuming that this will be an infrequent occurrence as this is not a normal cost of doing business.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, including Form 11R-48 (11/11), which is incorporated by reference in this rulemaking, are available on the Board's Internet website at http://www.dca.ca.gov/cba/laws_and_rules/pubpart.shtml and may also be obtained at the hearing or prior to the hearing upon request from the California Board of Accountancy at 2000 Evergreen Street, Suite 250, Sacramento, California 95815.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named in the following section.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named in the following section or by accessing the website listed in the following section.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Matthew Stanley
Address:	California Board of Accountancy 2000 Evergreen Street, Suite 250 Sacramento, CA 95815
Telephone No.:	916-561-1792
Fax No.:	916-263-3678
E-Mail Address:	mstanley@cba.ca.gov

The backup contact person is:

Name:	Kari O'Connor
Address:	California Board of Accountancy 2000 Evergreen Street, Suite 250 Sacramento, CA 95815
Telephone No.:	916-561-4311
Fax No.:	916-263-3678
E-Mail Address:	koconnor@cba.ca.gov

Website Access: Materials regarding this proposal can be found at http://www.dca.ca.gov/cba/laws_and_rules/pubpart.shtml.

Attachment 2

PROPOSED REGULATORY LANGUAGE

Adopt Sections 15, 15.1, 15.2, 15.3 and 15.4 in Article 2.5 of Division 1 of Title 16 of the California Code of Regulations to read:

Article 2.5 – Retired Status

Section 15 – Retired Status

Upon application, a licensee may request to have his/her license placed in a retired status. The holder of a license in a retired status shall not engage in the practice of public accountancy as defined in Section 5051 of the Business and Professions Code. This section does not prohibit a holder of a license in a retired status from receiving a share of the net profits from a public accounting firm or other compensation from a public accounting firm, provided that the licensee does not otherwise engage in the practice of public accountancy.

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Section 15.1 – Application for Retired Status

(a) A licensee of the Board shall apply for a license in a retired status on the following form: Application to Have a License Placed in a Retired Status, Form 11R-48 (11/11) which is hereby incorporated by reference.
(b) For an application to be approved, a licensee applying to have his/her license placed in a retired status shall have held a license as a certified public accountant or public accountant in the United States or its territories for a minimum of twenty total years; and during those twenty years, from the Board for a minimum of five years in an active status.
(c) An applicant for placing a license in a retired status shall pay the application fee required by Section 70(i)(1).

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Section 15.2 – Renewal of a License in a Retired Status

(a) A licensee shall renew a license in a retired status during the same time period in which a license in an active status is renewed.
(b) The fee for renewal described in Section 70(e) is not applicable at the time of renewal for a licensee renewing a license in a retired status.
(c) The continuing education requirements described in Section 87 are not applicable at the time of renewal for a licensee renewing a license in a retired status.

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Section 15.3 – Restoration of a License from a Retired Status to Active Status

(a) At the time of renewal, the holder of a license in a retired status may restore his/her license to an active status by paying the fee described in Section 70(i)(2) and complying with the continuing education requirements as described in Section 87. A minimum of 20 hours of continuing education shall be completed in the one-year period immediately preceding the time of renewal, 12 hours of which must be in subject areas described in Section 88(a)(1).
(b) The holder of a license in a retired status may restore the license to an active status prior to the next renewal by paying the fee described in Section 70(i)(2) and by meeting the continuing education requirements as described in Section 87.1.

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Section 15.4 – Limitation on Retired Status

A licensee may be granted a license in a retired status under this Article on no more than two separate occasions.

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Amend Sections 70 and 71 in Article 10 of Division 1 of Title 16 of the California Code of Regulations to read:

Section 70 – Fees

(a) Commencing January 23, 2004, the fee to be charged each California applicant for the computer-based Uniform Certified Public Accountant Examination shall be an application fee of $100 for issuance of the Authorization to Test to first-time applicants and an application fee of $50 for issuance of the Authorization to Test to repeat applicants.
(b) Commencing July 1, 2001, the fee to be charged each applicant for issuance of a certified public accountant certificate shall be $250.
(c) The fee to be charged each applicant for registration, including applicant for registration under a new name as a partnership or as a corporation, shall be $150.
(d)(1) Commencing July 1, 2000, the fee to be charged each applicant for the initial permit to practice as a partnership, a corporation, or a certified public accountant shall be $200.

(2) Commencing July 1, 2011, the fee to be charged each applicant for the initial permit to practice as a partnership, a corporation, or a certified public accountant shall be $120.
(3) Commencing July 1, 2015, the fee to be charged each applicant for the initial permit to practice as a partnership, a corporation, or a certified public accountant shall be $200 unless subsection (i) applies.
(e)(1) Commencing July 1, 2000, the fee to be charged each applicant for renewal of a permit to practice as a partnership, a corporation, a public accountant, or a certified public accountant shall be $200.
(2) For licenses expiring after June 30, 2011, the fee to be charged each applicant for renewal of a permit to practice as a partnership, a corporation, a public accountant, or a certified public accountant shall be $120.
(3) For licenses expiring after June 30, 2015, the fee to be charged each applicant for renewal of a permit to practice as a partnership, a corporation, a public accountant, or a certified public accountant shall be $200 unless subsection (i) applies.
(f) The fee for the processing and issuance of a duplicate copy of a certificate of licensure or registration shall be $10.
(g) The fee for processing and issuance of a duplicate copy of a registration, or permit or other form evidencing licensure or renewal of licensure shall be $2.
(h)(1) The fee to be charged an individual for submission of a Practice Privilege Notification Form pursuant to Business and Professions Code Section 5096 with an authorization to sign attest reports shall be $100.
(2) The fee to be charged an individual for submission of a Practice Privilege Notification Form pursuant to Business and Professions Code Section 5096 without an authorization to sign attest reports shall be $50.
(i) (1) The fee to be charged a licensee for submission of an application for a license in a retired status pursuant to Section 15.1 shall be $100.
(2) The fee to restore a license from a retired status to an active status shall be equal to the fees accrued had the licensee been renewing in an active status, and the total shall not exceed $1000.
~~(i)~~ (j) By May 31, 2014, the Board shall conduct a review of its actual and estimated costs. Based on this review, the Board shall determine the appropriate level of fees for the initial permit to practice pursuant to subsection (d) and renewal of the permit to practice pursuant to subsection (e) in order to maintain the Board's contingent fund reserve balance at an amount equal to approximately nine months of estimated annual authorized expenditures. If the Board determines that fees of less than $200 are indicated, the Board shall fix the fees by regulation at the indicated amounts by July 1, 2015.

Note: Authority cited: Sections 5010 and 5134, Business and Professions Code. Reference: Sections 122, 163, 5070.1, 5096, and 5134 Business and Professions Code.

Section 71 – Abandonment of the Application

(a) An applicant for the paper and pencil examination who fails to appear for the examination shall be deemed to have abandoned the application and shall forfeit the examination fee.
(b) A first-time applicant for an Authorization to Test pursuant to Section 8.1 shall be deemed to have abandoned the application and shall forfeit any application fee if the applicant fails to complete the application within one year of notification by the Board of any deficiency in the application.
(c) An application for a certificate, permit, registration, or license, including any application for renewal or retired status, shall be deemed abandoned and any application fee shall be forfeited, if the applicant fails to complete the application within two years of its original submission or within one year of notification by the Board of any deficiency in the application.

Note: Authority cited: Sections 5010 and 5018, Business and Professions Code. Reference: ~~Section~~ Sections 5010, 5070.1, and 5134, Business and Professions Code.

Amend Section 87.1 in Article 12 of Division 1 of Title 16 of the California Code of Regulations to read:

Section 87.1 – Conversion or Restoration to Active Status Prior to Renewal

(a) A licensee who has ~~renewed his/her~~ a license in an inactive or retired status may convert, or restore, the license to an active status prior to the next license expiration date by (1) completing 80 hours of continuing education credit as described in Section 88, to include the Ethics Continuing Education Requirement described in Section 87(b), within the 24-month period prior to converting to active status, of which a minimum of 20 hours shall be completed in the one-year period immediately preceding conversion to an active status, with a minimum of 12 hours in subject areas described in subsection (a)(1) of Section 88; (2) completing the regulatory review course described in Section 87.8 if more than six years have elapsed since the licensee last completed the course; (3) applying to the Board in writing requesting to convert the license to an active status; and (4) completing any continuing education that is required pursuant to subsection (j) of Section 89. The licensee may not practice public accounting until the application for conversion of the license to an active status has been approved.
(b) A licensee who, during the 24 months prior to converting his/her license to an active status, planned, directed, or conducted substantial portions of field work, or reported on financial or compliance audits of a governmental agency shall complete 24 hours of continuing education in governmental accounting and auditing as described in Section 87(c) as part of the 80 hours of continuing education required to convert his/her license to an active status under subsection (a). A licensee who meets the requirements of this subsection shall be deemed to have met the requirements of subsection (c).
(c) A licensee who, during the 24 months prior to converting his/her license to an active status, planned, directed, or performed substantial portions of the work or reported on an audit, review, compilation, or attestation service shall complete 24 hours of continuing education in accounting and auditing as described in Section 87(d) as part of

the 80 hours of continuing education required to his/her license to an active status under subsection (a).
(d) A licensee who must complete continuing education pursuant to subsections (b) and/or (c) of this section shall also complete an additional eight hours of continuing education specifically related to the detection and/or reporting of fraud in financial statements as described in Section 87(e). This continuing education shall be part of the 80 hours of continuing education required by subsection (a), but shall not be part of the continuing education required by subsections (b) or (c).
(e) Once a license is converted to an active status, the licensee must complete 20 hours of continuing education as described in Section 88 for each full six month period from the date of license conversion to an active status to the next license expiration date in order to fulfill the continuing education requirement for license renewal. If the time period between the date of change to an active status and the next license expiration date is less than six full months, no additional continuing education is required for license renewal.
(f) Once a license is converted to an active status, a licensee who engages in financial or compliance auditing of a governmental agency at any time between the date of license conversion to an active status and the next license expiration date shall complete six hours of governmental continuing education as part of each 20 hours of continuing education required under subsection (e). Continuing education in the areas of governmental accounting and auditing shall meet the requirements of Section 87(c). A licensee who meets the requirements of this subsection shall be deemed to have met the requirements of subsection (g).
(g) Once a license is converted to an active status, a licensee who engages in audit, review, compilation, or attestation services at any time between the date of license conversion to an active status and the next license expiration date shall complete six hours of continuing education in accounting and auditing as part of each 20 hours of continuing education required under subsection (e). Continuing education in the areas of accounting and auditing shall meet the requirements of Section 87(d).

Note: Authority cited: Sections 5010 and 5027, Business and Professions Code. Reference: Section 5028, Business and Professions Code.

Attachment 3

CALIFORNIA BOARD OF ACCOUNTANCY

INITIAL STATEMENT OF REASONS

Hearing Date: January 27, 2012

Subject Matter of Proposed Regulations: Retired Status

Sections Affected: Title 16, Division 1, of Article 2.5 in California Code of Regulations, Sections 15, 15.1, 15.2, 15.3, 15.4, and Sections 70, 71, and 87.1.

Legislation enacted in 2011 (Stats 2011, ch. 395 (AB 431)) added Section 5070.1 to the Business and Professions Code effective January 1, 2012 allowing the Board to establish, by regulation, a system for placing a license in a retired status for certified public accountants and public accountants who are not actively engaged in the practice of public accountancy or any activity which requires them to be licensed by the Board. This proposal would implement the requirements for obtaining and maintaining such a license in a retired status. The regulatory proposal is as follows:

1. Adopt New Article 2.5 in Division 1 of Title 16 of the California Code of Regulations.

This proposal would add a new Article 2.5 to Division 1 in the California Board of Accountancy's regulations that would be entitled "Retired Status."

Factual Basis/Rationale:

Existing law currently has no Article in regulations governing the requirements of licensees who wish to place their licenses in a retired status. This proposal would provide for such an Article and allow the Board to organize the requirements in a manner that allows for ease-of-use and reference by licensees.

2. Adopt Section 15 of Title 16 of the California Code of Regulations

Specific Purpose:

This proposal would adopt Section 15 in a newly created Article 2.5 regarding retired status. This proposal would allow a licensee to apply to have their license placed in a retired status. This new article would not prohibit a holder of a license in a retired status from receiving compensation or profits from a public accounting firm provided the licensee does not engage in the practice of public accountancy.

In addition, this proposal states that failure to maintain compliance with this new Article and Sections 5058.3 or 5070.1 of the Business and Professions Code is grounds for discipline.

Factual Basis/Rationale:

The Board has determined that licensees must apply for retired status to ensure that the licensees meet the qualifications set forth in this proposal and in statute. Section 5070.1 of the Business and Professions Code prohibits the holder of a license in a retired status from practicing public accountancy. However, to avoid confusion regarding what the Board considers active "practice", this proposal would specify that receiving compensation or profits from a public accounting firm is not considered active practice, provided the licensee does not engage in the practice of public accountancy, which is described in Section 5051 of the Business and Professions Code.

The Board must maintain its ability to discipline a license in a retired status as authorized by Section 5109 of the Business and Professions Code. Consequently, this proposal would specify the grounds for disciplining such a license.

3. Adopt Section 15.1 of Title 16 of the California Code of Regulations

Specific Purpose:

This proposal would require a licensee to apply for placing their license in a retired status using Form 11R-48 (11/11) which is incorporated by reference. Form 11R-48 (11-11) would include the following:

(1) Require disclosure of the name, address of record, license number, email address (optional), personal and business telephone number;
(2) Require disclosure of whether the applicant intends to practice public accountancy with a license in retired status;
(3) Require disclosure of whether the applicant is aware of any pending or current enforcement action against his or her license;
(4) Require disclosure of whether the applicant has held a license as a CPA or PA in the U.S. or its territories for a minimum of 20 total years and then require the applicant to provide the state or territory in which the license was held, the license number and the number of years the license was held;
(5) Require disclosure of whether the applicant held a CPA or PA license in an active status for a minimum of five years;
(6) Provide a notice regarding collection and use of personal information given on the application; and,
(7) Require the applicant to certify his or her statements under penalty of perjury.

The proposal would require a licensee to have held a license as a certified public accountant (CPA) or public accountant (PA) in the United States or its territories for a minimum of twenty years, and that five of those years must have been in an active status as a California licensee. Failure to meet the requirements of this new Article and Section 5070.1 of the Business and Professions Code is grounds for denying the

application.

The proposal also would also require the applicant to pay the application fee set forth in proposed Section 70(i)(1).

Factual Basis/Rationale:

The Board has determined that licensees must apply for retired status to ensure that the licensees meet the qualifications set forth in this proposal and in statute. Consequently, this proposal provides that failure to meet the minimum requirements and the applicable provisions of the Accountancy Act is grounds for denial of the application. The qualifications in this proposal, twenty years in the profession including five years in California in an active status, are meant to allow those who have made a significant contribution to the practice of public accountancy, specifically in California, the option of retiring their license. This also allows for a more accurate description of a licensee's status to be reflected on the Board's website for the benefit of consumers.

The foregoing form is necessary to create a process for the Board for review of an applicant's qualifications, to implement the requirements of Section 5070.1, and to assist with providing applicants with a simple method for determining the requirements for seeking retired status from the Board. The certification and disclosure requirements also assist in ensuring accurate and complete information is being provided to the Board prior to making a decision to grant or deny retired status.

4. Adopt Section 15.2 of Title 16 of the California Code of Regulations

Specific Purpose:

This proposal would require the holder of a license in a retired status to continue to renew their license on the same renewal schedule they were on prior to being granted retired status as described in Section 5070.5 of the Business and Professions Code. It exempts a licensee with a license in a retired status from the regular renewal fee and the regular CE requirements.

Factual Basis/Rationale:

The Board has determined that the holder of a license in a retired status should continue to be subject to the Board's biennial renewal cycle. The purpose was so that the Board can maintain contact with its licensees. Such a licensee would be exempt from all renewal fees and CE requirements as they are prohibited from practicing public accountancy.

5. Adopt Section 15.3 of Title 16 of the California Code of Regulations

Specific Purpose:

This proposal would allow the holder of a license in a retired status to restore that license to an active status at the time of renewal by paying the fee set forth in proposed Section 70(i)(2) and complying with the CE requirements of Section 87 with a minimum of 20 hours of CE in the year prior to renewal and 12 hours in specific subject areas prescribed in existing Section 88(a)(1).

This proposal would allow the holder of a license in a retired status to restore that license to an active status prior to their next renewal date by paying the fee described in proposed Section 70(i)(2) and completing the CE requirements set forth in existing Section 87.1.

Factual Basis/Rationale:

The Board has determined that restoring a license in a retired status to an active status should be similar to converting a license in an inactive status to an active status. To that end, the proposal mirrors the conversion process except for the fee amounts and the fact that this proposal requires a fee when restoring a license outside of the renewal process.

6. Adopt Section 15.4 of Title 16 of the California Code of Regulations

Specific Purpose:

This proposal limits the number of times a licensee may be granted retired status to two.

Factual Basis/Rationale:

The Board has determined that retiring is a process to which much thought must be given as it is meant to be a permanent decision. That said, the Board also understands that situations can arise that are outside of the control of individuals. The Board decided to limit the granting of retired status to two times in order to ensure thought is given to the decision before it is made, and yet maintain some flexibility to all for the unforeseen situations.

In addition, the Board did not want the retired status used as a means of temporarily escaping renewal fees or avoiding other requirements.

7. Amend Section 70 of Title 16 of the California Code of Regulations

Specific Purpose:

This proposal would set the fee for application for a license to be placed in a retired status at $100.

This proposal would set the fee for restoring a license in a retired status to an active

status on a scale based on the time that has elapsed between the retired status being granted and the time the Board receives a written request for restoration and the restoration fee. The restoration fee begins at $200 and increases by $200 for every two years up to the maximum of $1000.

Factual Basis/Rationale:

The amount of $100 was selected as the application fee as it is half of the Board's normal renewal fee. It is intended to be the last payment made by a licensee. If however, a licensee desires to return to active status, they are to pay a restoration fee that is based on the amount of time they were retired, up to the statutory cap of $1000. This amount is set in such a way as to discourage the use of retired status as a temporary status. In addition, the Board did not want the retired status used as a means of temporarily escaping renewal fees that are typically paid by active and inactive licensees

8. Amend Section 71 of Title 16 of the California Code of Regulations

Specific Purpose:

This proposal would adds an application for retired status to the list of applications that can be abandoned if the applicant fails to complete the application within two years of its original submission or within one year of notification by the Board of any deficiency in the application.

Factual Basis/Rationale:

If a licensee does not pay the application fee or complete the application process in any way, this will allow the Board to abandon the application after waiting a fixed amount of time. This is necessary to ensure the efficient processing of applications and a fair amount of time to remedy deficiencies uncovered by the Board in the application submission.

9. Amend Section 87.1 of Title 16 of the California Code of Regulations

Specific Purpose:

This proposal would ensure that the CE requirements for restoring a license in a retired status to active status prior to renewal are the same as those for converting a license in an inactive status to an active status prior to renewal.

Factual Basis/Rationale:

The Board has determined that restoring a license in a retired status to an active status should be similar to converting a license in an inactive status to an active status. This proposal makes the restoration CE requirements identical to the current inactive

conversion CE requirements.

Underlying Data

Technical, theoretical or empirical studies or reports relied upon (if any):
(1) Assembly Bill 431 (Stats. 2011, ch. 395)
(2) Minutes of the May 2011 CBA Meeting.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the following facts or evidence/documents/ testimony:
The only possibility of the proposal impacting businesses is if the application or restoration fees are paid for by a business. The CBA assumes that this will be an infrequent occurrence as this is not a normal cost of doing business.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

The Board considered not establishing a retired status. This was rejected because of the desire for such a status from licensees and the more accurate representation of a licensee's status on the Board's website for consumers.

January 18, 2012

Matthew Stanley
California Board of Accountancy
2000 Evergreen Street, Suite 250
Sacramento, CA 95815

RE: Proposed Rulemaking Action pertaining to AB417 set for hearing at 9:10 a.m., January 27, 2012.

Dear Mr. Stanley:

I would like to point out what appears to be a discrepancy between the Regulatory Proposal and the assumptions listed under Fiscal Impact Estimates.

Under Section 15.1 in Title 16 of the California Code of Regulations paragraph (4) states that a licensee seeking a retired status is required to disclose whether the applicant has held a license as a CPA or PA in the U.S. for a minimum of 20 years, and under paragraph (5) whether the applicant held a CPA or PA license in an active status for a minimum of five years.

However, under the Fiscal Impact Estimates assumptions: paragraph 3 states that "A licensee must have been practicing a minimum of 20 years to be eligible for the retired status." This assumption is in direct conflict with the wording of the Regulatory Proposal described above. In other words the Regulatory Proposal states an applicant needs to have been licensed a minimum of 20 years but active only a minimum of 5 years. Since a CPA can only "practice" if in active status, the fiscal impact estimate assumption is in direct conflict by stating that an applicant must have been practicing a minimum of 20 years to be eligible for retired status.

Thank you for reviewing this matter and correcting any potential conflict or discrepancy prior to the meeting scheduled for January 27, 2012.

Sincerely,

Clyde J. Francone
CPA license number 31898E

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CBA Item VI.A.1.
January 26-27, 2012

Discussion and Possible Action to Adopt or Amend Proposed Text at Title 16, CCR Sections 15, 15.1, 15.2, 15.3, 15.4, 70, 71, and 87.1, and Adopt New Article 2.5 Regarding Retired Status

Presented by: Kari O'Connor, Special Projects Analyst
Date: January 3, 2012

Purpose of the Item

Following a public hearing, the California Board of Accountancy (CBA) may discuss and take action to adopt or modify a proposed regulation.

Action Needed

Possible adoption of the proposed regulation.

Background

After the conclusion of the hearing under **CBA Agenda Item VI.A.,** the next step in the process is that the CBA must act to formally adopt the proposed regulations **(Attachment 1)** outlined in the subject of this memorandum.

Comments

The CBA may decide to make changes to the proposed regulations, or it may proceed with adopting the proposal without modification.

- ***If no changes are to be made after the public comment period and hearing closes:***
  Motion: Direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, authorize the Executive Officer to make any non-substantive changes to the proposed regulations, and adopt the proposed regulations as originally noticed.

- ***If substantive changes are to be made after the public comment period and hearing closes***:
  Motion: Direct staff to take all steps necessary to complete the rulemaking process, including sending out the modified text for an additional 15-day comment period. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations, and adopt the proposed regulations as described in the modified text notice.

Recommendation

Staff recommend the following:

- Adopt the staff provided motion above related to no changes in the proposed regulations.

Attachment

Proposed Regulations

PROPOSED REGULATORY LANGUAGE

Adopt Sections 15, 15.1, 15.2, 15.3 and 15.4 in Article 2.5 of Division 1 of Title 16 of the California Code of Regulations to read:

Article 2.5 – Retired Status

Section 15 – Retired Status

Upon application, a licensee may request to have his/her license placed in a retired status. The holder of a license in a retired status shall not engage in the practice of public accountancy as defined in Section 5051 of the Business and Professions Code. This section does not prohibit a holder of a license in a retired status from receiving a share of the net profits from a public accounting firm or other compensation from a public accounting firm, provided that the licensee does not otherwise engage in the practice of public accountancy.

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Section 15.1 – Application for Retired Status

(a) A licensee of the Board shall apply for a license in a retired status on the following form: Application to Have a License Placed in a Retired Status, Form 11R-48 (11/11) which is hereby incorporated by reference.
(b) For an application to be approved, a licensee applying to have his/her license placed in a retired status shall have held a license as a certified public accountant or public accountant in the United States or its territories for a minimum of twenty total years; and during those twenty years, from the Board for a minimum of five years in an active status.
(c) An applicant for placing a license in a retired status shall pay the application fee required by Section 70(i)(1).

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Section 15.2 – Renewal of a License in a Retired Status

(a) A licensee shall renew a license in a retired status during the same time period in which a license in an active status is renewed.
(b) The fee for renewal described in Section 70(e) is not applicable at the time of renewal for a licensee renewing a license in a retired status.
(c) The continuing education requirements described in Section 87 are not applicable at the time of renewal for a licensee renewing a license in a retired status.

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Section 15.3 – Restoration of a License from a Retired Status to Active Status

(a) At the time of renewal, the holder of a license in a retired status may restore his/her license to an active status by paying the fee described in Section 70(i)(2) and complying with the continuing education requirements as described in Section 87. A minimum of 20 hours of continuing education shall be completed in the one-year period immediately preceding the time of renewal, 12 hours of which must be in subject areas described in Section 88(a)(1).
(b) The holder of a license in a retired status may restore the license to an active status prior to the next renewal by paying the fee described in Section 70(i)(2) and by meeting the continuing education requirements as described in Section 87.1.

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Section 15.4 – Limitation on Retired Status

A licensee may be granted a license in a retired status under this Article on no more than two separate occasions.

Note: Authority cited: Sections 5010 and 5070.1, Business and Professions Code. Reference: Section 5070.1, Business and Professions Code.

Amend Sections 70 and 71 in Article 10 of Division 1 of Title 16 of the California Code of Regulations to read:

Section 70 – Fees

(a) Commencing January 23, 2004, the fee to be charged each California applicant for the computer-based Uniform Certified Public Accountant Examination shall be an application fee of $100 for issuance of the Authorization to Test to first-time applicants and an application fee of $50 for issuance of the Authorization to Test to repeat applicants.
(b) Commencing July 1, 2001, the fee to be charged each applicant for issuance of a certified public accountant certificate shall be $250.
(c) The fee to be charged each applicant for registration, including applicant for registration under a new name as a partnership or as a corporation, shall be $150.
(d)(1) Commencing July 1, 2000, the fee to be charged each applicant for the initial permit to practice as a partnership, a corporation, or a certified public accountant shall be $200.

(2) Commencing July 1, 2011, the fee to be charged each applicant for the initial permit to practice as a partnership, a corporation, or a certified public accountant shall be $120.
(3) Commencing July 1, 2015, the fee to be charged each applicant for the initial permit to practice as a partnership, a corporation, or a certified public accountant shall be $200 unless subsection (i) applies.
(e)(1) Commencing July 1, 2000, the fee to be charged each applicant for renewal of a permit to practice as a partnership, a corporation, a public accountant, or a certified public accountant shall be $200.
(2) For licenses expiring after June 30, 2011, the fee to be charged each applicant for renewal of a permit to practice as a partnership, a corporation, a public accountant, or a certified public accountant shall be $120.
(3) For licenses expiring after June 30, 2015, the fee to be charged each applicant for renewal of a permit to practice as a partnership, a corporation, a public accountant, or a certified public accountant shall be $200 unless subsection (i) applies.
(f) The fee for the processing and issuance of a duplicate copy of a certificate of licensure or registration shall be $10.
(g) The fee for processing and issuance of a duplicate copy of a registration, or permit or other form evidencing licensure or renewal of licensure shall be $2.
(h)(1) The fee to be charged an individual for submission of a Practice Privilege Notification Form pursuant to Business and Professions Code Section 5096 with an authorization to sign attest reports shall be $100.
(2) The fee to be charged an individual for submission of a Practice Privilege Notification Form pursuant to Business and Professions Code Section 5096 without an authorization to sign attest reports shall be $50.
(i) (1) The fee to be charged a licensee for submission of an application for a license in a retired status pursuant to Section 15.1 shall be $100.
(2) The fee to restore a license from a retired status to an active status shall be equal to the fees accrued had the licensee been renewing in an active status, and the total shall not exceed $1000.
~~(i)~~ (j) By May 31, 2014, the Board shall conduct a review of its actual and estimated costs. Based on this review, the Board shall determine the appropriate level of fees for the initial permit to practice pursuant to subsection (d) and renewal of the permit to practice pursuant to subsection (e) in order to maintain the Board's contingent fund reserve balance at an amount equal to approximately nine months of estimated annual authorized expenditures. If the Board determines that fees of less than $200 are indicated, the Board shall fix the fees by regulation at the indicated amounts by July 1, 2015.

Note: Authority cited: Sections 5010 and 5134, Business and Professions Code. Reference: Sections 122, 163, 5070.1, 5096, and 5134 Business and Professions Code.

Section 71 – Abandonment of the Application

(a) An applicant for the paper and pencil examination who fails to appear for the examination shall be deemed to have abandoned the application and shall forfeit the examination fee.
(b) A first-time applicant for an Authorization to Test pursuant to Section 8.1 shall be deemed to have abandoned the application and shall forfeit any application fee if the applicant fails to complete the application within one year of notification by the Board of any deficiency in the application.
(c) An application for a certificate, permit, registration, or license, including any application for renewal or retired status, shall be deemed abandoned and any application fee shall be forfeited, if the applicant fails to complete the application within two years of its original submission or within one year of notification by the Board of any deficiency in the application.

Note: Authority cited: Sections 5010 and 5018, Business and Professions Code. Reference: ~~Section~~ Sections 5010, 5070.1, and 5134, Business and Professions Code.

Amend Section 87.1 in Article 12 of Division 1 of Title 16 of the California Code of Regulations to read:

Section 87.1 – Conversion or Restoration to Active Status Prior to Renewal

(a) A licensee who has ~~renewed his/her~~ a license in an inactive or retired status may convert, or restore, the license to an active status prior to the next license expiration date by (1) completing 80 hours of continuing education credit as described in Section 88, to include the Ethics Continuing Education Requirement described in Section 87(b), within the 24-month period prior to converting to active status, of which a minimum of 20 hours shall be completed in the one-year period immediately preceding conversion to an active status, with a minimum of 12 hours in subject areas described in subsection (a)(1) of Section 88; (2) completing the regulatory review course described in Section 87.8 if more than six years have elapsed since the licensee last completed the course; (3) applying to the Board in writing requesting to convert the license to an active status; and (4) completing any continuing education that is required pursuant to subsection (j) of Section 89. The licensee may not practice public accounting until the application for conversion of the license to an active status has been approved.
(b) A licensee who, during the 24 months prior to converting his/her license to an active status, planned, directed, or conducted substantial portions of field work, or reported on financial or compliance audits of a governmental agency shall complete 24 hours of continuing education in governmental accounting and auditing as described in Section 87(c) as part of the 80 hours of continuing education required to convert his/her license to an active status under subsection (a). A licensee who meets the requirements of this subsection shall be deemed to have met the requirements of subsection (c).
(c) A licensee who, during the 24 months prior to converting his/her license to an active status, planned, directed, or performed substantial portions of the work or reported on an audit, review, compilation, or attestation service shall complete 24 hours of continuing education in accounting and auditing as described in Section 87(d) as part of

the 80 hours of continuing education required to his/her license to an active status under subsection (a).
(d) A licensee who must complete continuing education pursuant to subsections (b) and/or (c) of this section shall also complete an additional eight hours of continuing education specifically related to the detection and/or reporting of fraud in financial statements as described in Section 87(e). This continuing education shall be part of the 80 hours of continuing education required by subsection (a), but shall not be part of the continuing education required by subsections (b) or (c).
(e) Once a license is converted to an active status, the licensee must complete 20 hours of continuing education as described in Section 88 for each full six month period from the date of license conversion to an active status to the next license expiration date in order to fulfill the continuing education requirement for license renewal. If the time period between the date of change to an active status and the next license expiration date is less than six full months, no additional continuing education is required for license renewal.
(f) Once a license is converted to an active status, a licensee who engages in financial or compliance auditing of a governmental agency at any time between the date of license conversion to an active status and the next license expiration date shall complete six hours of governmental continuing education as part of each 20 hours of continuing education required under subsection (e). Continuing education in the areas of governmental accounting and auditing shall meet the requirements of Section 87(c). A licensee who meets the requirements of this subsection shall be deemed to have met the requirements of subsection (g).
(g) Once a license is converted to an active status, a licensee who engages in audit, review, compilation, or attestation services at any time between the date of license conversion to an active status and the next license expiration date shall complete six hours of continuing education in accounting and auditing as part of each 20 hours of continuing education required under subsection (e). Continuing education in the areas of accounting and auditing shall meet the requirements of Section 87(d).

Note: Authority cited: Sections 5010 and 5027, Business and Professions Code. Reference: Section 5028, Business and Professions Code.

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Attachment 3

12(d). General Experience Required Under Business and Professions Code Section 5092 and 5093.
(d) An applicant who is applying under Section 5092 or Section 5093 of the Business and Professions Code with experience obtained five (5) or more years prior to application may be required to obtain 48 hours of continuing education which shall include general accounting, and other comprehensive basis of accounting; and to submit the certificates of completion to the Board.

12.5(f). Attest Experience Under Business and Professions Code Section 5095.
(f) The applicant who is applying with experience obtained five (5) or more years prior to application may be required to obtain 48 hours of continuing education which shall include financial accounting standards, auditing standards, compilation and review, and other comprehensive basis of accounting; and to submit the certificates of completion to the Board.

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Attachment 4

CONTINUING EDUCATION REQUIREMENTS FOR OTHER STATE BOARDS OF ACCOUNTANCY

Arizona
80 hours every two years if the individual is in public practice, with 38 hours in technical areas (Accounting, Auditing, Tax, Management Advisory, Business Law or any combination thereof) and the remainder of the hours may fall into the Other category. 60 hours if the individual is in industry, with 28 hours in technical areas.

Four hours of Board-approved ethics during the two-year period immediately preceding registration renewal. The 4-hour requirement shall include a minimum of 1 hour of each of the following: Ethics related to the practice of accounting including the American Institute of Certified Public Accountants Professional Code of Conduct; and, Board statutes and administrative rules.

Florida
80 hours every two years of continuing professional education credits with at least 20 hours in accounting and auditing and 4 hours of a board approved ethics course and no more than 20 hours in behavioral subjects.

New York
Renew triennially based on date of issuance and birth month with a minimum of 40 contact hours per year of acceptable formal continuing education in any of the recognized subject areas, or complete a minimum of 24 contact hours per year of acceptable formal continuing education concentrated in one subject area. Four of the required hours must be in Ethics. Approved subject areas are: Accounting; Auditing; Taxation; Advisory Services; Specialized Knowledge and Applications related to specialized industries; and Ethics.

Ohio
The basic continuing professional education requirement to **obtain** or **renew** the Ohio permit is 120 credits over a three-year period. New CPAs holding the Ohio permit are required to report 40 credits over a two-year period. A new CPA licensed in 2011, for example, will have a continuing education reporting period of January 1, 2011 through December 31, 2012 and a requirement of 40 credits.

The following Ohio permit holders must earn 24 CPE credits in accounting or auditing:

- CPAs or PAs who work on financial reporting engagements

- CPAs or PAs who perform financial reporting work outside public accounting while using the CPA designation ("regulated services").

The following Ohio permit holders must earn 24 CPE credits in taxation:

- CPAs or PAs who work on taxation engagements or provide tax advice to clients.
- CPAs or PAs who perform tax work outside public accounting while using the CPA designation ("regulated services").

All CPAs holding the Ohio permit must take 3 credits in professional standards and responsibilities ("PSR") each reporting period. CPE sponsors that wish to present courses in Ohio professional standards and responsibilities must register with the Board and submit all course materials to the Board for review and approval.

A licensee may claim PSR credit for programs in the following four areas if the course is approved and documentation is retained: (1) the Ohio accountancy law and rules, (2) the accountancy law and rules of another state, (3) professional ethics for CPAs, or (4) ethical philosophy.

Oregon
Each biennial renewal period, certified public accountants and public accountants shall report satisfactory evidence of having completed 80 hours of CPE. At least 24 of the required 80 hours of CPE shall be completed in each year of the renewal period. Four hours of Professional Conduct & Ethics is required each renewal period.

Texas
120 hours of CE every 3 years with a minimum of 20 per year. A four-hour board approved ethics course must be taken every two years.

Washington
An individual licensed to practice must complete a total of 120 CPE hours every three years, including 4 CPE credit hours in an approved Washington ethics and regulations course. The total 120 CPE hours requirement is limited to no more than 24 CPE credit hours in nontechnical subject areas. All qualifying CPE hours must be taken after the date the initial CPA license was issued

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CPC Item IV. January 26, 2012
CBA Item X.B.4. January 26-27, 2012

Discussion on Initiating a Rulemaking to Amend Title 16, CCR Sections 40 and 45 – Peer Review

Presented by: April Freeman, Peer Review Analyst
Date: December 29, 2011

Purpose of the Item

The purpose of this item is to provide California Board of Accountancy (CBA) members an opportunity to discuss proposed amendments to peer review regulations.

Action Needed

The CBA will be asked to approve the proposed regulations and direct staff to initiate the rulemaking process to amend Title 16, CCR Sections 40 and 45, and Form PR-1, regarding the peer review reporting requirements.

Background

Effective January 1, 2010, AB 138 required accounting firms performing accounting and auditing (A&A) services to undergo a peer review once every three years as a condition of license renewal. Based on decisions made by the CBA in 2009, staff drafted regulations to implement mandatory peer review.

Comments

Staff has prepared proposed regulatory language to initiate the rulemaking process for Sections 40 and 45 **(Attachment 1)** and Form PR-1 **(Attachment 2)**. The proposed changes would be effective January 1, 2014. The most substantial changes are described as follows:

Section 40

- Simplifies the language to require that all firms performing A&A services have a peer review completed every three years in order to renew their license.
- Combines subsections (b) and (c) to address all firms that begin performing A&A services since their last renewal date.

Section 45

- Specifies that all licensees (not just firms) are required to report peer review information to the CBA at the time they renew their license.

- Deletes reporting dates as all reporting will be done at the time of renewal beginning January 1, 2014.
- Adds language to allow for disciplinary action against any licensee that willfully makes any false or misleading statement, in writing, regarding his/her peer review requirement. This would encompass the Form PR-1 and the renewal application.

Form PR-1

- Collects identifying information from the licensee prior to requesting information about the need for a peer review. This ensures the CBA staff can identify who submitted the form.
- Allows licensees to indicate the date they completed their first A&A engagement. Licensees who begin performing A&A services during their renewal period have 18 months to complete their peer review and, therefore, may not be able to report results at the time of renewal.

The proposed amendments will:

- Synchronize the peer review reporting date with the renewal period;
- Address the lack of reporting requirements beyond July 1, 2013;
- Address the lack of reporting requirements for new licensees and licensees not previously subject to peer review;
- Eliminate the unnecessary distinction between new licensees and licensees not previously subject to peer review.
- Reduce confusion as licensees are accustomed to reporting information to the CBA during their renewal process;
- Reduce staff workload by eliminating the need for notification and reminder letters separate from the renewal insert information;
- Reduce costs by eliminating separate mailings as described above;
- Clarify and improve the Form PR-1.

Recommendation

Staff recommends CBA members approve the proposed regulations and direct staff to initiate a rulemaking process for amending CCR Section 40 and 45 and Form PR-1.

Attachments

1. Propose Regulatory Language
2. Proposed Form PR-1 (1/12) and Form PR-1 (1/10)

Attachment 1

PROPOSED REGULATORY LANGUAGE

§ 40. Enrollment and Participation.

(a) ~~Commencing with the operative date prescribed by Section 45(b), a~~ A firm performing services as defined in Section 39(a) ~~operating or maintaining an accounting and auditing practice~~ shall have a peer review report accepted by a Board-recognized peer review program ~~within 36 months prior to its first reporting date and have a peer review report accepted by a Board-recognized peer review program~~ once every three years in order to renew its license.
(b) ~~Each firm licensed after the operative date of this Article that performs services in an accounting and auditing practice shall have a peer review report accepted by a Board-recognized peer review program within 18 months of the completion of the services.~~
~~(c) Should a firm begin performing services as defined in Section 39(a) of this Article after the operative date prescribed by Section 45(b), the~~ A firm performing services as defined in Section 39(a) for the first time shall have a peer review report accepted by a Board-recognized peer review program within 18 months of the date it completes those services. ~~completion of the services.~~

NOTE: Authority cited: Sections 5010 and 5076, Business and Professions Code. Reference: Section 5076, Business and Professions Code.

§ 45. Reporting to the Board.

(a) ~~Based on the dates identified in subsection (b),~~ At the time of renewal, a ~~firm~~ licensee shall report to the Board specific peer review information as required on Form PR-1 ~~(1/10)~~(1/12), which is hereby incorporated by reference.
(b) ~~The operative date of existing California-licensed firms to begin reporting peer review results shall be based on a firm's license number according to the following schedule: for license numbers ending with 01-33 the reporting date is no later than July 1, 2011; for license numbers ending with 34-66 the reporting date is no later than July 1, 2012; for license numbers ending with 67-00 the reporting date is no later than July 1, 2013.~~
~~(c) A firm licensed after the operative date of this Article that performs accounting and auditing services or a firm not previously required to undergo a peer review shall have a peer review report accepted by a Board-recognized peer review program no later than 18-months after the completion of the services as required by Section 40. Upon the acceptance of the peer review report, the firm shall report specific peer review information to the Board on form PR-1 (1/10).~~ A licensee's willful making of any false, fraudulent, or misleading statement, as part of, or in support of, his/her peer review reporting shall constitute cause for disciplinary action pursuant to Section 5100(g) of the Accountancy Act.

NOTE: Authority cited: Sections 5010, 5076, and 5100, Business and Professions Code. Reference: Section 5076, Business and Professions Code.

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PEER REVIEW REPORTING FORM

Attachment 2

LICENSEE/FIRM INFORMATION

1. **Licensee/Firm Name:** _____

2. **Business Telephone #:** _____

3. **Business E-mail Address:** _____

4. **License Number:** _____

5. **License Expiration Date:** _____

6. **Does the licensee operate as an accounting firm?**

☐ **NO** (Check one below and go to number 15.):

- ☐ Employee, partner or shareholder of an accounting firm
- ☐ Employee, partner or shareholder of a non-accounting firm
- ☐ Employee of the government
- ☐ Unemployed or retired
- ☐ Other _____

☐ **YES** (Select firm type below):

- ☐ Sole Proprietorship
- ☐ General Partnership
- ☐ Limited Liability Partnership
- ☐ Corporation

7. **Number of shareholders, partners, owners, and full-time licensees of the firm:**

☐ 1 ☐ 2 ☐ 3 ☐ 4
☐ 5-10 ☐ 11-99 ☐ 100+

8a. **Has the firm performed accounting and auditing services that require a peer review since the last license renewal?**

☐ Yes (Go to number 8b.)
☐ No (Go to number 15.)

8b. **If the firm completed its first accounting and auditing service within 18 months prior to the expiration date of the license, indicate the date the service was completed:**
(NOTE: The firm must have a peer review report accepted by a Board-recognized peer review program provider within 18 months of this date and report the results at the time of the next renewal.)

_____
(Go to number 15)

PEER REVIEW INFORMATION

9. **Date Last Peer Review Report Accepted:** _____

10a. **Peer Review Report Rating:**

☐ Pass (Go to question 11a.)
☐ Pass w/deficiencies (Go to question 11a.)
☐ Substandard (Go to question 10b.)

PEER REVIEW INFORMATION (continued)

10b. Did your firm submit the peer review report to the Board within the required 45-day reporting period?

- ☐ Yes
- ☐ No (Please attach a written explanation as to why the report was not submitted timely.)

11a. Was the peer review administered by the California Society of Certified Public Accountants using the American Institute of Certified Public Accountants Peer Review Program?

- ☐ Yes
- ☐ No (Go to question 11b.)

11b. Was the peer review administered by another organization using the American Institute of Certified Public Accountants Peer Review Program?

- ☐ Yes (Please provide the name of the American Institute of Certified Public Accountants administering entity.)

  _____

- ☐ No (Please provide the name of the Board-recognized peer review program that administered the peer review.)

  _____

12. What was the highest level of accounting and auditing service your firm provided during the three-year period encompassing your peer review?

- ☐ Audit
- ☐ Review
- ☐ Compilations w/disclosures
- ☐ Compilations w/o disclosures prepared using GAAP
- ☐ Compilations w/o disclosures prepared using OCBOA

13. What was the cost to have the peer review performed? $ _____

14. How much time did your firm spend preparing for the peer review?

- ☐ 0 days
- ☐ 1-5 days
- ☐ 6-10 days
- ☐ 10+ days

15. I hereby certify, under penalty of perjury under the laws of the State of California, that all statements, answers, and representations on this form, including supplementary attached hereto, are true, complete and accurate.

_____ _____

Signature **Date**

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PEER REVIEW REPORTING FORM

ACCOUNTING FIRM INFORMATION

Do you operate as a firm (including a sole proprietorship)? ☐ Yes ☐ No (If no, please sign and date on the reverse of the form.)

Firm Name: _____

License #: _____ **Expiration Date:** _____

Business Telephone #: _____ **Business E-mail Address:** _____

Firm Type (check one): ☐ Sole Proprietorship ☐ General Partnership ☐ Limited Liability Partnership ☐ Corporation

Number of shareholders, partners, owners, and full-time licensees of the firm: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5-10 ☐ 11-99 ☐ 100+

Did your firm perform any accounting and auditing services that require you to undergo a peer review? ☐ Yes ☐ No (If no, please sign and date on the reverse of the form.)

PEER REVIEW INFORMATION

1. Date Peer Review Report Accepted: _____

2a. Peer Review Report Rating: ☐ Pass (Go to question 3.) ☐ Pass w/deficiencies (Go to question 3.) ☐ Substandard (Go to question 2b.)

2b. Did your firm submit the peer review report to the Board within the required 45-day reporting period? ☐ Yes ☐ No (If no, please attach a written explanation as to why the report was not submitted timely.)

PEER REVIEW INFORMATION (continued)

3a. Was the peer review administered by the California Society of Certified Public Accountants using the American Institute of Certified Public Accountants Peer Review Program?

☐ Yes
☐ No (If no, see question 3b.)

3b. Was the peer review administered by another organization using the American Institute of Certified Public Accountants Peer Review Program?

☐ Yes (If yes, please provide the name of the American Institute of Certified Public Accountants administering entity.)

_____

☐ No (If no, please provide the name of the Board-recognized peer review program that administered the peer review.)

_____

4. What was the highest level of accounting and auditing service your firm provided during the three-year period encompassing your peer review?

☐ Audit
☐ Review
☐ Compilations w/disclosures
☐ Compilations w/o disclosures prepared using GAAP
☐ Compilations w/o disclosures prepared using OCBOA

5. What was the cost to have the peer review performed?

$ _____

6. How much time did your firm spend preparing for the peer review?

☐ 0 days
☐ 1-5 days
☐ 6-10 days
☐ 10+ days

I hereby certify, under penalty of perjury under the laws of the State of California, that all statements, answers, and representations on this form, including supplementary attached hereto, are true, complete and accurate.

_____ _____

Signature **Date**

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CPC Item II **January 26, 2012**

CBA Item X.B.2. **January 26-27, 2012**

Discussion on Title 16, CCR Sections 37 – Reissuance, 12(d) and 12.5(f) – Experience Obtained Five or More Years Prior to Application, Section 87 – Basic Requirements, Section 87.1 – Conversion to Active Status Prior to Renewal, and Section 88 – Programs Which Qualify

Presented by: Kris Rose, Licensing Manager
Date: January 3, 2012

Purpose of the Item

This agenda item is designed to provide information to members on the present Certified Public Accountant (CPA) continuing education (CE) requirements for entry or reentry into the practice of public accountancy to determine whether the requirements should be amended to achieve consistency. Also provided for members' review and reference are the requirements for active status license renewal (**Attachment 1**) and conversion from an inactive to active status license (**Attachment 2**) prior to renewal[1] to determine if revisions are needed.

Action(s) Needed

Policy decisions are needed, which will be used to amend the affected regulations.

Background

At the January 2011 CPA Qualifications Committee (QC) meeting, members reviewed the education requirements for reissuance of a cancelled license and for applicants with experience obtained five years prior to application (stale dated) to determine if the requirements need amending. Members discussed the 48 hour requirement and whether requirements should be placed on each subject area (for example: 16 hours of auditing standards) to ensure applicants for CPA licensure obtained an adequate amount of education in the appropriate subject areas to ensure consumer protection.

Prior to 2008, an applicant seeking reissuance of a cancelled CPA license was required to complete 120 hours of CE. The basis for the reduction in hours from 120 to 48 was to keep the requirements consistent with the requirements for an applicant who was applying for CPA licensure with stale dated experience. Applicants with stale dated experience are required to complete 48 hours of CE as identified in Sections 12(d) and 12.5(f) of the CBA Regulations (**Attachment 3**).

[1] The requirements for restoration of a retired license will be the same as conversion of an inactive license to active status prior to renewal. This decision was made by members at the November 2011 CBA meeting.

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Attachment 1

87. Basic Requirements.

(a) 80 Hours.
As a condition for renewing a license in an active status, a licensee shall complete at least 80 hours of qualifying continuing education as described in Section 88 in the two-year period immediately preceding license expiration, and meet the reporting requirements described in Section 89(a). A licensee engaged in the practice of public accountancy as defined in Section 5051 of the Business and Professions Code is required to hold a license in an active status. No carryover of continuing education is permitted from one license renewal period to another.
(1) A licensee renewing a license in an active status after December 31, 2011, shall complete a minimum of 20 hours in each year of the two-year license renewal period, with a minimum of 12 hours of the required 20 hours in subject areas as described in Section 88(a)(1).
(b) Ethics Continuing Education Requirement A licensee renewing a license in an active status after December 31, 2009 shall complete four hours of the 80 hours of continuing education required pursuant to subsection (a) in course subject matter specified pertaining to the following: a review of nationally recognized codes of conduct emphasizing how the codes relate to professional responsibilities; case-based instruction focusing on real-life situational learning; ethical dilemmas facing the accounting profession; or business ethics, ethical sensitivity, and consumer expectations. Courses must be a minimum of one hour as described in Section 88.2.
(c) Government Auditing Continuing Education Requirement.
A licensee who engages in planning, directing, conducting substantial portions of field work, or reporting on financial or compliance audits of a governmental agency shall complete 24 of the 80 hours required pursuant to subsection (a) in the areas of governmental accounting, auditing or related subjects. This continuing education shall be completed in the same two-year license renewal period as the report is issued. A governmental agency is defined as any department, office, commission, authority, board, government-owned corporation, or other independent establishment of any branch of federal, state or local government. Related subjects are those which maintain or enhance the licensee's knowledge of governmental operations, laws, regulations or reports; any special requirements of governmental agencies; subjects related to the specific or unique environment in which the audited entity operates; and other auditing subjects which may be appropriate to government auditing engagements. A licensee who meets the requirements of this subsection shall be deemed to have met the requirements of subsection (d).
(d) Accounting and Auditing Continuing Education Requirement. A licensee who engages in planning, directing, performing substantial portions of the work, or reporting on an audit, review, compilation, or attestation service, shall complete 24 hours of the

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Attachment 2

87.1. Conversion to Active Status Prior to Renewal.

(a) A licensee who has renewed his/her license in an inactive status may convert the license to an active status prior to the next license expiration date by (1) completing 80 hours of continuing education credit as described in Section 88, to include the Ethics Continuing Education Requirement described in Section 87(b), within the 24-month period prior to converting to active status, of which a minimum of 20 hours shall be completed in the one-year period immediately preceding conversion to an active status, with a minimum of 12 hours in subject areas described in subsection (a)(1) of Section 88; (2) completing the regulatory review course described in Section 87.8 if more than six years have elapsed since the licensee last completed the course; (3) applying to the Board in writing requesting to convert the license to an active status; and (4) completing any continuing education that is required pursuant to subsection (j) of Section 89. The licensee may not practice public accounting until the application for conversion of the license to an active status has been approved.
(b) A licensee who, during the 24 months prior to converting his/her license to an active status, planned, directed, or conducted substantial portions of field work, or reported on financial or compliance audits of a governmental agency shall complete 24 hours of continuing education in governmental accounting and auditing as described in Section 87(c) as part of the 80 hours of continuing education required to convert his/her license to an active status under subsection (a). A licensee who meets the requirements of this subsection shall be deemed to have met the requirements of subsection (c).
(c) A licensee who, during the 24 months prior to converting his/her license to an active status, planned, directed, or performed substantial portions of the work or reported on an audit, review, compilation, or attestation service shall complete 24 hours of continuing education in accounting and auditing as described in Section 87(d) as part of the 80 hours of continuing education required to his/her license to an active status under subsection (a).
(d) A licensee who must complete continuing education pursuant to subsections (b) and/or (c) of this section shall also complete an additional eight hours of continuing education specifically related to the detection and/or reporting of fraud in financial statements as described in Section 87(e). This continuing education shall be part of the 80 hours of continuing education required by subsection (a), but shall not be part of the continuing education required by subsections (b) or (c).
(e) Once a license is converted to an active status, the licensee must complete 20 hours of continuing education as described in Section 88 for each full six month period from the date of license conversion to an active status to the next license expiration date in order to fulfill the continuing education requirement for license renewal. If the time period between the date of change to an active status and the next license expiration date is less than six full months, no additional continuing education is required for

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Attachment 3

12(d). General Experience Required Under Business and Professions Code Section 5092 and 5093.
(d) An applicant who is applying under Section 5092 or Section 5093 of the Business and Professions Code with experience obtained five (5) or more years prior to application may be required to obtain 48 hours of continuing education which shall include general accounting, and other comprehensive basis of accounting; and to submit the certificates of completion to the Board.

12.5(f). Attest Experience Under Business and Professions Code Section 5095.
(f) The applicant who is applying with experience obtained five (5) or more years prior to application may be required to obtain 48 hours of continuing education which shall include financial accounting standards, auditing standards, compilation and review, and other comprehensive basis of accounting; and to submit the certificates of completion to the Board.

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Attachment 4

CONTINUING EDUCATION REQUIREMENTS FOR OTHER STATE BOARDS OF ACCOUNTANCY

Arizona
80 hours every two years if the individual is in public practice, with 38 hours in technical areas (Accounting, Auditing, Tax, Management Advisory, Business Law or any combination thereof) and the remainder of the hours may fall into the Other category. 60 hours if the individual is in industry, with 28 hours in technical areas.

Four hours of Board-approved ethics during the two-year period immediately preceding registration renewal. The 4-hour requirement shall include a minimum of 1 hour of each of the following: Ethics related to the practice of accounting including the American Institute of Certified Public Accountants Professional Code of Conduct; and, Board statutes and administrative rules.

Florida
80 hours every two years of continuing professional education credits with at least 20 hours in accounting and auditing and 4 hours of a board approved ethics course and no more than 20 hours in behavioral subjects.

New York
Renew triennially based on date of issuance and birth month with a minimum of 40 contact hours per year of acceptable formal continuing education in any of the recognized subject areas, or complete a minimum of 24 contact hours per year of acceptable formal continuing education concentrated in one subject area. Four of the required hours must be in Ethics. Approved subject areas are: Accounting; Auditing; Taxation; Advisory Services; Specialized Knowledge and Applications related to specialized industries; and Ethics.

Ohio
The basic continuing professional education requirement to **obtain** or **renew** the Ohio permit is 120 credits over a three-year period. New CPAs holding the Ohio permit are required to report 40 credits over a two-year period. A new CPA licensed in 2011, for example, will have a continuing education reporting period of January 1, 2011 through December 31, 2012 and a requirement of 40 credits.

The following Ohio permit holders must earn 24 CPE credits in accounting or auditing:

- CPAs or PAs who work on financial reporting engagements

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CPC Item III. January 26, 2012
CBA Item X.B.3. January 26-27, 2012

Discussion on Initiating a Rulemaking to Amend Title 16, CCR Sections 87(e) and 87.1(d) – Eight-Hour Fraud Continuing Education Requirement

Presented by: Matthew Stanley, Legislation/Regulation Analyst
Date: December 23, 2011

Purpose of the Item
Staff is providing members with proposed regulatory language for reducing the fraud continuing education (CE) requirement from eight to four hours.

Action(s) Needed
The California Board of Accountancy (CBA) will be asked to provide input and approve the draft regulations and direct staff to initiate the rulemaking process.

Background
At its November 2011 meeting, the CBA directed staff to draft regulatory language to reduce the fraud CE requirement from eight hours to four hours. In addition, it requested that staff develop language to ensure the currency and relevance of the course content in order to keep the course fresh. It was pointed out during the meeting that the reduction in CE hours is justified due to the fact that many schools now include fraud detection as a part of their curriculum.

Comments
The proposed language (**Attachment 1**) reduces the number of hours of fraud CE from eight to four. In addition, it states that a licensee must take their fraud CE from a provider who maintains the currency of the course. This requirement was put on the licensee rather than the course provider as the CBA has no authority over course providers.

For your information, the full, original language of the affected sections is attached. (**Attachment 2**).

Recommendation
Staff recommends that the CBA approve the draft regulations and direct staff to initiate the rulemaking process.

Attachment
Proposed Regulatory Language
Current Text of CBA Regulation Sections 87 and 87.1

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Attachment 1

Proposed Regulatory Language

87.
(e) A licensee who must complete continuing education pursuant to subsections (c) and/or (d) of this section shall also complete an additional ~~eight~~ four hours of continuing education specifically related to the detection and/or reporting of fraud in financial statements. Continuing education required by this subsection shall be obtained from providers using materials that are current; and any description of the course shall contain a publication, revision, or review date indicating that the course has been reviewed within the last two years to verify the currency of the content. This continuing education shall be part of the 80 hours of continuing education required by subsection (a), but shall not be part of the continuing education required by subsections (c) or (d).

87.1
(d) A licensee who must complete continuing education pursuant to subsections (b) and/or (c) of this section shall also complete an additional ~~eight~~ four hours of continuing education specifically related to the detection and/or reporting of fraud in financial statements as described in Section 87(e). This continuing education shall be part of the 80 hours of continuing education required by subsection (a), but shall not be part of the continuing education required by subsections (b) or (c).

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Attachment 2

Current Regulatory Language

§ 87. Basic Requirements.

(a) 80 Hours.
As a condition for renewing a license in an active status, a licensee shall complete at least 80 hours of qualifying continuing education as described in Section 88 in the two-year period immediately preceding license expiration, and meet the reporting requirements described in Section 89(a). A licensee engaged in the practice of public accountancy as defined in Section 5051 of the Business and Professions Code is required to hold a license in an active status. No carryover of continuing education is permitted from one license renewal period to another.
(1) A licensee renewing a license in an active status after December 31, 2011, shall complete a minimum of 20 hours in each year of the two-year license renewal period, with a minimum of 12 hours of the required 20 hours in subject areas as described in Section 88(a)(1).

(b) Ethics Continuing Education Requirement
A licensee renewing a license in an active status after December 31, 2009 shall complete four hours of the 80 hours of continuing education required pursuant to subsection (a) in course subject matter specified pertaining to the following: a review of nationally recognized codes of conduct emphasizing how the codes relate to professional responsibilities; case-based instruction focusing on real-life situational learning; ethical dilemmas facing the accounting profession; or business ethics, ethical sensitivity, and consumer expectations. Courses must be a minimum of one hour as described in Section 88.2.

(c) Government Auditing Continuing Education Requirement.
A licensee who engages in planning, directing, conducting substantial portions of field work, or reporting on financial or compliance audits of a governmental agency shall complete 24 of the 80 hours required pursuant to subsection (a) in the areas of governmental accounting, auditing or related subjects. This continuing education shall be completed in the same two-year license renewal period as the report is issued. A governmental agency is defined as any department, office, commission, authority, board, government-owned corporation, or other independent establishment of any branch of federal, state or local government. Related subjects are those which maintain or enhance the licensee's knowledge of governmental operations, laws, regulations or reports; any special requirements of governmental agencies; subjects related to the specific or unique environment in which the audited entity operates; and other auditing subjects which may be appropriate to government auditing engagements. A licensee who meets the requirements of this subsection shall be deemed to have met the requirements of subsection (d).

(d) Accounting and Auditing Continuing Education Requirement.
A licensee who engages in planning, directing, performing substantial portions of the work, or reporting on an audit, review, compilation, or attestation service, shall complete 24 hours of the 80 hours of continuing education required pursuant to subsection (a) in the course subject matter pertaining to financial statement preparation and/or reporting (whether such statements are prepared on the basis of generally accepted accounting principles or other comprehensive bases of accounting), auditing, reviews, compilations, industry accounting, attestation services, or assurance services. This continuing education shall be completed in the same two-year license renewal period as the report is issued. If no report is

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CPC Item IV. January 26, 2012
CBA Item X.B.4. January 26-27, 2012

Discussion on Initiating a Rulemaking to Amend Title 16, CCR Sections 40 and 45 – Peer Review

Presented by: April Freeman, Peer Review Analyst
Date: December 29, 2011

Purpose of the Item

The purpose of this item is to provide California Board of Accountancy (CBA) members an opportunity to discuss proposed amendments to peer review regulations.

Action Needed

The CBA will be asked to approve the proposed regulations and direct staff to initiate the rulemaking process to amend Title 16, CCR Sections 40 and 45, and Form PR-1, regarding the peer review reporting requirements.

Background

Effective January 1, 2010, AB 138 required accounting firms performing accounting and auditing (A&A) services to undergo a peer review once every three years as a condition of license renewal. Based on decisions made by the CBA in 2009, staff drafted regulations to implement mandatory peer review.

Comments

Staff has prepared proposed regulatory language to initiate the rulemaking process for Sections 40 and 45 **(Attachment 1)** and Form PR-1 **(Attachment 2)**. The proposed changes would be effective January 1, 2014. The most substantial changes are described as follows:

Section 40

- Simplifies the language to require that all firms performing A&A services have a peer review completed every three years in order to renew their license.
- Combines subsections (b) and (c) to address all firms that begin performing A&A services since their last renewal date.

Section 45

- Specifies that all licensees (not just firms) are required to report peer review information to the CBA at the time they renew their license.

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PEER REVIEW REPORTING FORM

Attachment 2

LICENSEE/FIRM INFORMATION

1. **Licensee/Firm Name:** _____

2. **Business Telephone #:** _____

3. **Business E-mail Address:** _____

4. **License Number:** _____

5. **License Expiration Date:** _____

6. **Does the licensee operate as an accounting firm?**

☐ **NO** (Check one below and go to number 15.):

- ☐ Employee, partner or shareholder of an accounting firm
- ☐ Employee, partner or shareholder of a non-accounting firm
- ☐ Employee of the government
- ☐ Unemployed or retired
- ☐ Other _____

☐ **YES** (Select firm type below):

- ☐ Sole Proprietorship
- ☐ General Partnership
- ☐ Limited Liability Partnership
- ☐ Corporation

7. **Number of shareholders, partners, owners, and full-time licensees of the firm:**

☐ 1 ☐ 2 ☐ 3 ☐ 4
☐ 5-10 ☐ 11-99 ☐ 100+

8a. **Has the firm performed accounting and auditing services that require a peer review since the last license renewal?**

☐ Yes (Go to number 8b.)
☐ No (Go to number 15.)

8b. **If the firm completed its first accounting and auditing service within 18 months prior to the expiration date of the license, indicate the date the service was completed:**
(NOTE: The firm must have a peer review report accepted by a Board-recognized peer review program provider within 18 months of this date and report the results at the time of the next renewal.)

_____
(Go to number 15)

PEER REVIEW INFORMATION

9. **Date Last Peer Review Report Accepted:** _____

10a. **Peer Review Report Rating:**

☐ Pass (Go to question 11a.)
☐ Pass w/deficiencies (Go to question 11a.)
☐ Substandard (Go to question 10b.)

CALIFORNIA BOARD OF ACCOUNTANCY

DEPARTMENT OF CONSUMER AFFAIRS
CALIFORNIA BOARD OF ACCOUNTANCY
2000 EVERGREEN STREET, SUITE 250
SACRAMENTO, CA 95815-3832
TELEPHONE: (916) 263-3680
FACSIMILE: (916) 263-3675
WEB ADDRESS: *http://www.cba.ca.gov*

PEER REVIEW REPORTING FORM

ACCOUNTING FIRM INFORMATION

Do you operate as a firm (including a sole proprietorship)? ☐ Yes ☐ No (If no, please sign and date on the reverse of the form.)

Firm Name: _____

License #: _____ **Expiration Date:** _____

Business Telephone #: _____ **Business E-mail Address:** _____

Firm Type (check one): ☐ Sole Proprietorship ☐ General Partnership ☐ Limited Liability Partnership ☐ Corporation

Number of shareholders, partners, owners, and full-time licensees of the firm: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5-10 ☐ 11-99 ☐ 100+

Did your firm perform any accounting and auditing services that require you to undergo a peer review? ☐ Yes ☐ No (If no, please sign and date on the reverse of the form.)

PEER REVIEW INFORMATION

1. Date Peer Review Report Accepted: _____

2a. Peer Review Report Rating: ☐ Pass (Go to question 3.) ☐ Pass w/deficiencies (Go to question 3.) ☐ Substandard (Go to question 2b.)

2b. Did your firm submit the peer review report to the Board within the required 45-day reporting period? ☐ Yes ☐ No (If no, please attach a written explanation as to why the report was not submitted timely.)