



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Legislation and Regulation Committee

Andrea Zinder, Public Member, Chair
Ryan Brooks, Public Member
Jim Burgard, Public Member
Robert Swart, PharmD
Shirley Wheat, Public Member

Part 1: REGULATION REPORT AND ACTION

A. FOR ACTION: To Repeal Title 16 CCR Sections 1716.1 and 1716.2, Amend and Adopt Sections 1751 through 1751.8, and Adopt Sections 17.5 through 1735.8 – Pharmacies that Compound.

ATTACHMENT 1

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

The 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing.

More recently, during the January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt some of the record keeping requirements detailed in Section 1735.3 for sterile products that are compounded on a one-time basis for administration within 2 hours as specified. In response to this 15-day comment period, the board received a significant amount of comments. The comments submitted for both the 45-day and 15-day comment and staff response to each comment are provided in ATTACHMENT 1.

Executive staff of the board, after reviewing the comments submitted, suggests that the board has several options to potentially further modify Section 1735.3 (a)(6):

- (1) exempt compounded solutions made pursuant to a patient order for administration within 24 hours,
- (2) use 12 hours or
- (3) keep as noticed, at 2 hours.

B. FOR INFORMATION: Approved Regulations – Section 100 Changes

1. Amend 16 CCR §1715 – Self Assessment Forms for Community and Inpatient Pharmacies (Forms 17M-13 and 17M-14)

Section 1715 establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law.

These self-assessment forms are designed to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the pharmacy inspection process more meaningful and provide relevant information to pharmacies and their PICs. The law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the pharmacist-in-charge occurs.

At the October 2008 Board meeting, the board voted to pursue section 100 changes to update the forms. Board staff was recently advised that these forms were approved by the Office of Administrative Law. The revised forms are on the board's Web site. Additionally, a notice was provided in the recently published issue of *The Script* advising readers of the change.

2. Amend 16 CCR §1784 – Self-Assessment of a Wholesaler by a Designated Representative-in-Charge (Form 17M-26)

Section 1784 of the California Code of Regulations establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge (DRC) to complete this form to ensure compliance with pharmacy law. This self-assessment form is designed to assist wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the inspection process more meaningful and provide relevant information to wholesalers and their DRC. The law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the designated representative-in-charge occurs.

At the October 2008 Board meeting, the board voted to pursue section 100 changes to update this form as well. Board staff was recently advised that it was approved by the Office of Administrative Law. The revised form is on the board's Web site. Additionally, a notice was provided in the recently published issue of *The Script* advising readers of the change.

C. FOR INFORMATION: Board Approved Regulations – Undergoing Administrative Review

1. Proposed Amendment to 16 CCR §1760 – Disciplinary Guidelines

At the April 2008 board meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. After receiving additional clarifying comments from counsel, board staff submitted the completed rulemaking to the Department for review and approval in September 2008. While the department did approve this regulation, State and Consumer Services Agency was concerned about the optional language relating to automatic revocation when a probationer fails to submit cost recovery as mandated. As a result the matter was referred back to the board at the January 2009 Board Meeting.

During this meeting the board considered the option to withdraw the rulemaking and begin over, or to modify the language removing the specific term and notice the modification through a 15-day comment period. At the conclusion, the board directed staff to modify the text to remove the specific term / optional language discussed above and to take all steps necessary to complete the

rulemaking process, including preparing modified text for an additional 15-day comment period. The board further stated that if, after the 15-day public comment period, no adverse comments are received, the Executive Officer is authorized to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to 16 CCR §1760 – Disciplinary Guidelines.

This rulemaking is currently undergoing review by the Office of Administrative Law.

2. Amend 16 CCR §1773 and Adopt § 1773.5 – Establishment of an Ethics Course as an Optional Enforcement Component for Discipline.

ATTACHMENT 2

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

The board determined the requirements as necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). 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 before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

The 15-day comment period is over and no additional comments were received. This rulemaking is currently undergoing review by the department. A copy of the final language is provided in ATTACHMENT 2.

D. FOR INFORMATION: Board Approved Regulations Awaiting Notice

1. Proposed Addition to Title 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

The Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. A copy of the draft language and form is provided in attachment 3, however board staff do not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

2. Proposed Amendment to Title 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

ATTACHMENT 3

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §§1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and, if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

A copy of the language is provided in ATTACHMENT 3.

3. Proposed Adoption of Title 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Sterile Injectable Drug Products

ATTACHMENT 4

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

A copy of the language is provided in ATTACHMENT 4.

E. FOR INFORMATION: Regulations Under Development

1. Proposed Amendment to Title 16 CCR §1780 – Update the USP Standards Reference Material

CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

President Schell and Jim Burgard are serving in the subcommittee and will be working with board staff and industry. This subcommittee has not held any meeting.

2. Proposed Amendment to 16 CCR §1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. A committee member's term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically, committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

Current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

Board staff will be drafting regulation language for board consideration.

Attachment 1

*To Repeal Title 16 CCR §§ 1716.1 and 1716.2, Amend and Adopt §§ 1751 through 1751.8, and
Adopt §§ 1735 through 1735.8 – Pharmacies that Compound*

- 15-day notice language
- Summary of comments received and board staff responses
- Comments in response to 45-day comment period
- Comments in response to 15-day comment period

**DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF PHARMACY**

**To Repeal Title 16 CCR §§ 1716.1 and 1716.2,
Adopt Title 16 CCR §§ 1735 – 1735.8 And
Amend Title 16 CCR §§ 1751 – 1751.8 Regarding Requirements for Compounding**

Repeal Section 1716.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

- (a) "Reasonable quantity" means that quantity of an unapproved drug which:
 - (1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and
 - (2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.
- (b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.
- (c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

Repeal Section 1716.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.2. Record Requirements – Compounding for Future Furnishing.

(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

- (1) The date of preparation.
- (2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.
- (3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (4) The signature or initials of the pharmacist performing the compounding.
- (5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.
- (6) The name(s) of the manufacturer(s) of the raw materials.
- (7) The quantity in units of finished products or grams of raw materials.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

(8) ~~The package size and the number of units prepared.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.~~

Article 4.5 Compounding

Add Section 1735 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735. Compounding in Licensed Pharmacies

- (a) “Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
- (1) Altering the dosage form or delivery system of a drug
 - (2) Altering the strength of a drug
 - (3) Combining components or active ingredients
 - (4) Preparing a drug product from chemicals or bulk drug substances
- (b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
- (c) “Compounding” does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.
- (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

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

Add Section 1735.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.1. Compounding Definitions

- (a) “Integrity” means retention of potency until the expiration date noted on the label.
- (b) “Potency” means active ingredient strength within +/- 10% of the labeled amount.
- (c) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.
- (d) “Strength” means amount of active ingredient per unit of a compounded drug product.

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

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Add Section 1735.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.2. Compounding Limitations and Requirements

- (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
- (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.
- (c) Pursuant to Business and Professions Code section 4052(a)(1), a “reasonable quantity” of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where “reasonable quantity” is that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
- (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
 - (1) Active ingredients to be used.
 - (2) Inactive ingredients to be used.
 - (3) Process and/or procedure used to prepare the drug.
 - (4) Quality reviews required at each step in preparation of the drug.
 - (5) Post-compounding process or procedures required, if any.
 - (6) Expiration dating requirements.
- (e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.
- (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
- (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This “beyond use date” of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and

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packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

- (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.
- (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

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

Add Section 1735.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.3. Records of Compounded Drug Products

- (a) For each compounded drug product, the pharmacy records shall include:
 - (1) The master formula record.
 - (2) The date the drug product was compounded.
 - (3) The identity of the pharmacy personnel who compounded the drug product.
 - (4) The identity of the pharmacist reviewing the final drug product.
 - (5) The quantity of each component used in compounding the drug product.
 - (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
 - (7) The equipment used in compounding the drug product.
 - (8) A pharmacy assigned reference or lot number for the compounded drug product.
 - (9) The expiration date of the final compounded drug product.
 - (10) The quantity or amount of drug product compounded.
- (b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
- (c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.
- (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

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

Add Section 1735.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.4. Labeling of Compounded Drug Products

- (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

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

Add Section 1735.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.5. Compounding Policies and Procedures

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include the following
 - (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
 - (2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - (3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
 - (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

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

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Add Section 1735.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.6. Compounding Facilities and Equipment

- (a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
- (b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

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

Add Section 1735.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.7. Training of Compounding Staff

- (a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
- (b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- (c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

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

Add Section 1735.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.8. Compounding Quality Assurance

- (a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
- (b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
- (c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.
- (d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

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

Article 7 Sterile Injectable Compounding

Amend Section 1751 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751. Sterile Injectable Compounding; Compounding Area.

(a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

(b) ~~The~~ Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

- (1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
- (2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
- (3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
- (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
- (5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- (6) A sink shall be included in accordance ~~in~~ with Section 490A.3.4 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
- (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the

(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Renumber section 1751.3 to new section 1751.1 and amend section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.3, 1751.1. Sterile Injectable Recordkeeping Requirements.

- (a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~1716.4~~ 1735.2 shall, in addition to those records required by section ~~1716.2~~ 1735.3, ~~have make and keep~~ records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
- (b) In addition to the records required by section 1735.3 and subdivisions (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be ~~maintained for at least three years~~ made and kept by the pharmacy:
 - (1) The training and competency evaluation of employees in sterile product procedures.
 - (2) Refrigerator and freezer temperatures.
 - (3) Certification of the sterile compounding environment.
 - (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
 - (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
 - (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
- (c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years~~ Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

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

Amend Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.2. Sterile Injectable Labeling Requirements.

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

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

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

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

Renumber section 1751.02 to new section 1751.3 and amend section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.02. 1751.3. Sterile Injectable Policies and Procedures.

- (a) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to~~ Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:
- (1) Compounding, filling, and labeling of sterile injectable compounds.
 - (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
 - (3) Equipment and supplies.
 - (4) Training of staff in the preparation of sterile injectable products.
 - (5) Procedures for handling cytotoxic agents.
 - (6) Quality assurance program.
 - (7) Record keeping requirements.
- (b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
- (c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- (d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
- (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
 - (2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
 - (3) Policies and procedures must address at least the following:
 - (A) Competency evaluation.
 - (B) Storage and handling of products and supplies.
 - (C) Storage and delivery of final products.
 - (D) Process validation.
 - (E) Personnel access and movement of materials into and near the controlled area.
 - (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
 - (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
 - (H) Disposal of packaging materials, used syringes, containers, and needles to

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- (I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
- (J) Sterilization.
- (K) End-product evaluation and testing.

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

Renumber section 1751.01 to new section 1751.4 and amend section 1751.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.01. 1751.4. Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.

- (a) No sterile injectable product shall be ~~prepared~~ 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 for the safe compounding of sterile injectable drug products.
- (b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
- (c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
- (d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.
- (e) Pharmacies preparing parenteral cytotoxic agents shall be do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Repeal Section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.1. Laminar Flow Biological Safety Cabinet.

~~Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation~~

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Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Repeal Section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.3. Recordkeeping Requirements.

- (a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 1735.2, shall, in addition to those records required by section 1716.2 1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~
- (b) ~~In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:
 - (1) ~~The training and competency evaluation of employees in sterile product procedures.~~
 - (2) ~~Refrigerator and freezer temperatures.~~
 - (3) ~~Certification of the sterile compounding environment.~~
 - (4) ~~Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
 - (5) ~~Inspection for expired or recalled pharmaceutical products or raw ingredients.~~
 - (6) ~~Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~~~
- (c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.~~

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

Renumber section 1751.4 to new section 1751.5 and amend section 1751.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.4. 1751.5. Sterile Injectable Compounding Attire.

- (a) When preparing cytotoxic agents, gowns and gloves shall be worn.
- (b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
 - (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
 - (2) Cleanroom garb must be donned and removed outside the designated area.
 - (3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed

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- (4) Head and facial hair must be kept out of the critical area or be covered.
- (5) Gloves made of low-shedding materials are required.

(c) The requirements of this subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

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

Renumber section 1751.5 to new section 1751.6 and amend section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.5, 1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.

- (a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- (b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
- (c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
- (d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
- (e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:
 - (1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
 - (A) Aseptic technique.
 - (B) Pharmaceutical calculations and terminology.
 - (C) Sterile product compounding documentation.
 - (D) Quality assurance procedures.
 - (E) Aseptic preparation procedures.
 - (F) Proper gowning and gloving technique.
 - (G) General conduct in the controlled area.
 - (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
 - (I) Sterilization techniques.
 - (J) Container, equipment, and closure system selection.
 - (2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's

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Results of these assessments must be documented and retained in the pharmacy for three years.

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

Repeal Section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.6. Disposal of Waste Material.

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

~~Authority cited: Section 4005 Business and Professions Code. Reference: Section 4005 Business and Professions Code.~~

Amend 1751.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, ~~There shall be a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:~~
- (1) Cleaning and sanitization of the parenteral medication preparation area.
 - (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
 - (3) Actions to be taken in the event of a drug recall.
 - (4) Written justification of the chosen expiration dates for compounded sterile
- (b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable

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result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

- (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- (d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

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

Renumber section 1751.9 to new section 1751.8 and amend section 1751.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.9, 1751.8. Sterile Injectable Compounding Reference Materials.

In any pharmacy engaged in compounding sterile injectable drug products, there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

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

**Comments from Clara E. Evans, Director, Public Policy & Fiscal Advocacy,
Catholic Healthcare West (CHW).**

Comment #1

CHW stated that they support the regulation proposal to strengthen regulations for pharmacies that compound medications, but have serious concerns regarding the new labeling requirements and pharmacy record requirements on certain compounded IV medications, particularly for pharmacies in acute care facilities dispensing one-time and immediate-use (STAT) medications. CHW is concerned that the added documentation requirements will delay preparation and delivery of medications, placing patients at risk for no additional patient safety benefit.

Board Response

The board appreciates CHW's general support for the regulation proposal, however, it disagrees with their conclusion that the documentation requirements will delay preparation and delivery and, therefore, rejects this comment. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines timely.

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacist who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. An internal pharmacy reference number is necessary to allow for a recall of a product if necessary, another essential consumer protection component.

Comment #2

CHW sees the value of documenting pharmacy reference numbers or lot numbers on the label of each dispensed IV as well as providing additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. However, CHW suggests that this information is not useful when the medication dispensed on a one-time, immediate-use basis. CHW urges the board to exempt one-time, immediate-use sterile products from the manufacturer or supplier and lot number for each component requirement, equipment used in compounding the drug products, the pharmacy assigned reference or lot number for the compounded drug product as well as the expiration date of the final compounded drug product requirements.

Board Response

The board appreciates CHW's understanding of the necessity of the labeling requirements. The intent of the regulation proposal is to improve patient safety. Following the 45-day comment period, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comment #3

CHW is concerned the minimum 3-year record retention policy is unrealistic considering the hundreds or thousands of products compounded daily, whether STAT or non-urgent. CHW requests this timeframe be reevaluated and take into account common record retention policies.

Board Response

The 3-year time frame required in this proposal is consistent with current pharmacy law that specifies that all records must be maintained for three years from the date of dispensing.

Comments from Steve Sloan**Comment #4**

The proposed regulations do not take into consideration emergency situations where the additional logging and labeling requirements will be burdensome and cause delays in therapy. These requirements do not improve patient safety because the dose is administered immediately after compounding. Please make an exception for emergency use.

Board Response

The intent of the regulation proposal is to improve patient safety. Following the 45-day comment period, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comments from Stephan Flascha**Comment #5**

Mr. Flascha states "I am really concerned about the documentation requirements in Compounding in an IV room in a major hospital. Please consider this requirement as undoable."

Board Response

Mr. Flascha's comment is vague. In general, the documentation is necessary to ensure the integrity, potency, quality and strength of the compounded drug product(s) prepared and delivered to patients. Should Mr. Flascha's comments be specific to requesting an exemption from one-time immediate use compounded medications, in an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines timely.

Comments from Suzanne Baertsch**Comment #6**

Ms. Baertsch states, "I work in a hospital where we compound hundreds of IVs daily in a sterile environment. The additional time it would take for all this record keeping would mean we would have to cut back in other areas which will make it worse for overall patient care. I am especially concerned about first dose antibiotics or cardiovascular drips."

Board Response

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final

drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacist who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. An internal pharmacy reference number is necessary to allow for a recall of a product if necessary, another essential consumer protection component.

Comment #7

Ms. Baertsch states, "I understand it is valuable to be able to trace back how something is made, but remember, this still does not prevent an error. It only allows you to see what the error is."

Board Response

The board appreciates Ms. Baertsch's understanding of the necessity of these requirements, but disagrees that these requirements do not prevent errors. To the contrary, allowing for a complete system's review after an error occurs should result in a systematic change, which may prevent the same error from occurring in the future—this is key to improved future patient outcome

**Comments received from Deborah A. Hass, Pharm.D., BCOP,
Stanford/Oncology Clinical Pharmacist, Stanford Hospitals and Clinics**

Comment #8

I agree with the CSHP in asking for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as immediate-use. This means every STAT alteplase, epinephrine, diltiazem or other like-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed in a few minutes longer to assure logging, assignment, and labeling of the IV bag with the pharmacy lot number.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comment #9

For all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the thousands of records daily that would be generated here at Stanford to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic.

Board Response

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacists who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. An internal pharmacy reference number is necessary to allow for a recall of a product if necessary, another essential consumer protection component. Further, the 3-year time frame required in this proposal is consistent with current pharmacy law that specifies that all records must be maintained for three years from the date of dispensing.

Comments from Rob Chopyk, Clinical Pharmacist, Community Hospital of the Monterey Peninsula

Comment #10

I ask for an exemption of the logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would have already been administered as an immediate-use.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the recordkeeping requirements found in section 1735.3 do not need to be completed in advance of the administration of the compounded drug. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding.

Additionally, upon recall of a product, a systematic review could not be accomplished without the appropriate documentation and recordkeeping required of compounded products. Without adequate documentation, necessary or systematic changes may not be realized and made to prevent future errors, a key patient safety issue.

Comment #11

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other like-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed in a few minutes longer to assure logging, assignment, and labeling of the IV bag with the pharmacy lot number.

Board Response

It would appear that Pharmacist Chopyk's comment is in support of the board's proposal and that it is unreasonable that identified products would be delayed because of the proposals requirements.

However, should Dr. Chopyk's comment assert that the proposed regulations *would* delay the administration of compounded drug products in a critical care setting, the board does not agree that the documentation requirements of compounded drug products will delay preparation and delivery. In an acute care setting, the regulation proposal allows for one-time preparations of compounded drug products to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient timely receives STAT medications. The board did modify the proposed text of §1753.3(a)(6) to exempt that subsection's specified labeling requirements from those records of sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comment #12

For all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Board Response

This proposal does not specify a method for recordkeeping, rather just specifies what records must be kept and for how long. The 3-year time frame required in this proposal is consistent with current pharmacy law that specifies that all records must be maintained for three years.

Comments from Robert Fukano, Pharm.D., Intensive Care Unit/Critical Care Unit Clinical Pharmacist, Community Hospital of the Monterey Peninsula**Comment #13**

I have some serious concerns pertaining to the proposed changes for medication regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential

of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

Board Response

This comment mirrors that of Comment #10. Please see the board's response to comment #10.

Comment #14

It is unreasonable to think that every STAT antepulse, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Board Response

This comment mirrors that of Comment #11. Please see the board's response to Comment #11.

Comment #15

There are dozens of hospitals in California without 24-hour pharmacy services in which nurses are compounding and mixing intravenous products without the aid of any sterile preparation area or laminar flow hood/biological safety cabinet. Why the separation of record-keeping of pharmacy-prepared versus nurse-prepared or physician-prepared (thinking of anesthesiologists who prepare medication in the operating room)?

Board Response

The board believes that nurses and physicians performing reconstitution and administration are covered in B&PC 4127.1(e). Documentation of those activities is maintained in the patient's record. Nurses and physicians that compound medications outside of the hospital pharmacy is outside of the board's jurisdiction.

Comment #16

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals) thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Board Response

This proposal does not specified a method for recordkeeping, rather just specifies what records must be kept and for how long. The 3-year time frame required in this proposal is consistent with current pharmacy law that specifies that all records must be maintained for three years.

Comments received from Joanne Hayashi, Pharm.D, Clinical Pharmacist at the Community Hospital of the Monterey Peninsula**Comment #17**

Dr. Hayashi voiced some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. She asked for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP, stating these products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

Board Response

Board of Pharmacy's priority mandate is to protect the public. This mandate extends to the compounding and labeling of prescription drugs. It is unclear as to what portion of the proposed regulation Dr. Noud-Ikuta is referencing with regard to labeling of a dispensed IV. The board did modify the proposed text of §1753.3(a)(6) to exempt specified labeling requirements from those records of sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

The board realizes that recall of a product could be moot for an IV that has already been administered; however, without the specified recordkeeping requirements, a systematic review could not be accomplished. Without this, necessary systematic changes would not be realized and made to prevent future errors, a key patient safety issue.

Comment #18

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in an emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy log number.

Board Response

This comment mirrors that of Comments #11 and #14. Please see the board's response to Comment #11.

Comment #19

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated, to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful. It may also compromise patient safety since the focus will be shifted from the real task at hand – safe, aseptic compounding of CSPs to the task of recordkeeping.

Board Response

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacists who reviewed the final drug product. First the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications.

This proposal does not specify a method for recordkeeping, rather just specifies what records must be kept and for how long. The 3-year time frame required in this proposal is consistent with current pharmacy law that specifies that all records must be maintained for three years.

**Comments received from Dawn Benton, Executive Vice President, CEO,
California Society of Health-System Pharmacists****Comment #20**

The California Society of Health-System Pharmacists (CSHP) commends and supports the California Board of Pharmacy (Board) for their previous and current efforts to strengthen the regulations surrounding pharmacies that compound medications.

Board Response

The board appreciates CSHP support with our efforts to strengthen the regulations surrounding pharmacies that compound medications. The intent of the regulation proposal is to improve patient safety.

Comment #21

CSHP has concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direst of patients.

Board Response

The intent of the regulation proposal is to improve patient safety. While Ms. Benton's comments do not address any specific section or subsection of the proposed regulation, the board does address labeling requirements of compounded drug products in §1753.3. Section 1753.3(a)(6) provides that the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code, are exempt from the recordkeeping requirements of that subsection. In an acute care setting, the regulation proposal allows for one-time preparations of compounded drug products to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula.

Comment #22

CSHP members are concerned that the added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore placing the patient at risk without any additional benefit to patient safety and care.

Board Response

This comment mirrors that of Comment #10 and Comment #13. Please see the board's response to Comment #10.

The intent of the regulation proposal is to improve patient safety. Following the 45-day comment period, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. However,

several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacists who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. An internal pharmacy reference number is necessary to allow for a recall of a product if necessary, another essential consumer protection component.

Comment #23

CSHP fails to see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. CSHP believes that such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would already be administered to the patient.

Board Response

The board's response to CSHP's comment #8 addresses Ms. Benton's comment regarding those recordkeeping requirements for those products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Additionally, even for an IV that has already been administered, where a subsequent recall of a product is issued, a systematic review could not be accomplished without the recordkeeping requirements specified in the regulation. Without this, necessary systematic changes could not be realized and made to prevent future errors, a key patient safety issue.

Comments from Mona Ghomeshi, Pharm.D., Mercy San Juan Medical Center

Comment #24

Dr. Ghomeshi stated her opposition to the proposed regulations relating to compounding. She was concerned that delays in patient care will occur due to logging medication prepared in emergent situations, such as cardiac arrest.

Board Response

This comment is similar to Comment #10. Please see the board's response to Comment #10.

Comment #25

Dr. Ghomeshi asked the board to exempt acute care hospitals from the proposed record keeping requirements the pharmacy reference number or the lot number on the label for those compounded drug products prepared for one-time or immediate-use IV medications.

Board Response

This comment mirrors that of Comment #10. Please see the board's response to Comment #10.

The intent of the regulation proposal is to improve patient safety. Following the 45-day comment period, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. However, several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacists who reviewed the final drug product. First, the regulation was updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. An internal pharmacy reference number is necessary to

allow for a recall of a product if necessary, another essential consumer protection component.

Joint comments from Heidi Barsuglia, California Retailers Association (CRA), and Mary Staples, National Association of Chain Drug Stores (NACDS)

Comment #26

Ms. Barsuglia and Ms. Staples acknowledged the board's decision to exclude flavor enhancements of commercially available oral medications from the definition of "compounding." They also expressed appreciation to the board for their decision not requiring establishment of a professional relationship between a pharmacist and (both) a prescriber and a patient prior to compounding a drug.

Board Response

The board accepts the comments of the California Retailers Association and the National Association of Chain Drug Stores

Comment #27

The CRA and the NACDS oppose compounding regulations preventing pharmacies from engaging in "non-sterile basic" compounding. They referred to the Pharmacy Compounding Accreditation Board definition of "non-sterile basic" compounding which involved preparation of a formulation containing two or more non-sterile commercially available products employing basic pharmacy training skill sets. They asked the board to reconsider whether pharmacies which engage in non-sterile basic compounding are required to meet the same requirements (including complete self-assessment) as more complex types of compounding.

Board Response

Section 1735 specifies what does and does not constitute compounding. The Pharmacy Compounding Accreditation Board's definition of compounding is not incorporated by reference into the board's statutes or regulations. As such, that definition does not control the board's enforcement of its own regulations regarding pharmacy compounding.

Comment #28

Ms. Barsuglia and Ms. Staples acknowledged the board's determination that allows pharmacies to record the master formula on the prescription document for preparations that pharmacies do not routinely compound. However, they asked the board to reconsider whether pharmacies that only engage in non-sterile basic compounding should have to comply with requirements for a compounding policy and procedure manual, documentation of the facilities and equipment necessary for compounding, documentation of pharmacy staff training and on-going competency evaluation, and a written quality assurance plan. The CRA and NACDS position is that

these additional requirements are unnecessary and will act as a hindrance to pharmacies that provide only non-sterile basic compounding services to patients.

Board Response

If a pharmacy 'compounds' drug products as defined in §1735, that pharmacy is subject to the provisions of Title 16, Article 4.5 (general compounding) or Article 7 (sterile compounding), and is required to comply with those requirements as defined by those Articles.

The intent of the proposed regulations is to improve patient safety. Even for those products that are not designated 'sterile' it is an essential consumer protection component to ensure that products compounded by or under the direction of a pharmacist are in compliance with pharmacy law and regulations, to ensure patient safety.

Comments from Geralyn Trujillo, MPP, Director, State Government Affairs, American Society of Health-System Pharmacists (ASHP)

Comment #29

Ms. Trujillo stated opposition to proposed regulation changes to California Code of Regulations Article 4.5, Compounding. On behalf of ASHP, Ms. Trujillo asked the board to consider the professional judgment of pharmacies and the policies of the institutions they practice in during situations demanding flexibility to decide what is best for patients. She referenced label requirements shown in Chapter 797 of the United States Pharmacopoeia (USP), Guidebook to Pharmaceutical Compounding – Sterile Preparations:

“...unless immediately and completed administered...the [compounded sterile preparation (CSP)] shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour beyond-use date (BUD) and time.”

Board Response

The board recognizes that U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) provides good *practices* for compounding sterile products. U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding. The intent of the regulation is to ensure patient safety. The policies and procedures of health facilities are not under the jurisdiction of the board. The board is acting within its consumer protection mandate to appropriately regulate the practice of pharmacy.

Comment #30

Ms. Trujillo referenced ASHP practice guidelines for labeling requirements that exclude compounding of sterile preparations for emergency treatments from its scope, a vital distinction they believe is necessary. She states:

“...ASHP guidelines *do not* apply to the manufacture of sterile pharmaceuticals as define in state and federal laws and regulations, *nor* do they apply to the preparation of medications by pharmacists, nurses, or physicians in emergency situations for *immediate* administrations to patients (e.g., cardiopulmonary resuscitation)...It is recognized that, in certain emergency situations, a pharmacist may be requested to compound products under conditions that do not meet these guidelines. In such situations, it is incumbent upon the pharmacist to employ professional judgment in weighing the potential patient risks and benefits associated with the compounding procedure in question.”

ASHP requests that the board reconsider the regulatory language affecting labeling during emergency situations that could negatively impact patient care and introduce delays in medication delivery.

Board Response

ASHP practice guidelines are not incorporated by reference into the board’s statutes or regulations. As such, these guidelines do not control the board’s enforcement of its own regulations regarding pharmacy compounding, and the board is acting within its consumer protection mandate to appropriately regulate the practice of pharmacy. Section 1735.3—Records of Compounded Drug Products, exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The regulations do not require that recordkeeping requirements be completed in advance of the administration of the compounded drug product. The intent of the regulation is to improve patient safety.

Comment #31

Ms. Trujillo stated that there is confusion as to whether the proposed documentation requirement applies to every product that is prepared, including those for an individual patient, or if the requirement will apply solely to those products prepared in batch for a yet-to-be-determined patient. ASHP asked the board to consider the potential implications of the added documentation, which could delay preparation and delivery of one-time and immediate-use medications to patients.

Board Response

Section 1735 of Article 4.5 defines compounding and further specifies in subdivision (d) of §1735 that Article 4.5 applies to all compounding practices. Further, Article 7 specifies that the provisions of Article 4.5 are applicable to all compounding and provides additional parameters and requirements that are applicable solely to sterile injectable compounding. Section 1735.2(b) provides for the advance preparation of compounded drug products in advance of receipt of a patient-specific prescription. Finally, the regulations do not require that recordkeeping requirements be completed in advance of the administration of the compounded drug product; therefore, the regulations do not delay the preparation and delivery of one-time and immediate-use medications to patients.

Comments from Reid Toda, MS, R.Ph**Comment #32**

Mr. Toda asked the board to clarify how the proposed compounding regulations will affect pharmacies where a nurse reconstitutes and administers a medication on the [nursing] floor.

Board Response

This comment is outside the scope of the proposed regulation. Article 4.5 Section 1735(b) provides that compounding does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

Comments from Mary Noud-Ikuta, Pharm.D.

Comment #33

Dr. Noud-Ikuta expressed concern that the proposed compounding regulations requiring additional labeling and pharmacy recordkeeping would put patients at risk by delaying treatment. Preparation of compounded medications in an acute care facility include one-time and immediate-use (STAT) medications such as alteplase, epinephrine, or diltiazem. Dr. Noud-Ikuta stated that added documentation requirements for both the label and pharmacy log will delay preparation and delivery of these medications, with no additional benefit to patient safety and care.

Board Response

In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the recordkeeping requirements found in section 1735.3 do not need to be completed in advance of the administration of the compounded drug. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacists who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. The intent of the regulation proposal is to improve patient safety.

Comment #34

Dr. Noud-Ikuta did not recognize any benefits relating to product recalls by requiring the recording of a pharmacy reference number or lot number on the label of a dispensed IV and additional information in the pharmacy log. She stated that in situations where patients are in

need of one-time and immediate-use compounded products, any future recall of a product would be moot because the IV would have already been administered to the patient.

Board Response

Board of Pharmacy's priority mandate is to protect the public. This mandate extends to the compounding and labeling of prescription drugs. It is unclear as to what portion of the proposed regulation Dr. Noud-Ikuta is referencing with regard to labeling of a dispensed IV. The board did modify the proposed text of §1753.3(a)(6) to exempt specified labeling requirements from those records of sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

The board realizes that recall of a product could be moot for an IV that has already been administered; however, without the specified recordkeeping requirements, a systematic review could not be accomplished. Without this, necessary systematic changes would not be realized and made to prevent future errors, a key patient safety issue.

Comment #35

Dr. Noud-Ikuta referred to Chapter 797 of the United States Pharmacopoeia (USP) and a section related to Immediate-Use Compounded Sterile Products. She asked the board to exempt from additional record keeping requirements the preparation of one-time and immediate-use injectable products in acute care facilities.

Board Response

U.S. Pharmacopoeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding. The board has responded to Dr. Noud-Ikuta (see board's response to comments #1 and #2) with regard to record keeping requirements of preparation of one-time and immediate-use injectable products in acute care facilities.

The board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comments from Maria D. Serpa, Pharm.D.

Comment #36

Dr. Serpa expressed concern that the proposed compounding regulations would unnecessarily apply to 'sterile injectable' products. She acknowledged that the board was charged with the task of strengthening 'traditional' compounding practices in order to enhance patient safety. Dr. Serpa asked the board to ensure separation of 'traditional' compounding regulations and 'sterile injectable' compounding regulations. She referenced United States Pharmacopeia (USP) Chapter 797 (sterile preparations) and Chapter 795 (nonsterile preparations).

Board Response

The board recognizes that U.S. Pharmacopeia (USP) General Chapters 797 and 795 (effective January 1, 2004) provide good *practices* for compounding sterile and nonsterile preparations, respectively. U.S. Pharmacopeia (USP) General Chapters 795 and 797 are not incorporated by reference in this regulation proposal. These guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding. Compounding within the scope of pharmacy is within the board's authority and the regulation thereof is necessary to ensure patient safety.

Comment #37

Dr. Serpa supported the board's efforts to address patient safety through the proposed 'traditional non-sterile' compounding regulations, stating that those changes are urgently needed. However, she advised against changes affecting regulations for 'sterile injectable' compounding.

Board Response

The board agrees with Dr. Serpa's comments that ensuring patient safety through "traditional non-sterile" compounding regulations is needed. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacist who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. An internal pharmacy reference number is necessary to allow for a recall of a product if necessary, another essential consumer protection component.

Comments from Robert Batman, Pharm.D., Kaiser Permanente

Comment #38

Dr. Batman stated that regulations requiring additional record keeping and labeling would be burdensome for acute care hospitals with a large number of compounded IV medications. He advised that typical batch compounding issues encountered in a chronic care setting such as home health or ambulatory care would not apply because acute care settings administer medications immediately after compounding. Dr. Batman asked the board to consider an exemption from record keeping and labeling requirements for acute care facilities, specifically for the compounded IV medication for immediate-use.

Board Response

The intent of the regulation is to improve patient safety. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board disagrees with Dr. Bateman's assertion that the record-keeping and labeling requirements would be burdensome. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. The patient's chart order can serve as the master formula. Further the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug.

The board did modify the proposed text of §1753.3(a)(6) to exempt specified labeling requirements from those records of sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The board believes this modified text addresses Dr. Batman's concerns.

Comments from Raffi Svadjian, Pharm.D., MBA, USC School of Pharmacy

Comment #39

Dr. Svadjian advised that the proposed compounding regulations were provided to the 3rd Year Community Pharmacy Management Elective course at USC. Applicable students were instructed to conduct a survey to determine whether the proposed compounding regulations would affect community pharmacies. Results of the survey revealed that only 2 of the 12 contacted pharmacies had knowledge of the proposed regulatory changes prior to participating in the survey. Pharmacies contacted expressed concern that the proposed regulations would result in some community pharmacies that would halt compounding activities due to cost factors of meeting the new regulatory standards (end product testing, possible purchase of software, etc.).

Board Response

The board appreciates the comments of Dr. Svadjian; however, the survey referred to and the results thereof are outside the scope of the proposed regulation. As required by Government Code section 11346 et seq., the board held public discussions of its regulatory proposal before proposed language was noticed to the public on September 5, 2008. The board also posted to its website various agendas, minutes and meeting summaries referencing the topic and discussion of compounding at public meetings. The board would be happy to add to its mailing list those pharmacies contacted by the USC students.

Comment #40

Results of the survey conducted by USC School of Pharmacy students referred to a lack of clear definition of end-product testing and quality assurance. Community pharmacists contacted expressed concern that the proposed regulations do not specify the requirements of frequency of end-product testing, record keeping, and which products would need to be tested.

Board Response

These comments do not address any specific text within the regulatory proposal. The results of the survey referenced by Dr. Svadjian are outside of the scope of the regulation proposal.

Comment #41

Results of the survey conducted by USC School of Pharmacy students referred to a lack of distinction between regulations that should be necessary to mix two different products versus complex compounding formulas. Community pharmacies contacted suggested that less oversight should be required in certain instances; for example, when changing a tablet to a liquid dosing form for short-term administration to a patient.

Board Response

The survey referenced is outside of the scope of the regulation proposal. However, the board has adequately described the definitions and requirements of compounding (§1735). In responding to the example offered (changing a tablet to a liquid dosing form), such alteration of the dosage form or delivery of the drug does fall within the definition of "compounding" as provided in proposed section 1735(a). To alter a tablet to a liquid form, a component would have to be added. The patient has a right and a need to know what components or drugs were "compounded" that provided such alteration.

Comments from Kenneth Breslow, MS, R.Ph., FAPh, PETNET Solutions

Comment #42

Mr. Breslow referred to the lack of statutory distinction in the State of California for operation and licensure of Nuclear Pharmacies (Radiopharmacies). He urged the board to exempt application of any revised sterile compounding regulations to PET drug compounding. Mr. Breslow suggested that the board stipulate the requirement to comply with relevant USP chapters, until such time the board proposes and adopts its own regulations pertinent and applicable to radiopharmaceutical and PET radiopharmaceutical compounding.

Mr. Breslow provided a listing of unique differences between conventional drugs, conventional radiopharmaceuticals, and PET radiopharmaceuticals.

Board Response

The comments offered by Mr. Breslow are not related to the proposed modified text found in proposed 16 CCR 1735.5(a)(6). Therefore, the comments are outside of the scope of the proposed modified text contained in the 15-day comment period. The board may wish to address exemptions to radiopharmaceuticals, should specific language be offered.

Comments from Ben J. Devine, Pharm.D., Director of Pharmacy, Sutter Lakeside Hospital

Comment #43

Dr. Devine expressed concern that additional labeling and maintenance of a log serves no purpose in the event of a recall, when an immediate-use compounded medication has already been administered to a patient. He strongly urged the board to reconsider the proposed regulatory change, and grant an exemption for medications compounded for immediate or emergency use.

Board Response

The intent of the regulation proposal is to improve patient safety. Following the 45-day comment period, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comments from Gary W. Chan, Clinical Pharmacist, Mercy San Juan Medical Center

Comment #44

Dr. Chan strongly opposed the proposed regulation requiring pharmacist to record in a log each IV that is compounded. He stated that serving as a clinical pharmacist in a hospital requires him to attend codes, rapid responses, and cardiac alerts. Dr. Chan expressed concern that harm will

come to patients if the proposed regulation is put in place, particularly in instances where these patients required immediate and one-time (STAT) medications. He asked the board to exempt additional pharmacy record keeping requirements for preparation of one-time and immediate use IV products in acute care hospitals.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. The chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comments from Karen Azama-Kihara, Pharm.D., Pharmacy Supervisor, Mercy San Juan Medical Center

Comment #45

Dr. Azama-Kihara expressed concern that additional record keeping and log preparation will result in a delay in services to patients during emergency situations, including cardiac arrests. She strongly urged the board to exempt preparation of one-time and immediate use IV products in acute care hospitals. Dr. Azama-Kihara asked the board to exempt one-time and immediate use IV medications from the requirement to record the pharmacy reference number or lot number on the label.

Board Response

Please see the board's response to comment #44.

Comments from Larry W. Schallock

Comment #46

Mr. Schallock stated his support of CSHP's position regarding labeling and record keeping exemptions for one-time and immediate-use medications. He referenced USP Chapter 797 relating to Immediate Use Compounded Sterile Products, which allows exemptions for emergency or immediate use of a compounded product. Mr. Schallock urged the board to grant the exemption in the best interest of patient safety and quality of care.

Board Response

It is inferred that Mr. Shallock is referring to CSHP's Comment #22. Additionally, the board recognizes that U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) provides good *practices* for compounding sterile products. U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding. The intent of the regulation is to ensure patient safety.

Comments from Gloria Lee Wilder, Pharm.D., CBHS Pharmacy Director, San Francisco Department of Public Health

Comment #47

Dr. Wilder acknowledged that the underlying reason for the new requirement would be for a pharmacy to be able to trace each unit of IV medication to its specific compounding information. She asked the board to reconsider this requirement, and instead require a pharmacy to trace pedigree (compounding information), rather than prescriptively specifying the method of the 'trace-back.' Dr. Wilder stated that information currently printed on the label included prescription number, patient name, and date/time admixing would allow for this 'trace-back.' She is concerned that adding the pharmacy reference number or lot number would be redundant information for identifying pedigree of a compound product.

Board Response

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacists who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. The intent of the regulation proposal is to improve patient safety.

The board does not prescriptively specify the method of "trace-back" rather, just information that must be recorded; the method by which this is achieved will be determined by the pharmacy.

Comment #48

Dr. Wilder requested clarification of proposed regulation 1735.2(a) where "the prescriber has approved use of a compounded drug product either orally or in writing...." She asked for

clarification from the board as to whether this would be required for all prescriptions compounded in the hospital setting, or would it include prescriptions which can only be dispensed compounded (such as an individualized TPN). Dr. Wilder is concerned that pharmacists would be required to call prescribers to obtain a verbal order, and then add the compounding specifics to the prescription.

Board Response

Proposed regulation §1735.2(a) provides that, except as specified in subsections (b) or (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Subsection (b) allows a pharmacy to prepare and store a limited quantity of compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity 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. Subsection (c) defines “reasonable quantity.” Section 1735.2 applies to all compounded drug products.

Comments from Carolyn Nguyen, Pharm.D., ED Clinical Pharmacist, Stanford and Clinics Hospital

Comment #49

Dr. Nguyen does not support the proposed labeling and pharmacy record keeping requirements relating to certain compounded IV medications. She stated that the additional requirements will inevitably delay treatment of patients. Dr. Nguyen expressed concern that preparation of emergency compounded medications for patients experiencing heart attack, stroke, and other life-threatening events will be placed at risk by unnecessary labeling and record keeping requirements.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy’s copy of the patient’s chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1735.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comment #50

Dr. Nguyen referred to USP Chapter 797, relating to Immediate-Use Compounded Sterile Products. She advised that Chapter 797 contained a special section related to Immediate-Use Compounded Sterile Products as the provision intended only for those situations where there is a need for emergency or immediate patient administration of a compounded product. Dr. Nguyen asked the board to exempt from additional record keeping requirements the preparation of one-time and immediate-use injectable products in acute care facilities. She suggested that an exemption would benefit patients and ensure that one-time and immediate-use needs are treated in a safe and appropriate timeframe.

Board Response

U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding.

The board responded to Dr. Nguyen's comment as it relates to one-time and immediate-use needs in its response to Comment #49.

Comments from Margaret C. Bradshaw, R.Ph., Mendocino Coast District Hospital

Comment #51

Ms. Bradshaw questioned the feasibility of having only one set of regulations governing both general compounding and sterile compounding. She also expressed concern about ability to regulate all types of compounding without making specific regulations accounting for specific needs encountered in practice sites. Ms. Bradshaw stated that not recognizing inherent differences in services or populations served results in regulations that are incomplete, ambiguous, and unduly burdensome. She asked the board provide pharmacy practitioners with a clear, unambiguous statement of the regulations.

Board Response

As stated in the Initial Statement of Reasons, the regulations remove duplication between Article 4.5 and Article 7 and reorganizes Article 7 to make it consistent with Article 4.5.

Additionally, the regulations address, among other items, the strength, efficacy and quality in compounding, as well as require a quality assurance program for general compounding. Currently, there are no provisions that either define these items for general compounding or set any parameters established in the Pharmacy law (Business and Professions Code §§ 4000 and following) detailing general compounding by a pharmacy.

The regulations also are crafted to remove redundancies between the requirements for general compounding and sterile injectable compounding, as well as to ensure consistent sequencing of related requirements contained in both Articles. The regulations provide uniformity in compounding for California consumers.

Comment #52

Ms. Bradshaw referred to USP Chapter 797, and asked if it is the intent of the board to exempt California pharmacies that compounding sterile preparations from the provisions of USP 797 that differ from the proposed regulations. If not, she suggested that it would serve the board's purpose to protect the public by adopting provisions of USP Chapter 797 as the rules, which govern sterile compounding in California. Ms. Bradshaw stated that current USP Chapter 797 is a direct reflection of the most current discussion in the pharmaceutical community regarding compounded sterile preparations, while the underlying data referred to in the Initial Statement of Reasons was reported in a workgroup that last met in January 2005.

Board Response

U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding.

Comment #53

Ms. Bradshaw noted specific sections of the proposed regulations that she considers problematic, stated below. To address each comment thoroughly, a board comment follows each alphabetized item.

a. Compounding Definitions – there is a need for definition of additional terms. For example, designated area, critical area, and controlled area are terms used when referring to sterile compounding.

Board response to #53a

The terms referenced in Ms. Bradshaw's comment are not within the scope of the proposed regulations.

b. Compounding Limitations and Requirements, Section 1735.2(a) – Does the requirement that the prescriber approve use of a compounded drug either orally or in writing apply to chart orders?

Board response to #53b

If a chart order specifies a prescription for a compounded drug product, then that compounded drug product is subject to the provisions of 1735.2(a).

c. Compounding Limitations and Requirements, Section 1735.2(h) – Expiration date or beyond use date for compounded sterile preparations depends on both stability and sterility concerns. Determining a beyond use date might also be determined by the nature of the compound.

Board response to #53c

Section 1735.2(h) specifies that a compounded drug product shall be given an expiration date, as specified. This subsection also provides that the pharmacist

performing or supervising the compounding may use professional judgment with regard to the expiration date or beyond use date, as specified.

d. Compounding Limitations and Requirements, Section 1735.2(i) – The pharmacist performing or supervising compounding may not be the same pharmacist responsible for delivery of a compounded drug product. These activities may be performed by different individuals.

Board response to #53d

As stated in the proposed regulation, the pharmacist that performs or supervises the compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product. The board acknowledges that every function described in Comment 53d may not be performed by the same individual; however, the pharmacist who performs or supervises the compounding is responsible for that compounded drug product.

e. Records of Compounded Drug Products Section 1735.3(a) – Requiring the maintenance of these records for compounded sterile products administered in the hospital inpatient or outpatient setting would be unduly burdensome. These products are used in a short period of time, if not immediately. Except for batch-prepared items, the detailed records this regulation requires would offer little value.

Board response to #53e

The intent of the regulation is to improve patient safety. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board disagrees with Ms. Bradshaw's assertion that the record-keeping and labeling requirements would be unduly burdensome. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. The patient's chart order can serve as the master formula. Further the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug.

The board did modify the proposed text of §1735.3(a)(6) to exempt specified labeling requirements from those records of sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Adequate recordkeeping of compounded drug products would provide for a meaningful quality assurance review should a problem occur with such compounded medications.

f. Records of Compounded Drug Products Section 1735.3(b) – Would this require pharmacies compounding sterile products to maintain records of the acquisition of all sterile medications that are used to prepare sterile products, including IV solutions, and any medication that might be added to an IV solution? Would a hospital pharmacy performing minimal general compounding for an inpatient be required to keep records of items that might not have been purchased with the intent to use those items for compounding?

Board response to #53f

Section 1735 .3(b) provides that a pharmacy shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding. If the products referred to in Ms. Bradshaw's comment are used in compounding as defined in §1735 then – yes – the record keeping requirements provided in §1753.3(b) would apply to those products.

g. Labeling of Compounded Drug Products, Section 1735.4 – Does Section 1735.4 refer to outpatient dispensing? Labeling requirements for sterile compounded preparations for administration in a hospital should have certain exemptions.

Board Response to #53g

The provisions of §1735.4 apply to all sterile injectable compounded products. Section 1735.3(a)(g) provides limited exemptions from the labeling requirements of all compounded drug products, including those that are compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under 1250 of the Health and Safety Code.

h. Training of Compounding Staff, Section 1735.7 – There is a need for guidelines stating the minimum skills, training, competency or competency assessment. Absent guidelines, the determination of the sufficiency of the training or competency assessment would be left to a board inspector.

Board Response to 53h

The determination of the sufficiency of the training or competency assessment of pharmacy compounding staff is defined in §1735.7. The pharmacist-in-charge is responsible to ensure that the training of compounding staff pursuant to the criteria found in §1735.7 is met.

i. Article 7, Sterile Injectable Compounding – Adoption of USP Chapter 797 would provide necessary regulation of sterile compounding.

Board Response to #53i

U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding.

- j. Compounding Area – Definition of a compounding aseptic barrier should be added to Section 1751.

Board Response to #53j

Section 1751.3 provides the provisions that a pharmacy's written policies and procedures shall comply with for those pharmacies that compound sterile injectable products from one or more non-sterile ingredients (see 1751.3(d)(3)(F)), including barrier isolator workstations.

- k. Sterile Injectable Labeling Requirements, Section 1751.2 (d) – The proposed regulations do not address hazardous drugs; as designate by NIOSH and OSHA.

Board Response to #53k

Those hazardous drugs described by Ms. Bradshaw are not within the scope of the proposed regulations.

- l. Sterile Injectable Policies and Procedures, Section 1751.3 – Most of the requirements of subsection (d) should apply to all sterile injectable compounding, not just sterile compounding from one or more non-sterile ingredients.

Board Response to #53l

This comment is outside the scope of this regulation change. Section 1751.3(d) is existing regulation. The board is not proposing any changes to this subdivision.

- m. Facility and Equipment Standards for Sterile Injectable Compounding, Section 1751.4(b) – Proper attire required should be specified.

Board Response to #53m

Section 1751.5 defines proper attire, as referenced in §1751.4(b).

- n. Facility and Equipment Standards for Sterile Injectable Compounding, Section 1751.4(d) – Weekly cleaning schedule specified conflicts with USP Chapter 797 in pharmacies compounding only low and medium risk preparations.

Board Response to #53n

U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding.

- o. Facility and Equipment Standards for Sterile Injectable Compounding, Section 1751.4(e) – Use of a compounding aseptic isolator for preparing parenteral cytotoxic agents should be allowed.

Board response to #53o

The board incorporates by reference those facility and equipment requirements found in Title 24 of the California Administrative Code. Section 1751.4 provides that no sterile injectable product shall be compounded if it is known, or reasonably known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products. The pharmacy may incorporate in its policies and procedures the additional requirements as specified by Ms. Bradshaw, in addition to those provided for in that section.

- p. Sterile Injectable Compounding Attire, Section 1751.5 – Gloves used for sterile compounding should be more than gloves made from low shedding materials. If not sterile gloves, then at least latex or nitrile gloves should be specified. Gloves that are ASTM rated for chemotherapy should be specified for personnel preparing cytotoxic agents.

Board Response to #53p

This comment is outside the scope of this regulation change. Section 1751.5 is existing regulation. The board is not proposing any changes to this subdivision.

- q. Training of Sterile Injectable Compounding Staff – Requirements listed in (e)(1) A-H should be required of all personnel compounding sterile preparations.

Board Response to #53q

Section 1751.6(b) provides that the pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have the training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents. Subsection (e) provide the training requirements of such staff.

Comments from Bryan Carlson, Pharmacy Department, Children's Hospital of Central California

Comment #54

Mr. Carlson asked the board to consider a 'phase-in' period of 12 months to effect the changes proposed to Section 1716, Requirements for Pharmacies that Compound Medications. He expressed concerns about necessary budget and process changes that will need to occur at Children's Hospital of Central California in order to comply with the regulatory changes proposed.

Board Response

The comments offered by Mr. Carlson are outside of the scope of the proposed changes to 16 CCR §1716. However, the board may want to consider any phase-in period, if such a specific amendment is offered.

Comment #55

Mr. Carlson suggested that if manufacturers would standardize bar coding technology to include lot numbers and expiration dates along with the NDC, this would facilitate the proposed record keeping process.

Board Response

The board thanks Mr. Carlson for his comment, however, the technology utilized by manufacturers is not within the scope of the proposed regulations.

Comment #56

Mr. Carlson asked the board for clarification regarding the term "equipment" referred to in Section 1735.3(a)(7). He asked whether every lot number of every syringe and every needle used in the compounding process would need to be documented and stored. Mr. Carlson expressed concern about the extent of documentation needed, and the difficulty in meeting this requirement.

Board Response

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacists who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a

problem occur with such compounded medications. The intent of the regulation proposal is to improve patient safety.

The board does not prescriptively specify the method of 'trace-back' rather, just information that must be recorded; the method by which this is achieved will be determined by the pharmacy. The lot number requirement is specific to each component, not equipment used.

Comments from Alan Y. Endo, Pharm.D., Director of Pharmacy, Presbyterian Intercommunity Hospital

Comment #57

Dr. Endo acknowledged the board's efforts to strengthen compounding regulations, but he expressed concern regarding the proposed labeling and pharmacy record keeping requirements for compounded IV medications in acute care hospitals. Dr. Endo referred to a distinction between prescription compounding and bulk manufacturing. He suggested that manufacturing practices applied to acute care settings can seriously jeopardize a hospital pharmacist's ability to respond to acute needs of patients. He asked the board to accept the recommended changes submitted by CSHP, or create a working group of practicing hospital pharmacists to ensure safe guarding the protection of patients.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1735.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Further, §1735.2(b) provides that a pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription, as specified. Section 1735.2(c) further defines "reasonable quantity." The board believes this subsection adequately addresses Dr. Endo's concern about a hospital pharmacist's ability to respond to acute needs of patients.

Comments from David Elder, Pharm.D., Director of Pharmacy Services, Sierra Kings District Hospital

Comment #58

Dr. Elder expressed support for comments provided by CSHP, emphasizing that adequate documentation is already being performed for compounded items. He stressed that compounding skills are already defined, and the proposed regulations would create tedious work that does not protect patients. Dr. Elder asked the board to exempt logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. He added that future recall of a product would be moot as the IV would have already been administered as immediate use.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1735.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

In the event of a recall, recordkeeping requirements are needed so that a systems review can be accomplished. Without this, necessary systematic changes would not be realized and made to prevent future errors, a key patient safety issue.

Comments from Lois F. Leister, R.Ph, M.S., M.B.A., Mendocino Coast District Hospital**Comment #59**

Ms. Leister strongly opposed the proposed regulations relating to compounding. She referenced USP Chapter 797 requirements, which have already been refined and are continually updated by the pharmacy profession. Ms. Leister urged the board not to associate IV admixture preparation practice with compound prescriptions, such as topical, oral, or injectables compounded from non-sterile product or intended for sale or distribution to a patient or provider. She stated that if applied to all IV admixtures prepared in a hospital pharmacy environment, the proposed regulations would create a recordkeeping nightmare, even for a small rural hospital mixing 100 IV admixtures in a single day. Ms. Leister asked the board to reconsider how the "sterile compound" regulations pertain to the practice of IV admixture services.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comment #60

Ms. Leister asked the board to reconsider the language proposed in Sections 1751.5, 1751.6, and 1751.7. She suggested following the practice guidelines provided in USP Chapter 797 in areas such as training, cleaning, garbing, and quality assurance.

Board Response

U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding.

Comments from Dharma Naidu, Pharm.D., Pharmacy Supervisor, Community Hospital of the Monterey Peninsula

Comment #61

Dr. Naidu stated concerns relating to the proposed regulations, specifically with IV medication preparation and the urgent needs to administer immediate use products as defined by USP. She advised that these products are needed urgently, and there is a potential delay caused by logging and pharmacy lot number assignment/labeling. Dr. Naidu stressed that administration of life-saving medications, such as those prepared by pharmacists during cardiac resuscitation, would be delayed by a few minutes to assured logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis

for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) is not incorporated by reference in this regulation proposal. USP 797 guidelines do not control the board's enforcement of its own regulations regarding pharmacy compounding.

Comment #62

Dr. Naidu asked the board to reconsider the 3-year recordkeeping requirement proposed for all products, whether STAT or non-urgent, citing it as wasteful and unrealistic.

Board Response

The 3-year time frame required in this proposal is consistent with current pharmacy law that specifies that all records must be maintained for three years from the date of dispensing.

Comments from Kimberly Jones, Pharm.D., Clinical Pharmacist, Community Hospital of the Monterey Peninsula

Comment #63

Dr. Jones expressed concerns about potential delays in administering immediate-use medications during emergencies caused by unnecessary logging and pharmacy lot number assignment/labeling.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comment #64

Dr. Jones opposed the 3-year recordkeeping requirement that would be required for each product prepared, calling the practice unrealistic and wasteful.

Board Response

The 3-year time frame required in this proposal is consistent with current pharmacy law that specifies that all records must be maintained for three years from the date of dispensing.

Comments from Alexander Berger, Staff Pharmacist, O'Connor Hospital, San Jose

Comment #65

Dr. Berger strongly opposed the board's proposed regulations, stating that it will jeopardize patient care. He urged the board to exempt from added documentation requirements IVs for immediate/STAT administration.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comments from Man Yi, R.Ph, MS, Clinical Pharmacist, Community Hospital of the Monterey Peninsula

Comment #66

Mr. Yi expressed concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medication preparations. He stated that it is unreasonable to ask that life-saving medication prepared by a pharmacist in an operating room or other critical-care areas would be delayed because of unnecessary logging, assignment, and labeling of an IV bag.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis

for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comment #67

Mr. Yi opposed the proposed regulations requiring 3-year recordkeeping for each product prepared. He cited the practice as unrealistic and wasteful.

Board Response

The 3-year time frame required in this proposal is consistent with current pharmacy law that specifies that all records must be maintained for three years from the date of dispensing.

Comments from Michael W. Sanders, Pharm.D., President, North Coast Society of Health-System Pharmacists

Comment #68

Dr. Sanders voiced his objection to the proposed regulations pertaining to 'stat' or 'now' compounded IV and other products for acutely ill patients. He stated that the board would be placing unreasonable and unnecessary recordkeeping and labeling requirements on already overburdened health care systems in California. Dr. Sanders asked the board to accommodate immediate and one-time use compounded products.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comments from Lynn Hendrick, Pharm.D., Clinical Pharmacist, Community Hospital of the Monterey Peninsula

Comment #69

Dr. Hendrick opposed the regulations relating to logging and pharmacy lot number assignment/labeling for immediate-use products. She suggested that life-savings medications would not be administered to patients in a timely manner, if delayed by unnecessary recordkeeping.

Board Response

The intent of the regulation proposal is to improve patient safety. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines. Finally, the board modified the recordkeeping requirements of §1735.3—Records of Compounded Drug Products, to exempt from the recordkeeping requirements specified in §1753.3(a)(6) the manufacturer and lot number of each component, for those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comment #70

Dr. Hendrick opposed the requirement of 3-year records retention for each product, citing the practice as unrealistic and wasteful.

Board Response

The 3-year time frame required in this proposal is consistent with current pharmacy law that specifies that all records must be maintained for three years from the date of dispensing.

Comments from Ray Miller, Pharm.D., Director of Pharmacy, St. Francis Memorial Hospital**Comment #71**

Dr. Miller asked for clarification from the board as to whether the proposed regulations applied to hospital pharmacies that compound admixtures for immediate use on in-patients. He stated that the proposed self-assessment distributed was titled, "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" which implies that it is not intended for hospitals that are accredited by TJC.

Board Response

Pharmacy law specifies that all pharmacies, either licensed by the board to compound sterile injectable products, or exempt from licensure because of specified accreditation, must comply with regulations.

DRAFT SUMMARY OF COMMENTS
TO COMPOUNDING REGS

COMMENTS RECEIVED DURING THE 15-DAY COMMENT PERIOD

Comment from Ernest M. Aldama, Adapt Consulting, Grants Pass, Oregon

Comment #72

In an undated letter, Mr. Aldama stated that Title 24 section 4-1106(b) is not readily available to all persons and it would be helpful to have the applicable information provided within paragraph 1751(b).

Board Response

This comment as it is outside of the scope of the modified text provided for comment during the 15-day comment period.

Comments received from Dawn Benton, Executive Vice President, CEO, California Society of Health-System Pharmacists

Comment #73

Ms. Benton expressed the California Society of Health-System Pharmacists (CSHP) thanks for changes made to section 1735.3(a)(6) that exempts the manufacturer and lot number of each component if the sterile product is compounded "on a one-time basis for administration within two hours to an inpatient in a health care facility..." She further stated that CSHP believes the exemption will help to prevent delay of medications to patients with immediate and urgent needs, but nonetheless still questions the *necessity* of including any inpatient pharmacy currently covered by Article 7: Sterile Injectable Compounding also under the proposed Article 4.5: Compounding regulations.

Board Response

The board appreciates CSHP's comments that the proposed modified text in §1735.5(a)(6) will help prevent delay of medications to patients with immediate and urgent needs.

However, with regard to the applicability of proposed regulations to those pharmacies currently covered by Article 7, to be subject to Article 4.5 as well, the board refers Ms. Benton to the Initial Statement of Reasons. There are currently no provisions that address the various issues for general compounding, or that set parameters established in the Pharmacy Law (Business & Professions Code §§ 4400 and following) for general compounding. The proposal provides uniformity in compounding for California consumers with the goal of improving patient safety. The board may want an amendment that strikes a better balance between the need of pharmacy operations in an acute care setting.

Comment #74

Ms. Benton provided a history of the various letters that CSHP has provided to the board on the topic of compounding regulations. She referenced a September 17, 2008, letter where she states CSHP submitted a letter and provided public comment requesting an exemption of immediate and one-time use (STAT) compounded drugs from the recordkeeping and labeling requirements in proposed compounding regulations. She summarized the board's effort to form a 2-person subcommittee to evaluate the requested exemption. She further stated that, in January 2009, the recommendation of the board subcommittee was to exempt the need to track manufacturer and lot number for each immediate and one-time use sterile injectable product; although the pharmacy assigned lot number is still required in immediate and one-time use sterile injectable products. She states CSHP hopes this is an oversight of the board and can be corrected by also exempting the pharmacy assigned lot number in urgent situations.

Board Response

The pharmacy assigned lot number is not included in the exemption. This was not an oversight of the board and was not included in the 15-day comment period.

Comment #75

Ms. Benton stated that CSHP members have additional issues with the proposed regulations. Specifically, she referenced concerns with proposed sections 1735.3(d), 1735.3(a)(7), 1735(a)(2), 1735(b), as well as the "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" form. Ms. Benton requested various exemptions within each section referenced and asked that the board consider these exemptions.

Board Response

The comments offered to the self-assessment form and to sections §1735(b)(1), §1735(a)(2) and §1735(b), §1735.3(a)(7), and §1735.3(d) are not within the scope of the proposed text provided during the 15-day comment period.

The board agrees that the pharmacy profession is dedicated to patient safety – that is the stated intent of the regulation proposal. While Ms. Benton's general comments are not expressly directed to the text of §1735.5(a)(6), the board has thoroughly considered what documentation requirements provide for patient safety and has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The board may want to consider an amendment that strikes a better balance between the need of pharmacy operations in an acute care setting.

Comments received from William J. Blair, Pharm.D., MBA, McGuff Compounding Pharmacy Services, Inc.

Comment #76

Dr. Blair provided a copy of proposed regulations to 16 CCR §§1716.1 and 1716.2, §§1735-1735.8, §§1751-1751.8, and the board's Initial Statement of Reasons. This copy was transmitted in a strike-out and underscore format with no commentary.

Board Response

Comments offered to the proposed text of 16 CCR §§1716.1 and 1716.2, §§1735 through 1735.8 (with the exception of §1735.5(a)(6)), §§1751 through 1751.8, and the Initial Statement of Reasons are outside of the scope of the modified text provided for comment during the 15-day comment period. With regard to the specific language contained in the notice of modified text (15-day comment period), it appears that Dr. Blair changed the word "manufacturer" to "manufacturer's" in the sentence "If the manufacturer's name is demonstrably unavailable," The board believes this comment is nonsubstantive and does not change the meaning of the proposed text. Common usage can reflect that, at times, a noun that the possessive modifies is not expressed but merely understood. However, the board may want to make this nonsubstantive change within proposed 16 CCR §1735.5(a)(6) if it determines the text would be clearer.

Comments received from Margaret Bradshaw, R.Ph., Albion, California

Comment #77

Ms. Bradshaw stated she is a pharmacist employed in a critical access hospital. She provided various patient-pharmacy scenarios for her pharmacy which she states is not staffed 24 hours a day. She added that some pharmacies are closed on weekends. Ms. Bradshaw states that in her scenarios, there would be no greater benefit from the required recordkeeping, as it relates to exemption of sterile products compounded on a one-time basis for administration within two hours than for a 24-hour period.

Board Response

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacist who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance

review to be complete should a problem occur with such compounded medications. The intent of the regulation proposal is to improve patient safety. The board may want to consider amending the proposed language to address the time frames within which an exemption, as specified in the modified text, would apply, if such an amendment is offered.

Comment #78

Ms. Bradshaw states that the volumes of records that will result from the board's record keeping requirements will tax already scarce personnel resources. She adds that small hospitals are negatively impacted because [they] cannot afford to invest in proprietary premixed products that would be more widely available at larger institutions with bigger drug budgets. She adds that even if [they] could afford to purchase products, the volumes would be so small that they could not meet minimum quantities without generating waste from products that expire before they are used. She "rejects the implication that we cannot provide safe products for our patients without the added requirements for the voluminous records that will result from maintaining batch records for individualized compounded sterile products.

Board Response

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacist who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. The intent of the regulation proposal is to improve patient safety. Compounding cannot be done for commercially available products, except as specified. Standards are necessary to ensure the quality, potency, integrity and strength of a compounded product.

Comment #79

Ms. Bradshaw commented on hospitals that provide compounded sterile products to their outpatient departments on an individual, as needed basis. She referenced those that are utilized by oncology departments, infusion departments, outpatient surgery department, emergency department and recovery rooms – adding that the patient never takes possession of them, and that they are administered by hospital personnel. She stated that some situations require that STAT medications be given in life or death situations. She stated "the emphasis should be on providing accurate, aseptic products to these patients in a timely manner, not on generating compounding drug records.

Board Response

In this situation, the requirement to keep records is absolutely necessary, as in the event of a recall, one would need to be able to identify which of those products were administered, and to whom. The board may want to consider amending the proposed language to address the time frame within which an exemption, as specified in the modified text, would apply, if such an amendment is offered. Further, the proposed regulations do not require that all documentation be completed before the product is delivered.

Comment #80

Ms. Bradshaw urged that the exemption to the compounding records requirements should at least extend to outpatients in health care facilities licensed under Section 1250 of the Health and Safety Code.

Board Response

While Ms. Bradshaw's letter does not explicitly state what her recommendation is, the board has thoroughly considered what documentation requirements provide for patient safety and has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The board may want an amendment that strikes a better balance between the need of pharmacy operations in an acute care setting. The exemption is for one-time immediate use to address concerns that STAT medications could be delayed. Patients receiving an IV on site, in an outpatient setting are not STAT meds.

Comments from Kevin R. Brown, Pharm.D.**Comment #81**

In response to the 15-day comment period, Dr. Brown provided a general statement that he is concerned about the "sweeping changes" that are proposed to the compounding and documentation of sterile injectable products. He added that current regulations regarding sterile injectable compounding are specific and detailed in both the U.S. Pharmacopoeia (USP) Convention guidelines (federal level) and in current state Board of Pharmacy regulations. He added that additional regulations require assessment of the patient benefits and risks.

Board Response

The broad statement made by Dr. Brown is not entirely within the scope of the 15-day comment period. However, with regarding to Dr. Brown's comment regarding "documentation of sterile injectable products" the proposed regulations allows for preparations to be documented in the pharmacy's copy of the patient's chart order. This chart order can serve as the master formula. Further, the records required in section 1753.3 do not need to be completed in advance of the administration of the compounded drug, thus ensuring that the patient receives STAT medicines timely.

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacist who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. The intent of the regulation proposal is to improve patient safety.

Comment #82

Dr. Brown states that no documentation has been offered to show changing compounding regulations for sterile injectable products will have a beneficial impact to patient care. He further states that current board regulations and the USP provide adequate safeguards and documentation. He states that adding regulations for additional documentation to sterile injectable products that will be administered within 24 hours is labor intensive and provides no benefit or clear value.

Board Response

Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements, and now also includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board included the requirements for the identity of the person who compounded the drug as well as the pharmacist who reviewed the final drug product. First, the regulations were updated to allow a nonpharmacist to compound the medication as allowed in other areas of pharmacy law, and to require that a pharmacist complete a review. This check is an essential consumer protection component. Second, the equipment used is necessary to allow for a quality assurance review to be complete should a problem occur with such compounded medications. The intent of the regulation proposal is to improve patient safety.

The board recognizes that U.S. Pharmacopoeia(USP) General Chapter 797 (effective January 1, 2004) provides good practices for compounding sterile products, but USP 797 is not incorporated by reference into these regulations. USP 797 does not control the board's enforcement of its own regulations regarding pharmacy compounding.

Comment #83

Dr. Brown states that in contrast to the proposed regulations, patient care is likely to be jeopardized by the additional documentation. He states that the added workload will take pharmacy staff away from other patient care functions and programs and, as a result, patient care activities with documented patient benefit will be decreased or eliminated. He closes by stating that current regulations assure patient safety and those changes or additional regulations are not needed.

Board Response

The intent of the regulation is to improve patient safety. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board rejects Dr. Brown's assertion that the record-keeping and labeling requirements would be burdensome or that it would decrease beneficial patient care activities. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. The patient's chart order can serve as the master formula. Further the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug.

The board recognizes that U.S. Pharmacopoeia(USP) General Chapter 797 (effective January 1, 2004) provides good practices for compounding sterile products, but USP 797 is not incorporated by reference into these regulations. USP 797 does not control the board's enforcement of its own regulations regarding pharmacy compounding.

Comments from Alan Endo, Pharm.D., Presbyterian Intercommunity Hospital, Whittier, California**Comment #84**

Dr. Endo provided comments to proposed regulation 16 CCR §§ 1735(c), 1735.2(f), 1735.3(c), 1735.4(b), and 1751.7(c).

Board Response

These comments are outside of the scope of the modified text provided for comment during the 15-day comment period.

Comments from Steven W. Gray, Pharm.D., JD, Kaiser Permanente

Comment #85

Dr. Gray attached to an email a comment regarding proposed language at 16 CCR §1751.4(d) and to the board's Initial Statement of Reasons. Dr. Gray stated that a reference consolidating 1751.01 and 1751.1 is incorrect. He also provided proposed language changes to subdivisions (d) and (e), with a note to move an existing item regarding preparing cytotoxic agents to a new item (f).

Board Response

The specific comments are outside of the scope of the modified text provided for comment during the 15-day comment period. However, the board may wish to consider the comments and the proposed language changes in a future rule making.

Comments from Inaya Hazime, Pharm.D., Director of Pharmacy, Methodist Hospital of Sacramento, Sacramento, California

Comment #86

Dr. Hazime states "I believe your modifications to the text of section 1735.5 in Title 16 Cal.Code Reg. does not improve the care delivered in California's Joint Commission Accredited Hospitals." She adds "the record-keeping required by the changes will add burden and expense to our licensed hospital pharmacies without positively impacting patient care.

Board Response

Changes made to proposed 16 CCR 1735.5 are not within the scope of the modified text provided for comment during the 15-day comment period. The board considered the requirements on §1735.5 during the initial rule making. Such comments are addressed in board responses to comments submitted during the 45-day comment period.

Comment #87

Dr. Hazime states she has no problem with implementing rules as they apply to control compounding in the outpatient setting and adds "to expect that every admixture bag mixed in a hospital pharmacy will follow the same rules is time consuming and not productive to the end of improving patient safety."

Board Response

Dr. Hazime's comments are general and do not apply to the 15-day comment period. The board disagrees with the statement that the regulation is not improving patient safety.

Comments from Andree S. Hest, R.Ph, MScPharm, California Pacific Medical Center

Comment #88

The comments received from Andree Hest mirror those of Dr. Kevin R. Brown (see comments 79, 80, and 81 and the accompanying response from the board). Andree Hest concludes by asking that the "Board address the patient safety needs of "traditional" non-sterile compounding and move forward on those regulations. This is urgently needed. There is no need to change the current status and regulations for sterile injectable compounding."

Board Response

The broad comment offered does not specifically address the modified text contained in proposed 16 CCR 1735.3(a)(6). As such, these comments appear to be outside of the scope of the modified text provided during the 15-day comment period.

Comments from Kathleen Lee, Pharm.D., Clinical Pharmacist, St. Joseph's Medical Center, Stockton, California

Comment #89

Dr. Lee provides comments to various sections of proposed 16 CCR §1735, specifically referencing §1735(a), §1735(b), and §1735.3(d). She adds that the scope of the modified text is unclear. She states she believes the intent of the regulation is to define and set quality assurance parameters for compounding in an outpatient setting. She states that the current language in the regulation makes no distinction between inpatient and outpatient pharmacies, and the definition of compounding is broad enough to be interpreted several ways. She states it would be preferred that the language be made specific to hospital outpatient pharmacies and exclude inpatient hospital pharmacies.

Board Response

The comments offered by Dr. Lee did not address the modified language provided for comment during the 15-day comment period. As such these comments are outside of the scope of the 15-day comment period.

Comments from Gary Louie, Pharm.D., California Pacific Medical Center, San Francisco, California

Comment #90

Dr. Louie's comments mirror those of Dr. Kevin R. Brown (please see comments 81, 82, and 83).

Board Response

Please see the board's response to comments 81, 82, and 83, as the text of Mr. Louie's letter mirrors that of Dr. Brown.

Comment from Ed Maurino, R.Ph. FCSHP, Pharmacy Manager, Banner Lassen Medical Center, Susanville, California

Comment #91

Mr. Maurino states "Dawn's letter about the Board of Pharmacy's proposed record keeping for compounded sterile products is right on track." He continues by adding that record keeping would be immense, and there would be little, if any, benefit to the patient. He states most hospitals do a very good job compounding sterile IV's and asks "what percentage of harm comes knowing that California make millions of CSP's every day?" He asks that the board heed the points made in Ms. Benton's letter.

Board Response

The board received comments from Dawn Benton, CSHP, which are summarized in the board's responses to comments 73, 74 and 75.

With regard to Mr. Maurino's comments that record keeping would be immense with little benefit to the patients, the board has thoroughly considered what documentation requirements provide for patient safety and has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. Documentation of compounded medications administered is absolutely necessary, especially in the event of a recall where one would need to be able to identify which products were administered, and to whom.

Comments from Ray Miller, Pharm.D., Director of Pharmacy, Saint Francis Memorial Hospital, San Francisco, California

Comment #92

Dr. Miller states "I believe your modifications to the text of section 1735.5 in Title 16 Cal.Code Reg. does not improve the care delivered in California's Joint Commission Accredited Hospitals." He adds "the record-keeping required by the changes will add burden and expense to our licensed hospital pharmacies without positively impacting patient care.

Board Response

Changes made to proposed 16 CCR 1735.5 are not within the scope of the modified text provided for comment during the 15-day comment period. The board considered the requirements on §1735.5 during the initial rule making. Such comments are addressed in board responses to comments submitted during the 45-day comment period.

Comment #93

Dr. Miller states he has no problem with implementing rules as they apply to control compounding in the outpatient setting and adds "to expect that every admixture bag mixed in a hospital pharmacy will follow the same rules is time consuming and not productive to the end of improving patient safety."

Board Response

The intent of the regulation is to improve patient safety. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board rejects Dr. Miller's assertion that the record-keeping and labeling requirements would be burdensome or that it would decrease beneficial patient care activities. In an acute care setting, the regulation proposal allows for preparations to be documented in the pharmacy's copy of the patient's chart order. The patient's chart order can serve as the master formula. Further the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug.

However, with regard to Dr. Miller's statement that documentation of compounded medications be consuming and not productive to the end of improving patient safety, the board has thoroughly considered what documentation requirements provide for patient safety and has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comments from Eduardo Morin, Pharm.D., Jackson, California**Comment #94**

Mr. Morin's letter mirrors that of Dr. Kevin R. Brown and that of Dr. Inaya Hazime. (Please see comments 81, 82, and 83.)

Board Response

Please see the board's responses to comments 81, 82, and 83.

Comments from Tracey Okabe-Yamamura, Pharm.D., Mercy San Juan Medical Center, Carmichael, California**Comment #95**

Dr. Okabe-Yamamura states "I am supportive of the changes made to the proposed regulation to section 1735.5(a)(6), which now exempts the manufacturer and lot number of each

component if the sterile product is compounded “on a one-time basis for administration within two hours to an inpatient in a health care facility...” “

Board Response

The board appreciates Dr. Okabe-Yamamura’s support of the modified language.

Comment #96

Dr. Okabe-Yamamura states her concern regarding the self-assessment form titled “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment”; text found in §1735(b)(1), §1735(a)(2) and §1735(b), §1735.3(a)(7), and §1735.3(d). Dr. Okabe-Yamamura asks that the board consider the exemptions she offers within these sections. She states she believes that the intent of the regulation is for the documentation within the practice of mass compounding in the event of a potential safety recalls; however, within the inpatient hospital setting, the majority of IV admixtures involve small batches that are generally used within 24 hours. She concludes by stating the pharmacy profession is dedicated to patient safety; however, she states the proposed regulations will not add significantly to patient safety while dramatically increasing the workload for hospital inpatients.

Board Response

The comments offered to the self-assessment form and to sections §1735(b)(1), §1735(a)(2) and §1735(b), §1735.3(a)(7), and §1735.3(d) are not within the scope of the proposed text provided during the 15-day comment period.

The board agrees that the pharmacy profession is dedicated to patient safety – that is the stated intent of the regulation proposal. While her general comments are not expressly directed to the text of §1735.5(a)(6), the board has thoroughly considered what documentation requirements provide for patient safety and has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The board may want to consider an amendment that strikes a better balance between the need of pharmacy operations in an acute care setting.

Comments from Charles A. Reynolds, Pharm.D., B.C.P.P., Residency Program Director, Department of Pharmaceutical Services, UCLA Health System

Comment #97

Dr. Reynolds states that he believes the proposed regulations will negatively affect the ability of hospital pharmacists to safely care for patients. He stated the proposal impairs hospital practices without any change in patient safety. He adds that the additional documentation burden could actually be detrimental to hospitalized patients as limited staff capabilities are further stretched with another agency’s regulations. He reminded the board of the classic anxiety/performance curve principle – which demonstrates that as stress is increased past a critical point, performance (i.e. safety) decreases.

Board Response

Comments are general and do not address the change proposed in the regulation. The board disagrees that the proposed regulations will negatively affect patient care to the contrary.

With regard to Dr. Reynold's comment that additional documentation could be detrimental to hospitalized patients, the board disagrees. The board has thoroughly considered what documentation requirements provide for patient safety and has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The board may want to consider an amendment to the proposed regulations that would demonstrate added patient safety components, if one is offered.

Comment #98

Dr. Reynolds asserts that the proposed regulations would negatively affect the compounding of medication in every hospital's Intravenous Additive Service (IVAS) in the State of California. He adds that in his institution, he predicts the minimum effect would be an increase of 30 technician hours a day to perform the tasks required for the volume of IV preparations they produce and an additional number of unknown pharmacists FTE to adequately supervise their activities. He asserts that this increased cost to health care cannot be justified.

Board Response

Comments are general and not specific to the modified text provided for comment during the 15-day comment period.

Comment #99

Dr. Reynolds comments that most of changes to the compounding regulations directly effect manual labor activities and will greatly increase the time to prepare a compounded IV solution for a patient. He states the recent exemption provided in §1735.5(a)(6) is a first step, but does not address the whole issue.

Board Response

The board appreciates Dr. Reynolds comment that the exemption language addressed in the scope of the 15-day comment period is a good first step. The board may want to consider any suggested amendments related to manual labor activities within the board's jurisdiction, should such amendments be offered.

Comment #100

Dr. Reynolds asks that the board "not pass this proposal without a more intensive evaluation of how it will affect hospital practices." He states "these kinds of massive changes to well

established, safe, compounding practices (which by the way have been historically driven not by regulations, but by the professionalism of many) can only increase risk not improve safety.”

Board Response

While Dr. Reynold’s comment is not expressly applicable to the scope of the 15-day comment period, the board disagrees with Dr. Reynold’s comments. The board held several workgroup meetings with industry, including hospital pharmacies to develop the proposed regulations.

Comments from Richard Sakai, Pharm.D., Director of Pharmacy Services, Children’s Hospital Central California, Madera, California

Comment #101

Dr. Sakai stated he is in support of CSHP’s comments.

Board Response

The board thanks Dr. Sakai for his comment. CSHP’s comments related to the scope within the 15-day comment period can be found at comments 73, 74, and 75, along with the board’s response to each comment.

Comment #102

Dr. Sakai asks that the board exempt hospitals from compliance with any regulation the board approves in ‘this area’ for a period of five years, at which time full compliance is expected: He states this five-year exemption will allow organizations time to properly budget for the development if needed and plan for the resources to fully comply with regulations. He further provides his comments related to possible board actions if hospitals are found to not be in compliance with the regulation after the five-year exemption.

Board Response

Typically, regulations take effect 30 days after approval from the Office of Administrative Law. If it so desires, the board may want to specify an alternative effective date.

Comment #103

Dr. Sakai asks that the board exempt the compounding of medications if one follows USP797 guidelines for beyond use dating as a guideline when lot numbers are required. He states that in the OR (operating room), Anesthesiology often prepares medications of critical nature. He States these medications are often necessary in an event something goes wrong. He states that the time frame the board set (inferred, for record keeping) is not within the normal length of time for a complex surgical case. He asserts the board will hold the PIC ultimately responsible for the physician’s actions. He states that regulations jointly prepared and/or endorsed by the Board of Registered Nursing and the Board of Medicine can help better control the safe use of medications.

Board Response

The board recognizes that U.S. Pharmacopoeia(USP) General Chapter 797 (effective January 1, 2004) provides good practices for compounding sterile products, but USP 797 is not incorporated by reference into these regulations. USP 797 does not control the board's enforcement of its own regulations regarding pharmacy compounding.

Documentation of those activities is maintained in the patient's record. Nurses and physicians that compound medications are outside of the board's jurisdiction.

Comment #104

Dr. Sakai requested clarification of the definition of compounding. He is concerned that a single manipulation such as taking a partial amount from a larger vial and putting it into a syringe is not compounding; rather, it is unit dosing of medication. In this example, he infers that the current definition of compounding applies, since the dose is not in the original container. He asserts that the simple transfer of a product from a large container to a smaller one should not be considered compounding.

Board Response

Dr. Sakai's comment is not within the scope of the proposed text of the 15-day comment period. The board directs Dr. Sakai to proposed regulation 16 CCR §1735(a) for the definition of compounding.

Comments from Maria D. Serpa, Pharm.D., Elk Grove, California**Comment #105**

Dr. Serpa states "I believe your modifications to the text of section 1735.5 in Title 16 Cal.Code Reg. does not improve the care delivered in California's Joint Commission Accredited Hospitals." She adds "the record-keeping required by the changes will add burden and expense to our licensed hospital pharmacies without positively impacting patient care.

Board Response

Changes made to proposed 16 CCR 1735.5 are not within the scope of the modified text provided for comment during the 15-day comment period.

Comment #106

Dr. Serpa states she has no problem with implementing rules as they apply to control compounding in the outpatient setting and adds "to expect that every admixture bag mixed in a hospital pharmacy will follow the same rules is time consuming and not productive to the end of improving patient safety."

Board Response

Dr. Serpa's comments are very general and do not apply to the 15-day comment period. The board disagrees with the statement that the regulation is not improving patient safety.

Comments from Rita Shane, Pharm.D., FASHP, Director, Pharmacy Services, Cedars-Sinai Medical Center, Los Angeles, California

Comment #107

Dr. Shane offered comments to proposed regulation sections §1735.2(d)(4), §1735.2(f), §17353(b), §1735.5(c)(4), and §1751.2(c).

Board Response

The sections referenced by Dr. Shane are not within the scope of the modified text proposed in the 15-day comment period.

Comment #108

Dr. Shane stated that in propose §1735.5(a)(6) maintaining records of lot numbers for each component is a significant requirement and would require recording for lot numbers for any IV product that is diluted such as antibiotics that are administered IVPB, complex products such as TPN, IVs with multiple electrolytes, chemotherapy with multiple vials, etc.

Board Response

The intent of the regulation is to improve patient safety. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy's copy of the patient's chart order. The patient's chart order can serve as the master formula.

Comments from Michael Thompson, Ph.D., Director, Healthcare Operations and Technology Services, University of California, Office of the President, Oakland, California

Comment #109

Mr. Thompson comments on two components of the §1716 Revised Notice document, in that the UC Medical Centers' Department of Pharmacies does not agree with the "business impact" statement in the notice which states "no significant, statewide adverse economic impact." Likewise, the UC Medical Centers' Department of Pharmacies disagrees with the statement in the "Impact n Jobs" sub-section of the notice that states "this regulatory proposal will not have a significant impact on the creation of jobs."

Board Response

The text of the "§1716 Revised Notice" is not within the scope of the modified text provided for comment during the 15-day comment period.

Comment #110

Mr. Thompson comments on the revision document of §1716 which describes the “Specific Purpose of the Proposed Changes.” He states the UC Medical Centers’ Department of Pharmacies respectfully disagrees with text stating the purpose of the changes is to ‘address, among other items, the strength, efficacy, and quality in compounding’ and further ‘there are no provisions that ... define these items for general compounding’ in current laws. He states all licensed acute care hospitals in California are required by the FDA to comply with current USP 797 regulations, which mandate appropriate compounding of sterile products. He adds that [USP 797] regulations are widely accepted as the most comprehensive and evidence-based guidance to ensure safe preparation of aseptic products, do not require the documentation elements included in 1753.3(a)(6) and (8). He makes further comments regarding statements found in the notice documents related to “factual basis” to which UC Medical Centers’ Department of Pharmacies disagrees. He summated that the proposed regulations could incur a large increase in costs for acute care hospitals and increased labor demands.

Board Response

The comments by Mr. Thompson did not expressly address the proposed language of §1735.5(a)(6) and are not within the scope of the modified text provided for comment during the 15-day comment period. The board recognizes that U.S. Pharmacopoeia (USP) General Chapter 797 (effective January 1, 2004) provides good practices for compounding sterile products, but USP 797 is not incorporated by reference into these regulations. USP 797 does not control the board’s enforcement of its own regulations regarding pharmacy compounding.

Comments from Gerald R. Trindade, Pharm.D., Director of Pharmacy, Mendocino Coast Hospital**Comment #111**

Dr. Trindade expressed concern that the proposed requirements do not differentiate between preparation of sterile intravenous admixtures for hospital inpatients having short expiration dates and those products compounded for extended use in physician’s offices or a patient’s home. He asked that the board adopt the standards developed by USP 797 to prevent inconsistencies between USP and additional regulations created in Section 1735.3.

Board Response

The board recognizes that U.S. Pharmacopoeia (USP) General Chapter 797 (effective January 1, 2004) provides good practices for compounding sterile products, but USP 797 is not incorporated by reference into these regulations. USP 797 does not control the board’s enforcement of its own regulations regarding pharmacy compounding. The board may want to consider an amendment that strikes a better balance between the need of pharmacy operations in an acute care setting.

Comment #112

Dr. Trindade stated that the proposed additional record keeping requirements will not prevent adverse events or improve patient safety. He acknowledged, however, that the additional record keeping requirements may help determine the cause of an adverse reaction.

Dr. Trindade expressed concern that additional record keeping will increase the cost of IV Admixture Service to hospitals that are already struggling to keep their doors open.

Board Response

The board agrees with Dr. Trindade's statement regarding the value of the record keeping requirements. The intent of the proposed regulation is to improve patient safety. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. This proposal does not dictate how the records are to be made and stored, rather just what information must be retained. Hospitals can implement a business solution that is least "burdensome" to their operations.

Comments from Geralyn Trujillo, MPP, American Society of Health-System Pharmacists, Bethesda, Maryland**Comment #113**

Ms. Trujillo states that the American Society of Health-System Pharmacists (ASHP) seeks to preserve patient safety and ensure that pharmacy practice continues to evolve and develop. She states that "the proposed exemption is in the best interest of all parties and support the adoption of such language. However, she stated ASHP is concerned that there is an overall focus on documentation that is impractical for inpatient situations, which may lead to a reduction in patient care and the effective and timely delivery of medication.

Board Response

The board appreciates ASHP's comments and support of the proposed modified text to 16 CCR 1753.3(a)(6). Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Comment #114

ASHP asks the board to be mindful of the potential implications of other proposed modifications to the regulations. She states that “we need to balance the value of documentation with a recognition that onerous requirements may lead to delay in care and have a negligible impact on patient safety.

Board Response

The board appreciates ASHP’s comments. Should the board consider any additional modified language, such language will be provided for public consideration and comment in accordance with California’s regulatory statutes.

Comment #115

Ms. Trujillo states that documentation is clearly an important step in the delivery of any medication. “Lot numbers are recorded for large batches, a practice that is reasonable. However, recording lot numbers for small or individual compounds that are administered immediately or within 24-hours is a requirement that removes the focus of the pharmacy from patient care and effective delivery to documentation.” She states that ASHP would question the value of such language, from both a workforce perspective as well as that of patient safety and delivery of care.

Board Response

This particular comment by Ms. Trujillo appears to be in contrast with ASHP’s earlier comment that ASHP believes “the proposed exemption is in the best interest of all parties and support the adoption of such language. “ The board agrees that documentation is an important step in the delivery of any medication. The board thoroughly considered what documentation requirements provide for patient safety and has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The board may want to consider an amendment that strikes a better balance between the need of pharmacy operations in an acute care setting.

The intent of the regulation is to improve patient safety. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. In an acute care setting, the regulation proposal allows for one-time preparations to be documented in the pharmacy’s copy of the patient’s chart order. The patient’s chart order can serve as the master formula. Further the records required in section 1735.3 do not need to be completed in advance of the administration of the compounded drug.

Comment #116

Ms. Trujillo states that ASHP applauds the board's intent to modernize the regulations and its recognition to exempt the sterile compounds for immediate use. She adds that ASHP recommends that the board continue to assess how documentation is being currently achieved and to seriously consider the consequences of requiring hospitals to rapidly divert scarce resources into documentation, rather than critical patient care services. She asks that the board, as the process moves forward, consider a phased-in approach, with defined milestones and deadlines, should the board continue to proceed with the current proposed language.

Board Response

The board appreciates ASHP's comments. The board may want to consider amending the proposed language to determine a separate effective date.

Comments from Carl Washburn, Pharm.D., Pharmacy Director, Dominican Santa Cruz Hospital**Comment #117**

Dr. Washburn asked the board to recognize the differences between safe medication practices in hospitals versus retail-focused pharmacies. He stated that the proposed additional record keeping constitutes 'busy work' and does not enhance patient safety.

Board Response

The intent of the proposed regulation is to improve patient safety. Several of the record keeping requirements for sterile products are already required in current regulation. This proposal does expand on the requirements and now includes the identity of the person who compounded the drug, the identity of the pharmacist reviewing the final drug product, the quantity of each component, the equipment used in compounding the drug product as well as a pharmacy assigned reference number. The board has determined that the exemption to these requirements would be those sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The board may want to consider an amendment that strikes a better balance between the need of pharmacy operations in an acute care setting.

Comment #118

Dr. Washburn asked the board to utilize USP 797, stating that additional mandates would add unnecessary cost to an already difficult healthcare environment.

Board Response

The board recognizes that U.S. Pharmacopoeia(USP) General Chapter 797 (effective January 1, 2004) provides good practices for compounding sterile products, but USP 797 is not incorporated by reference into these regulations. USP 797 does not control the board's enforcement of its own regulations regarding pharmacy compounding.

Comments from Don Willis, CPhT., Pharmacy Manager, California Pacific Medical Center

Comment #119

Mr. Willis expressed concern about proposed regulations affecting sterile injectable products. He acknowledged that traditional non-sterile compounding practice lacked specific regulations to adequately protect patients, but that the proposed regulations affecting sterile injectable products would not impact patient care. Mr. Willis asked the board to address patient safety by recognizing the distinctions between USP 797 (Sterile Preparations) and USP 795 (Nonsterile Preparations).

Board Response

Mr. Willis' comments did not explicitly comment on the language contained in the proposed modified text within §1735.5(a)(6). Neither USP 797 nor USP 795 control the board's enforcement of its own regulations regarding pharmacy compounding.

Comments from Bill Yee, Pharm.D., Clinical Information Coordinator, St. Joseph's Medical Center

Comment #120

Dr. Yee supports proposed changes to Section 1735.5(a)(6) exempting the manufacturer and lot number of each component if the sterile product is compounded on a one-time basis for administration within two hours to an inpatient in a health care facility.

Board Response

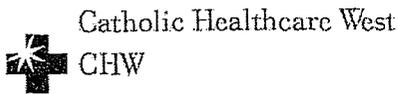
The board appreciates Dr. Yee's support of the modified text provided for comment during the 15-day comment period.

Comment #121

Dr. Yee provided comments to sections 1735.3(d), 1735.3(a)(7), 1735(a)(2), 1735(b), as well as the "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" form. Mr. Yee requested various exemptions within each section referenced and asked that the board consider these exemptions.

Board Response

The comments offered to the self-assessment form and to sections §1735(b)(1), §1735(a)(2) and §1735(b), §1735.3(a)(7), and §1735.3(d) are not within the scope of the proposed text provided during the 15-day comment period.



September 26, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834
Virginia_Herold@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Herold:

On behalf of 34 of our hospitals in California, Catholic Healthcare West (CHW) appreciates the opportunity to provide comment on the proposed requirements for pharmacies that compound medications. As California's largest non-profit hospital system, we are committed to our mission of providing compassionate, high quality healthcare to all.

While CHW supports the California Board of Pharmacy (Board) for its efforts to strengthen regulations for pharmacies that compound medications, we have serious concerns regarding the new labeling and pharmacy record requirements on certain compounded IV medications, particularly for pharmacies in acute care facilities dispensing one-time and immediate-use (STAT) medications.

Pharmacies in acute care facilities are charged with the timely preparation of emergency compounded medications for the treatment of conditions that require quick treatment and response, such as heart attack, stroke, and other life-threatening situations. These conditions require STAT medications, such as alteplase, epinephrine, or diltiazem for treatment. **CHW is concerned the added documentation requirements will delay preparation and delivery, placing patients at risk for no additional patient safety benefit.**

CHW sees the value of documenting pharmacy reference numbers or lot numbers on the label of each dispensed IV as well as providing additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. However, CHW suggests this information is not useful when the medication is dispensed on a one-time, immediate-use basis. **CHW urges the Board to exempt one-time, immediate-use sterile products in the final regulation, including the requirement to provide:**

- **The manufacturer or supplier and lot number or each component;**
- **The equipment used in compounding the drug product;**
- **The pharmacy assigned reference or lot number for the compounded drug product;**
- **and,**
- **The expiration date of the final compounded drug product.**

There is some president to exempting STAT products from pharmaceutical regulations. In fact, in the recently updated United States Pharmacopeial Convention (USP) Chapter 797, there is a section related to *Immediate-Use Compounded Sterile Products*. In this section, these types of products are considered under separate requirements because they are used in situations where there is a need for emergency or immediate patient administration of a compounded product.

Finally, CHW is concerned the minimum 3-year record retention policy is unrealistic, considering the hundreds or thousands of products compounded daily, whether STAT or non-urgent. **CHW requests this timeframe be reevaluated and take into account common record retention policies.**

Thank you for your consideration of these comments. Please feel free to contact me at (916) 851-2007 or via email at Clara.Evans@chw.edu.

Respectfully,



Clara E. Evans
Director, Public Policy & Fiscal Advocacy



"Sloan, Steve"
<steve.sloan@cpspharm.com
>

09/10/2008 09:27 AM

To <karen_cates@dca.ca.gov>

cc

bcc

Subject Board of Pharmacy

Dear Ms. Cates,

This is intended to state our concerns about proposed compounding regulations by the Board of Pharmacy. The proposed regulations do not take into consideration emergency situations where the additional logging and labeling requirements will be burdensome and cause delays in therapy. Our position, and that of the California Society of Health-System Pharmacists, is that these requirements do not improve patient safety because the dose is administered immediately after compounding. Please make an exception for emergency use.



Stephan Flascha
<flascha@ca.rr.com>
09/04/2008 06:25 AM

To karen_cates@dca.ca.gov
cc
bcc
Subject 30 year veteran hospital pharmacist concerned about
documentation requirements.

Dear Ms. Karen Cates:

As a hospital pharmacist licensed since 1978, 30 years, I am really concerned about the documentation requirements in Compounding in an IV room in a major hospital. We are required to prepare there are probably a thousand items involved in one shift which are activated.

Just consider a t supermarket check out counter you want the cash register noted Manufacturer, Expiration Date and Lot number of every item you buy. We do that if we compound bigger batches like a manufacturer but most items are for a personalized use.

Please consider this requirement as undoable. It will make the environment so "crazy-Busy" that you will have more centennial events.

Sincerely

Dr. Stephan Flascha R.Ph. Pharm.D.
Kaiser Sunset



"Baertsch, Suzanne"
<BaertsS@sutterhealth.org>
09/04/2008 12:15 PM

To <Karen_cates@dca.ca.gov>

cc <philip@cshp.org>

bcc

Subject Board of Pharmacy new compounding regulations

I just heard about the proposed compounding regulations, and while I understand the concern for patient safety, I think these regulations will have the opposite effect.

I work in a hospital where we compound hundreds of IVs daily in a sterile environment. The additional time it would take for all this record keeping would mean we would have to cut back in other areas. We are already stretched too thin, and this will make it worse for overall patient care, with little benefit.

I am especially concerned about 1st dose antibiotics or cardiovascular drips. This may result in a further delay to patient therapy.

I understand it is valuable to be able to trace back how something is made, but remember, this still does not PREVENT an error. It only allows you to see what the error is.

In summary, I strongly feel these new regulations will be a detriment to patient care and our healthcare system as a whole, especially in regard to IV medications.

Suzanne Baertsch
NICU Pharmacist
Alta Bates Summit Medical Center
Berkeley, CA 94705



"Hass, Deborah"
<DHass@stanfordmed.org>
09/05/2008 12:54 PM

To karen_cates@dca.ca.gov
cc philip@cshp.org
bcc
Subject New Board of Pharmacy Regulations regarding IV
Compounding

Dear Ms. Cates: I am a clinical pharmacist at Stanford University Hospital in Stanford, CA. I am writing to strongly object to the newly proposed regulations regarding compounding sterile IV products:

I would agree with the CSHP (and am quoting them) in asking for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use. This means every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the thousands of records daily that would be generated here at Stanford to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic.

I would urge you to seriously reconsider passing this proposed regulation.

Respectfully yours,

Deborah A. Hass, Pharm.D., BCOP
Hematology/Oncology Clinical Pharmacist
Stanford Hospitals and Clinics
300 Pasteur Drive
Room H0301, M/C 5616
Stanford, CA. 94305
Central Pharmacy Phone: 650-723-5970
Central Pharmacy Fax: 650-725-5028
Satellite Pharmacy Phone: 650-725-5299
Pager: 650-723-8222 ID 16045
E-mail: DHass@stanfordmed.org <mailto:DHass@stanfordmed.org>



"Chopyk, Rob"
<Rob.Chopyk@chomp.org>
09/16/2008 02:07 PM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
 - * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
 - * Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
 - * Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
 - * Records of all supplies and ingredients purchased, used or destroyed are maintained.
 - * All records and logs are maintained for a minimum of 3 years.
 - * Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
 - * Limits supply to MD offices to 72 hour supply of compounded medications.
- Sterile Injectable Compounding Changes (in addition to those above)
- * Written policies/procedures on disposal of infectious materials and cytotoxics.
 - * Labeling of each compounded product to include route and rate of administration.
 - * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Rob Chopyk RPh
Clinical Pharmacist
Community Hospital of the
Monterey Peninsula
(831) 625-4905



Virginia
Herold/Pharmacy/DCANotes
09/30/2008 11:50 AM

To "Anne Sodergren" <anne_sodergren@dca.ca.gov>
cc
bcc
Subject Fw: BOP Compounding Reg Statement Letter - 9-15-08

Sent from Blackberry
Virginia Herold
"Harold Mathis"

----- Original Message -----

From: "Harold Mathis" [hjmathis@tds.net]
Sent: 09/30/2008 11:47 AM
To: <Virginia_Herold@dca.ca.gov>
Subject: BOP Compounding Reg Statement Letter - 9-15-08

September 10, 2008

Virginia Herold

Executive Officer

California Board of Pharmacy

1625 N. Market Blvd N219

Sacramento, California 95834

Virginia_Herold@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

The following message accurately outlines a vital error / misunderstanding of the emergency practice of pharmacy in the acute hospital. Delays mandated under the proposed legislation WILL CAUSE LOSS OF LIVES!

Harold Mathis, Consultant Pharmacist, former Director of Pharmacies – Mercy Hospital, Denver, Colorado, Former Chairman of the Committee to Revise Pharmacy Regulations, Colorado.

Dear Ms. Herold:

The California Society of Health-System Pharmacists (CSHP) commends and supports the California Board of Pharmacy (board) for their previous and current efforts to strengthen the regulations surrounding pharmacies that compound medications. However, CSHP has concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direst of patients.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require *one-time and immediate-use (STAT) medications*, such as alteplase, epinephrine, or diltiazem for treatment. CSHP members are concerned that the added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

CSHP fails to see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. CSHP believes that such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done

before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to Immediate-Use Compounded Sterile Products as the immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate-use injectable products in acute care facilities, *CSHP requests all proposed additional pharmacy record requirements be exempted from the pharmacy records. CSHP also requests an exemption of having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.* CSHP believes that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

These exemptions in STAT situations will certainly benefit and prolong patients' lives as they receive compounded medications urgently. CSHP hopes the following suggestions will help to meet our shared goal of better and safer patient care, and appreciate the board's willingness to consider our requests.

Founded in 1962, CSHP is a professional society representing more than 4,000 pharmacists, pharmacy technicians, and associates who serve patients and the public by promoting wellness and the best use of medications. CSHP members practice in a variety of organized health care settings including, but not limited to hospitals, integrated healthcare systems, clinics, home health care and ambulatory settings.

If you have any questions, please do not hesitate to contact me at (916) 447-1033 or CSHP's Legislative Advocate Bryce Docherty at (916) 446-4343.

Respectfully,

[IMAGE]

Dawn Benton

Executive Vice President, CEO

cc. Bryce Docherty

Alan Reed



- header.htm



MNikuta <mnikuta@aol.com>

09/30/2008 08:03 AM

To karen_cates@dca.ca.gov

cc

bcc

Subject Proposed Requirements for Pharmacies that Compound Medication

I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direst of patients.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require *one-time and immediate-use (STAT) medications*, such as alteplase, epinephrine, or diltiazem for treatment. I am concerned that the added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

I fail to see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. Such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to *Immediate-Use Compounded Sterile Products* as the immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate-use injectable products in acute care facilities, I believe that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

Sincerely,

Mary Noud-Ikuta, PharmD

Find phone numbers fast with the New AOL Yellow Pages!

Maria D. Serpa, Pharm.D.
6744 Paseo Del Sol
Elk Grove, California 95758
serpam@sutterhealth.org

October 3, 2008

Board of Pharmacy
Attn: Karen Cates (Proposed Compounding Regulation)
1625 N. Market Blvd. N219
Sacramento, CA 95834
karen_cates@dca.ca.gov

Re: Proposed Regulations - Article 4.5 General Compounding

Dear Ms Cates:

I am very concerned with the sweeping changes proposed to the compounding and documentation of **sterile injectable** products. As I understand it, the California Board of Pharmacy was originally tasked to strengthening compounding practice and safety for **"traditional"** compounding. This area of pharmacy practice lacks specific regulation to adequately protect patients. My concern is that now **sterile injectable** compounding is lumped together with the **"traditional"** form of compounding and this added a layer of regulation is not necessary at this time. Current regulations regarding **sterile injectable** compounding are very specific and detailed from both the United States Pharmacopeia (USP) Convention guidelines at the federal level and current state BOP regulations.

I suggest **sterile injectable** and **non-sterile** compounding be maintained in separate regulations. Current California regulations, Article 7 Section 1751 (Sterile Injectable Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug Products) cover the issues related to **sterile injectable** compounding. These current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) to assure patient safety. In addition, the Board requires additional licensure or accreditation of pharmacies to perform the functions of **sterile injectable** compounding. Changes or additional regulations to these sections are NOT needed.

The requirements for the safe preparation of **sterile injectable** and **"traditional" non-sterile** products are distinctly different. The United States Pharmacopeia (USP) regulates these processes separately in 2 distinct chapters. USP 797 deals with Pharmaceutical Compounding – Sterile Preparations and USP 795 deals with Pharmaceutical Compounding – Nonsterile Preparations.

I am additionally concerned patient care may be jeopardized by the additional documentation requirements suggested for **sterile injectable** compounding if lumped together with **"traditional" non-sterile** compounding. It is common practice for a pharmacy in an acute care facility to prepare emergency medications for the treatment of heart attack, stroke and other life-threatening situations. Currently these STAT, one-time, immediate-use medications are prepared in the pharmacy and labeled with adequate information to assure patient safety and recall should a medication be recalled in the next few hours during administration. Additional record keeping or generation of a pharmacy specific lot number for each injectable product compounded does not serve the patient. It only delays STAT medication preparation and delivery and places an

additional burden on the pharmacy. If changes are planned for sterile injectable compounding, exempting *immediate-use* sterile products from some of the documentation requirements is prudent to assure patient safety. This has been done before. The recently updated USP Chapter 797 has a special section related to Immediate-Use Compounded Sterile Products.

Thank you for considering these issues. I ask that the Board address the patient safety needs of **“traditional” non-sterile** compounding and move forward on those regulations. This is urgently needed. There is no need to change the current status and regulations for **sterile injectable** compounding.

Respectfully,

Maria D. Serpa, PharmD



Robert.L.Batman@kp.org

10/06/2008 12:53 PM

To karen_cates@dca.ca.gov

cc

bcc

Subject Compounding Regulations

October 6, 2008

Board of Pharmacy
Attn: Karen Cates
1625 N. Market Blvd. N219
Sacramento, CA 95834
Fax: (916) 574-8618
karen_cates@dca.ca.gov

Re: Proposed Compounding Regulation

I am writing in regards to the proposed compounding regulations (starting with Section 1716), specifically the record keeping and labeling requirements.

I am very concerned that these requirements in acute care hospitals with large number of compounded IV medications would be very burdensome. The majority of these compounded IV medications are used within 24 hours, sometimes immediately, after being compounded.

In the acute care setting these compounded IV medications are used by very few patients, sometimes a single patient and for a very limited amount of time. Thus the typical batch compounding issues encountered in an chronic care setting (e.g., Home health or ambulatory care) do not apply.

I would respectfully request that the Board consider an exemption from the record keeping and labeling requirements in acute care facilities for IV compounded IV medications for immediate use.

Sincerely,

Robert Batman, Pharm.D.



Raffi Svadjian
<svadjian@usc.edu>
10/06/2008 01:22 PM

To karen_cates@dca.ca.gov
cc
bcc
Subject Commentary on Title 16, requirements for pharmacies that
compound

Dear Karen,

Please accept the attached letter as commentary Title 16 on behalf of the USC School of Pharmacy
Community Pharmacy Management Elective. Thank you.

Raffi Svadjian Pharm.D, MBA
USC Medical Plaza Pharmacy
USC School of Pharmacy
1510 San Pablo Street # 144
Los Angeles, CA 90033
(323)442-6121
(323)442-5970 Fax
(818)632-0505 Mobile



svadjian@usc.edu Dear_State_Board_of_Pharmacy second revision.doc

Dear State Board of Pharmacy,

This letter is being written on behalf of the 3rd Year Community Pharmacy Management Elective at the University of Southern California School of Pharmacy. As a class project, our students were instructed to conduct a survey of community pharmacies to ascertain whether or not the proposed compounding regulation changes would affect community pharmacies. In contacting 12 random community pharmacies we were surprised that only 2 of the pharmacies were aware of the proposed regulation changes and the balance of pharmacies were unaware of the proposals. The conclusions that our class arrived at from our interview with these pharmacists are the following:

- 1) The regulation seems to hinder access in some unique situations. Particularly, community pharmacies that prepare compounded medications on a limited basis may completely halt their compounding activities due to the cost factors of having to meet the regulatory standards (end product testing, possible purchase of software, etc.). In our opinion, this may limit some pharmacies from changing dosing forms on a patient need basis. It will also make access to this service more limited for the general population. Furthermore, pharmacies that may stop preparing compounded medications have long standing relationships with certain patients that have been receiving their compounded prescriptions from the same pharmacy that prepares their non-compounded prescriptions. These regulations may cause these patients to switch pharmacies, and result in loss of revenue for the pharmacy and the loss of a long standing relationship between a pharmacist and a patient.
- 2) The regulations refer to end-product testing and quality assurance without clearly defining it. Pharmacists that were spoken to seemed to all agree that the proposed regulations do not clearly define issues regarding end-product testing, such as frequency of end-product testing, requirements for record keeping, and which products need to be tested.
- 3) The regulation did not make any distinction between the complexity of compounding and the amount of regulation needed. For example mixing two different products to create a cream or changing a tablet to a liquid dosing form for short term administration should not require as much oversight as complex compounding formula. We feel that this area needs to be further explored.

In conclusion we all agreed that regulations were needed in this area, but there needed to be some criteria for the amount of regulation needed vs. the difficulty of preparing a particular compounded medication. We want to thank you for the opportunity to present our opinion and those of community pharmacists in the Southern California community we interviewed.

Raffi Svadjian Pharm.D, MBA
Co-course Coordinator

Michael J. Rudolph Pharm.D
Co-course Coordinator



"Breslow, Kenneth (MED US)"
<kenneth.breslow@siemens.com>

10/06/2008 01:25 PM

To <karen_cates@dca.ca.gov>
<virginia_herold@dca.ca.gov>, "Nazerias, Michael (MED US)" <michael.nazerias@siemens.com>, "Mar, Dwayne (MED US)" <Dwayne.Mar@petnetsolutions.com>, "Nutting,"
bcc
Subject Comments on proposed changes to compounding and sterile compounding regulations

Dear Karen and Virginia,

Please accept the attached letter which expresses our company's comments and concerns regarding the proposed changes to the CA BOP compounding regulations, Division 17, Title 16.

Sincerely,

Kenneth Breslow; MS, R.Ph, FAPhA | Senior Regulatory Affairs Specialist
PETNET Solutions | A Siemens Company
810 Innovation Drive | Knoxville, TN 37932

865.218.2383 Office | 865.603.1047 Cell
kenneth.breslow@siemens.com

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The Science of Molecular Imaging

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Thank you



Comments letter to CA BOP on changes to compounding regs 10-08.pdf

PETNET Solutions

VIA EMAIL

California Board of Pharmacy
Attention: Karen Cates and Virginia Herold (Proposed Compounding Regulation)
1625 N. Market Blvd., N219
Sacramento, CA 95834
virginia_herold@dca.ca.gov
karen_cates@dca.ca.gov

October 6, 2008

RE: Title 16, Division 17 Proposed Changes

PETNET Solutions, Inc., a Siemens Company (DBA PETNET Pharmaceutical), operates specialty compounding nuclear pharmacies preparing solely radiopharmaceuticals for use in Positron Emission Tomography (PET) nuclear medicine diagnostic imaging studies. PETNET operates forty-five PET Nuclear Pharmacies in the US, with four locations in the state of California operating under both retail and sterile compounding pharmacy licenses.

The State of California does not provide unique regulations or significant special requirements for the operation and licensure of Nuclear Pharmacies (Radiopharmacies) in its statutes. Recently, the USP, in their revised Chapter <797>, *Pharmaceutical Compounding, Sterile Preparations*, recognized the significant differences in the nature of the products compounded for use in nuclear medicine and the nature by which such products are compounded. USP Chapter <797> further differentiates the relevant differences in radiopharmaceuticals used in PET from traditional radiopharmaceuticals by deferring most of the requirements in USP <797> to USP Chapter <823>, *Radiopharmaceuticals for Positron Emission Tomography-Compounding*.

The Food and Drug Administration Modernization Act of 1997 (public Law 105-115, FDAMA '97), Section 121, sets the legal requirements for the compounding of PET radiopharmaceuticals in the US. Producers of PET radiopharmaceuticals are legally bound by this law, and FDA currently inspects PET Nuclear Pharmacies for compliance to this law regardless of whether the PET compounding facility is registered as a drug establishment with FDA or not. Ultimately, as stipulated under FDAMA '97, FDA is required to regulate the compounding (production) of such drugs under a specific PET GMP regulation once the regulation is formally adapted into the Code of Federal Regulations in the future. Two years after FDA codifies the PET cGMP regulations in the CFR, FDA will require PET drug producers to register their drug establishments with FDA and to submit Human Drug Applications to the FDA.

Some unique differences between conventional drugs, conventional radiopharmaceuticals, and PET radiopharmaceuticals are:

- They cannot be purchased from a traditional commercial source.
- No radionuclide generators are employed

PETNET SOLUTIONS, Inc.
A Siemens Company

810 Innovation Drive
Knoxville, TN 37932

Tel: (800) 738-0488
Fax: (865) 218-3563

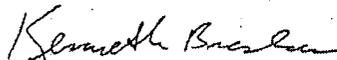
- No pre-manufactured radiopharmaceutical kits are employed.
- The physical half-life of the radionuclides used in PET radiopharmaceuticals ranges from 2 minutes to 110 minutes.
- The radioactive emissions are of very high energy compared with traditional radiopharmaceuticals thus requiring much more rigorous radiation shielding and remote physical handling.
- The radio-labeling of the ligand takes place in situ via an automated chemical synthesis unit utilizing a radionuclide extracted from a cyclotron target after the bombardment of a stable starting isotope. The synthesis module cannot be placed in an aseptic environment.
- Some non-sterile reagents and precursors are used.
- The final products are aseptically processed and sterilized by filtration into a sterile product vial.
- The quality control testing of each batch produced prior to release for patient use is extensive.
- The delivery of the finished radiopharmaceutical is highly time-critical because of the very short physical half-life of the isotopes employed.
- The expiration date is no greater than 12 hours after compounding
- Sterility testing is started when compounded, but the product must be used prior to the completion of the sterility test.

PETNET urges the California Board of Pharmacy to carefully consider the potential impact of their proposed revised regulations on Nuclear Pharmacies and PET Nuclear Pharmacies in light of the special nature of these drugs. PETNET further encourages the Board to avoid regulations that conflict with the requirements of those currently in place in the current revision of the USP Chapters <797> and <823> as applied to radiopharmaceuticals in general, and specifically to compounded PET radiopharmaceutical products.

PETNET suggests that it may be prudent for the Board to exempt the application of any revised sterile compounding regulations to PET drug compounding and stipulate the requirement to comply with the relevant USP chapters until such time the Board proposes and adopts its own regulations pertinent and applicable to radiopharmaceutical and PET radiopharmaceutical compounding

PETNET anticipates having a representative attend the October public hearings on this topic to offer expert input into the Boards rule making activities.

Sincerely,



Kenneth Breslow, MS, R.Ph., FAPhA

CC:

Michael Nazerias
Dwayne Mar
Josh Nutting
Jerry Kuhs



Sutter Lakeside Hospital

To: California Board of Pharmacy
Attention: Karen Cates (Proposed Compounding Regulation)
1625 N. Market Blvd. N219
Sacramento, CA 95834
Fax: (916) 574-8618

I would like to register my professional opinion regarding this proposed change. I am a 1972 graduate of U.C. San Francisco, also completing a clinical residency from U.S.C. School of Pharmacy in 1973. I have been a faculty member of the University of Michigan, U.S.C. and Western University Schools of Pharmacy; I have published articles pertaining to antibiotic therapy, pharmacokinetics, and pharmacy practice. For the last 30 years, my practice has been in acute care hospitals, primarily as a manager & clinical pharmacy practice promoter. During that time I have been either director or assistant director of 13 acute care facilities ranging from 25 beds to 530 beds.

I have seen many positive changes in our practice, witnessed the growth of our profession from a dispenser of medications to a true member of the health care team. I have also seen the barrage of regulations that have obvious good intentions come from various regulatory agencies including the Board of Pharmacy, but do not seem to "connect" in practice. Often the issues are related to inability to decipher the specific intent of the regulations - usually because they are written in legal language, and not in the language of the public nor healthcare. This confusion is reflected by various "interpretations" by individual inspectors of the same regulation. This regulation change is clear!

With respect to the proposed changes, my primary focus is on the requirement for one-time or administered immediately "compounded" preparations. I ask the question, "What is the purpose?" In the event of a recall, even that very day, the medication has been administered & can not be returned to the Pharmacy! To require additional labeling & maintenance of a log seems to be illogical and serves absolutely no useful purpose for the public with respect to safety, nor to the Board of Pharmacy.

I am aware that various official organizations, including CSHP and others, have made similar requests. As a practicing pharmacist, I ask that you strongly reconsider this aspect of the proposed regulatory change and grant an exemption for medications "compounded" for immediate or emergency use.

Thank you for your consideration,
Sincerely,

Ben J Devine, PharmD (RPh 27902)
Director of Pharmacy
Sutter Lakeside Hospital
5176 Hill Road East
Lakeport, CA 95453



"Chan, Gary - MSJ"
<gary.chan001@chw.edu>
10/06/2008 12:33 AM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Proposed IV Compounding Regulations

October 6, 2008

Karen Cates
California Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento, CA 95834
karen_cates@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Cates,

I am writing to let you know that I am strongly opposed to the new proposed regulation to require pharmacists to record in a log each IV compounded. Being a clinical pharmacist working in the different units of a hospital, I am required to attend codes, rapid responses, and cardiac alerts. I do not see a benefit in the new regulation proposed. In fact, I see plenty of harm to the patient if this regulation were actually put in place. There are plenty of instances when these patients require "immediate" and "one time" STAT medications. The new proposed regulation would only hinder our ability to provide quick and safe care for these critical patients at their bedside. This would only create unnecessary stress, and would not provide any added safety benefit to the dying patient.

I am requesting that all proposed additional pharmacy record keeping requirements for the preparation of one-time and immediate use IV products in the acute care hospital be exempted. I am also requesting an exemption from having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.

Thank for your time and consideration.

Gary W. Chan
Clinical Pharmacist
Mercy San Juan Medical Center



"Azama-Kihara, Karen - MSJ"
<Karen.Azama-Kihara@chw.edu>

10/05/2008 09:22 PM

To <karen_cates@dca.ca.gov>

cc

bcc

Subject Against Proposed IV Compounding Regulations

Dear Ms. Cates,

I am writing to let you know I am against the new proposed regulation to require pharmacists to record in a log each IV compounded. I feel there must be exemptions in life threatening and emergent situations. To require a delay in services to log a medication prepared during a cardiac arrest or other emergent situation could be detrimental to the patient. As a former ICU pharmacist who attended many code blues, this would have created unnecessary stress, and would not have provided any added safety benefit to the dying patient.

I am requesting that all proposed additional pharmacy record keeping requirements for the preparation of one-time and immediate use IV products in the acute care hospital be exempted.

I am also requesting an exemption from having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.

Thank you for taking my concerns for our profession and our patients' safety into consideration.

Karen Azama-Kihara, Pharm. D.
Pharmacy Supervisor
Mercy San Juan Medical Center

October 3, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834

**SUBJECT: PROPOSED REQUIREMENTS FOR PHARMACIES THAT
COMPOUND MEDICATIONS**

Dear Ms. Herold:

This letter is to support the California Society of Health-System Pharmacists position regarding labeling and record keeping exemptions for one-time and immediate-use medications.

I believe that the USP Chapter 797 section on Immediate Use Compounded Sterile Products allows exemptions for emergency or immediate use of a compounded product—in particular in an acute care setting.

As a long time hospital pharmacist, I urge the Board of Pharmacy to grant this exemption, which will be in the best interest of patient safety and quality of care.

Sincerely,

Larry W. Schallock
PO Box 428
San Luis Rey, CA 92068

RPh 25825

City and County of San Francisco
Department of Public Health
COMMUNITY BEHAVIORAL HEALTH SERVICES



Mayor Gavin Newsom

Pharmacy Services
1380 Howard Street, Rm 130
San Francisco, CA 94103
Phone: (415) 255-3659
FAX: (415) 252-3036

October 3, 2008

California State Board of Pharmacy
Attn: Karen Cates
1625 N. Market Blvd, N219
Sacramento, CA 95834

RE: Proposed New Compounding Regulations

Dear Ms. Karen Cates:

As a licensed working California pharmacist, with over 28 years experience in IV medication compounding, I've implemented compliance to USP <797> in multiple pharmacy practice sites for performance improvement and as a quality management function.

The proposed regulations require a "pharmacy reference number or lot number with each dispensed IV". I have strong concerns with this new requirement.

I understand the underlying reason for this new requirement is for the pharmacy to be able to trace back each unit of IV medication to its specific compounding information. **I recommend the regulations state that a pharmacy will be able to trace-back the pedigree (the compounding information) for an IV admixed product rather than prescriptively specifying the method of the trace-back.**

For many pharmacies, information currently on the label would allow for this trace-back. The information includes prescription numbers, patient name, date and time of admixing. Adding the pharmacy reference number or lot number would be redundant information for identifying the pedigree of a compounded product.

Adding this new requirement would require significant amounts of extra work and time. Our pharmacy labor and expense resources are limited and should be used for what is best to ensure quality of services to our patients, not be put redundant extra information on the labels of our dispensed products.

From medication safety standpoint, information on the label should be limited to only what is required for safe dispensing and administering the medication. Adding the lot number or pharmacy reference numbers adds more information to an already busy IV label, increasing the risk of confusion by patients or nurses in administering the

medication. An overload of information on the medication label discourages patients and nurses to verify critical basic information such as patient name, medication name expiration dating and proper storage information.

The proposed regulations 1735.2(a) would require prescribers to specify "the prescriber has approved use of a compounded drug product either orally or in writing". Will this be required for all prescriptions to be compounded including the hospital setting? Would it include prescriptions which can only be dispensed compounded such as an individualized TPN? My understanding of this proposed regulation is that prescribers are required to specify compounding on the prescription, and if not specified, the pharmacist would be required to call to obtain a verbal order. Based on my experience, it would be near impossible for prescribers to be aware and then remember the need to add the compounding specifics to the prescription. I am concerned that this requirement does not add to patient safety but rather would require additional pharmacist time and resources, and cause delays in filling the prescription. I urge the Board to remove this proposed requirement.

Please feel free to contact me for further discussion.

Sincerely,

Gloria Lee Wilder, Pharm.D
CBHS Pharmacy Director
San Francisco Department of Public Health
1380 Howard Street, #130, San Francisco, CA 94103
Gloria.wilder@sfdph.org
415-255-3703

October 2nd, 2008

Karen Cates
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834
Karen_cates@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Cates:

As an ED clinical pharmacist, I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direct of patient care.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require *one-time and immediate-use (STAT) medications*, such as alteplase, epinephrine, or diltiazem for treatment. Added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

I do not see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. I believe that such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to *Immediate-Use Compounded Sterile Products* as the immediate-use provision is intended only for those situations where there is a need

for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate-use injectable products in acute care facilities, *I request all proposed additional pharmacy record requirements be EXEMPTED from the pharmacy records. I also request an exemption of having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.* I believe that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

These exemptions in STAT situations will certainly benefit and prolong patients' lives as they receive compounded medications urgently. I hope the following suggestions will help to meet our shared goal of better and safer patient care, and appreciate the board's willingness to consider our requests.

If you have any questions, please do not hesitate to contact me at (650) 724-2467.

Respectfully,

Carolyn Nguyen, Pharm. D.
ED Clinical Pharmacist, Stanford and Clinics Hospital, Stanford, CA
Phone: 650-724-2467
Fax: 650-725-5028



"Margaret Bradshaw"
<mbradshaw@mcdh.net>
10/02/2008 11:00 AM

To "Karen Cates" <karen_cates@dca.ca.gov>
cc "Philip Swanger" <philip@thedochertygroup.com>
bcc
Subject Proposed Regulations: Requirements for Pharmacies that
Compound Medications

I would like to comment on the proposed regulations concerning compounding medications in pharmacies. I am sending these comments to you via email and US mail.

Thankyou,
margaret C. Bradshaw, R.Ph.



Comments to State Board New Regulations.doc

To: Karen Cates
California State Board Of Pharmacy

From: Margaret Bradshaw, R.Ph.
PO Box 836
Albion, Ca 95410
bradshaw@mcn.org

Re: Comments on Proposed Regulation: Requirement for Pharmacies that Compound Medications

I would like to take the opportunity to comment on the proposed regulations entitled Requirements for Pharmacies that Compound Medications. I am a pharmacist practicing in a small rural hospital. I have been a pharmacist for 35 years and I have practiced in both large and small hospitals and in retail settings. I am drawing on my experience as a pharmacist in these practice settings as well as my examination of the requirements of USP 797 to make the following comments and suggestions.

The stated purposes for the proposed regulations are to define certain terms when used in referring to compounding, and to establish parameters for general compounding including the requirement for a quality assurance program. The regulations as proposed attempt to set forth a single set of regulations that cover both general compounding and sterile compounding for use in a variety of settings. These products may be self administered by a patient, administered by an independent practitioner, or administered by personnel in an institution or under the control of an institution where the compounding pharmacy is located. Pharmacy practice has become so complex that these examples represent only a few of the possible sites where we provide pharmaceuticals. I question the feasibility of having one set of regulations to govern both general compounding and sterile preparations compounding. It is also not feasible to attempt to cover all types of compounding without making specific regulations that would account for the specific needs that one would encounter in a given practice site. The attempt to cover all practice sites with a single set of regulations, without recognizing the inherent differences in the services provided, or the populations served, will result in a set of regulations that is incomplete, ambiguous and unduly burdensome.

The highest priority of the Board of Pharmacy as stated at Section 4001.1, Article 1, Chapter 9 Div. 2 of the Business and Professions Code, is the protection of the public. This can be achieved by providing pharmacy practitioners with a clear, unambiguous statement of the regulations.

In order to comply with the regulations, practitioners must have notice of the requirements. The proposed regulations do not give practitioners notice of the requirements. It is stated in the Factual Basis in the Initial Statement of Reasons for the proposed regulations that: "An inspector conducting an inspection is frequently asked questions regarding aspects of the inspection as well as clarifications and requirements of pharmacy law." Obviously, there is confusion about the various provisions of the existing pharmacy law and regulations. The new regulations do not clarify any of the ambiguities. It is my understanding that the inspectors have the authority to inspect facilities, not to interpret the law (See 4008, Business and Professions Code, Art. 1, Ch. 9, Div. 2). A clear statement of the regulations would give for proper notice, simplify the self-assessment process and provide uniformity in the inspection process.

It is my understanding that all sterile compounding is subject to the provisions of USP 797. Is it the intent of the Board to exempt California pharmacies compounding sterile preparations from the provisions of USP 797 that differ from the proposed regulations? If not, would it serve the Board's purpose to adopt the provisions of USP 797 as the rules, which would govern sterile compounding in California? Although USP 797 is very detailed, it has been thoroughly vetted by sterile compounding experts in the pharmaceutical community. Adoption of USP 797 would serve the purpose of protecting the public, and providing a clear unambiguous statement of the law that would give practitioners notice of the expectations of the law. It would also provide a reasonable

alternative to the proposed regulations as written. Since pharmacies compounding sterile preparations are subject to USP 797, it would not result in an additional financial impact. The impact on patient care must be weighed against business impact. The regulations as proposed would have a significant impact on patient care in hospitals.

The underlying data referred to in the Initial Statement of Reasons was reported in workgroup meetings, the last of which occurred in January 2005. A significant amount of discussion has taken place in the pharmaceutical community about compounded sterile preparations since that last meeting. The current USP 797 regulations are a result of that discussion. Below, I have detailed specific sections of the proposed regulations that I believe are problematic.

Compounding Definitions

Many terms used throughout the body of the regulations have definitions that relate specifically to compounding. These terms should be defined. For example, the terms designated area, critical area and controlled area are all used when referring to sterile compounding.

Compounding Limitations and Requirements Sec. 1732.2

(a) The requirement that the prescriber approve use of a compounded drug either orally or in writing. Does this apply to chart orders? It is understood that most parenteral medications are compounded sterile products.

(h) Determining a beyond use date might also be determined by the nature of the compound. Evidence stronger than professional judgement of the pharmacist should be required. A requirement that the compounding provisions of USP 795 should apply could be added. The expiration or beyond use dating for compounded sterile preparations depends on both stability and sterility concerns. This should be stated.

(i) The pharmacist performing or supervising compounding, may not be the same pharmacist responsible for delivery of a compounded drug product. These activities may be performed by different individuals.

Records of Compounded Drug Products 1735.3

(a) Requiring the maintenance of these records for compounded sterile products administered in the hospital inpatient or outpatient setting would be unduly burdensome. These products are used if not immediately, then in a very short period of time thereafter. Except for batch prepared items, the detailed records this section would require offer little value.

(b) Would this require pharmacies compounding sterile products to maintain records of the acquisition of all sterile medications that are used to prepare sterile products, including IV solutions, and any medication that might be added to an IV solution? Would a hospital pharmacy performing minimal general compounding for an inpatient be required to keep records of items that might not have been purchased with the intent to use those items for compounding?

Labeling of Compounded Drug Products 1735.4

This section refers to Sec. 4076. Section 4076 (B) states that the paragraph applies to outpatient pharmacies only. Does Section 1735.4 refer to outpatient dispensing? Labeling requirements for sterile compounded preparations for administration in a hospital should have certain exemptions.

Training of Compounding Staff 1735.7

This section does not provide any guidelines about what is considered minimum skills, training or competency or competency assessment. As such, the determination of the sufficiency of the training or competency assessment would be left entirely to the inspector.

Article 7 Sterile Injectable Compounding

As stated before, I believe that adoption of USP 797 would provide the regulation of sterile compounding in California that the Board is attempting to achieve.

Compounding Area

The definition of a compounding aseptic barrier isolator should be added to Sec. 1751 concerning the compounding area.

USP 797 now requires certification of the ISO 5 compounding workstation twice a year in addition to other specified occasions. The proposed regulations require an annual certification with no requirement for recertification if the equipment is removed from service for repair or relocated.

Sterile Injectable Labeling Requirements 1751.2

(d) In addition to agents used in chemotherapy, NIOSH and OSHA have designated a group of agents as hazardous drugs. These agents are subject to special handling guidelines. The pharmacy regulations do not address hazardous drugs. Not all hazardous agents are used as chemotherapy. They can be used for a variety of other conditions. Proper handling, labeling, and disposal are important both for sterile compounding and general compounding. The regulations should address this topic.

Sterile Injectable Policies and Procedures 1751.3

Most of the requirements of (d) should apply to all sterile injectable compounding, not just to sterile compounding from one or more non-sterile ingredients.

Facility and Equipment Standards for Sterile Injectable Compounding 1751.4

The proper attire required in (b) should be specified.

(d) The weekly cleaning schedule specified conflicts with USP 797 in the pharmacies compounding only low and medium risk preparations are only required to clean monthly.

(e) The use of a compounding aseptic isolator for preparing parenteral cytotoxic agents should be allowed.

Sterile Injectable Compounding Attire 1751.5

This section specifies attire for personnel preparing cytotoxic and compounding from non-sterile ingredients. This section should be rewritten to cover all sterile compounding except for immediate use preparations.

The regulations do not adequately address the issue of protecting either compounding personnel or the public from unintended exposure to hazardous agents including chemotherapy. This should be included in the new regulations.

(5) The gloves used for sterile compounding should be more than gloves made from low shedding material. If not sterile gloves, then at least latex or nitrile gloves should be specified. Gloves that are ASTM rated for chemotherapy should be specified for personnel preparing cytotoxic agents.

Training of Sterile Injectable Compounding Staff

The requirements listed in (e) (1) A-H should be required of all personnel compounding sterile preparations.

These regulations will have a significant impact on the practice of pharmacy, especially in hospitals. This could be the opportunity for the Board to clarify some of the confusion with the existing regulations. This is the time to answer the questions and concerns of pharmacy practitioners. The vagueness and ambiguity of the regulations do not provide proper guidance to pharmacy practitioners.

I have only addressed some of the issues I find with the proposed regulations. I would be happy to discuss any of these with you.

Thankyou,

Margaret C. Bradshaw



"Bryan Carlson"
<BCARLSON@childrenscentr
alcal.org>

10/01/2008 06:55 PM

To <karen_cates@dca.ca.gov>

cc

bcc

Subject Title 16. Board of Pharmacy Comments

To the California Board of Pharmacy,

Concerning the proposed changes beginning with Section: 1716 Requirements for Pharmacies that Compound Medications, Children's Hospital of Central California Pharmacy Department would like to make the following comments. In order to accommodate the changes being made to the pharmacy law, we feel that a phase in period of 12 months be considered. This time would allow for the necessary budget and process changes to be made. Although the Board of Pharmacy feels that these changes will have little fiscal impact on pharmacy practice, we feel differently. With all of the regulations that we are currently facing from the DEA, DHS, JCAHO, USP797, and the Board of Pharmacy, simply reviewing and coordinating them can be a costly venture both on time and finances.

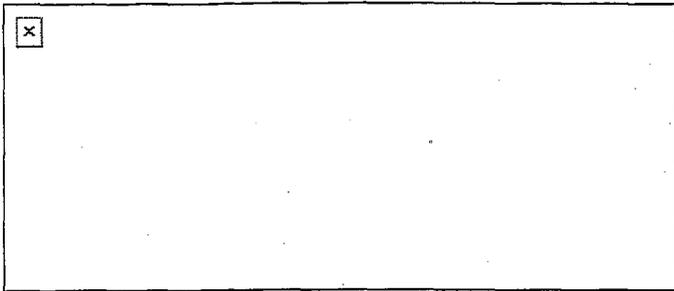
Secondly, we suggest placing some of the burden back on the manufacturing community. Standardization of barcoding technology to include lot numbers and expiration dates along with the NDC would facilitate the record keeping process.

Lastly, we would like clarification on what is meant by "equipment" in Section 1735.3 subsection (a) (7). Are you asking that every lot number of every syringe and every needle used in the compounding process be documented and stored? Please clarify your intent on this item as we feel that this would be very difficult to comply with.

We, as a Children's Hospital, already have a very complex system to manage. As regulations add to the complexity, risk for error increases. Although we agree that pharmacy practice needs to be monitored and regulated, please consider the comments of CSHP and others when making your decisions. We cannot delay or negatively impact patient care just to comply with a regulation that was not well thought out.

Thank you for your time and consideration.

Pharmacy Department
Children's Hospital Central California
9300 Valley Children's Place
Madera, California 93636-8762
(559) 353-5504



*12401 Washington Boulevard
Whittier, California 90602-1099
(562) 698-0811
Hearing Impaired TDD (562) 696-9267*

September 30, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento, California 958834

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Herold:

I have commended and supported the California Board of Pharmacy for their previous and current efforts to strengthen the regulations surrounding pharmacists that compound medications. However, I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to compounded IV medications in acute care hospitals.

In the past, there has always been a clear distinction between prescription compounding and manufacturing. Trying to apply manufacturing practices to an acute care setting can seriously jeopardize the hospital pharmacist's ability to respond to the acute needs of their patients. Clearly, the workflow process to manufacturer in bulk versus the compounding of sterile products for individual patient prescriptions are distinctly different in their response time and the need for timely administration to the patient.

I would highly recommend that the Board accept the recommended changes of the California Society of Health-System Pharmacists or create a working group of practicing hospital pharmacists and create a safe and workable process that will insure the ability of the hospital pharmacists to be responsive and responsible to safe guarding the protection of the patient. Creating regulations that mandate the same practice in all pharmacy practice arenas does not serve the specific needs of all of our patients.

If you have any questions, please do not hesitate to contact me at (562) 698-0811, Extension 2804.

Respectfully,

Alan Y. Endo, Pharm. D.
Pharmacy Director
RPh 27276



"David F. Elder"
<DElder@skdh.org>
09/29/2008 02:40 PM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Compounding Regulations

To The California Board of Pharmacy:

I agree with CSHP's concerns below. We already keep adequate records of compounded items in our logs. Items that must be used immediately in a code or other emergency are also documented adequately on the patients profile.....keeping records for 3 years and generating all the policies required below is not necessary, since compounding skills already are defined and this is tedious work that does not do anything to protect the patient, rather, all the labeling will adversely affect our patients. In addition to CSHP's concerns, I have placed my comments below. I also agree with the concerns of CSHP in addition to mine!

Thank you for considering my point of view. I do not agree with the Board on this issue.

David Elder, PharmD
Director of Pharmacy Services
Sierra Kings District Hospital
372 W. Cypress Ave.
Reedley, CA 93654
(559) 638-8155 Ext. **334**
(559) 637-7556 (FAX)
(559) 707-5143 (CELL)
delder@skdh.org

All compounding (each prescription vial/product or IV medication)

- Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
- Labeling must include a statement that the product was compounded by the pharmacy; **pharmacy reference number or lot number must be provided for each dispensed IV.**
- Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
- **Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.**
- Records of all supplies and ingredients purchased, used or destroyed are maintained.
- **All records and logs are maintained for a minimum of 3 years.**
- **Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes,**

methodology of determining expiration dating, etc.

- Limits supply to MD offices to 72 hour supply of compounded medications.



Sterile Injectable Compounding Changes (in addition to those above)

these

items are already being done or are written in existing policies and on labels etc. This is just un-necessary duplication.....

- **Written policies/procedures on disposal of infectious materials and cytotoxics.>>>>>>***
- **Labeling of each compounded product to include route and rate of administration.....***
- **Quality Assurance to include sterility testing of any batch prepared products.....***

CSHP has concerns with the above underlined and bolded language as it pertains to IV medications and the urgent needs of some of these medications. **We have asked for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.** Unfortunately, our concerns were not heard by the Board of Pharmacy and the proposed regulations have been posted without change. This means every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic.

This is just not necessary or practical???? Why would we want these fire hazards around so long, when we already generate enough flammable material in our storage areas????

David Elder, PharmD
Director of Pharmacy Services
Sierra Kings District Hospital
372 W. Cypress Ave.

Reedley, CA 93654
(559) 638-8155 Ext. **334**
(559) 637-7556 (FAX)
(559) 707-5143 (CELL)
delder@skdh.org

Board of Pharmacy
Attention: Karen Cates (Proposed compounding regulations)
1625 Market Blvd. N219
Sacramento, Ca 95834

September 27, 2008

Dear Board of Pharmacy,

I am writing as a pharmacist with a 27-year history in the practice of Hospital Pharmacy. I am writing to pass along my strong opposition to your proposed compounding regulations, which, if not edited or clarified would have a significant negative impact on established pharmacy practice.

The standard of practice in hospital pharmacy for preparing IV admixtures is one that has been refined and continually updated by the pharmacy profession. Most recently, the extensive changes of the USP 797 requirements have further defined and altered the hospital pharmacy practice of preparing IV admixtures. The major problem with the proposed regulations by the Board of Pharmacy is the definition and distinction of what is considered a compounded item. It is my strong belief, and one I believe is shared by anyone in the hospital pharmacy profession, is that IV admixture preparation practice should be not bundled in with compounded prescriptions, such as topical, oral, or injectables compounded from non-sterile product or intended for sale or distribution to a patient or provider.

The most significant problem is with regulations 1735.3 and 1751.1 – the proposed recordkeeping regulations and they should NOT be passed. If the regulations are passed as proposed, and the intent is to apply it to all IV admixtures prepared in a hospital pharmacy environment, it would be a recordkeeping nightmare. The majority of IV admixtures prepared in the hospital setting fall within the low to medium risk category as well defined and described by USP 797. If for every IV admixture prepared the Board would expect to see LOT #, manufacturer, equipment used, personnel identity, pharmacist identity, pharmacy lot number, expiration dating, quantity, etc as described in 1735.3, the treatment of acutely ill patients would be at risk. Even in a small, rural critical access hospital we often mix over 100 IV admixtures in a day. In a larger institution, this number would be 10-20 times higher and the recordkeeping requirements, which the regulations imply, would be overwhelming and create an enormous burden on pharmacy professionals. Furthermore, I believe this extensive recordkeeping would not significantly improve medication or patient safety.

I strongly recommend that you **do not pass** the proposed regulations as they are currently written and you evaluate the intent of the regulations for all aspects of professional pharmacy practice. Specifically, please consider the recommendations and consultation of pharmacy professionals within hospital pharmacy practice and how the “sterile compound” regulations pertain to the practice of IV admixture services.

In addition to the above considerations, please reconsider the language of 1751.5, 1751.6 and 1751.7. It would seem prudent to follow the practice guidelines for USP 797 in the areas such as training, cleaning, garbing, and quality assurance as these standards have reviewed by a group of nationally recognized individuals.

Thank you for your consideration of this letter.

Sincerely,

Lois F. Leister, RPh, M.S., M.B.A.
Practicing hospital pharmacist, Member of CSHP
29930 Sherwood Road
Fort Bragg, CA 95437
Email lfander@mcn.org



"Naidu, Dharma R"
<Dharma.Naidu@chomp.org>

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

09/24/2008 07:28 AM

bcc

Subject FW: Proposed changes for medication compounding

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
 - * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
 - * Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
 - * Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
 - * Records of all supplies and ingredients purchased, used or destroyed are maintained.
 - * All records and logs are maintained for a minimum of 3 years.
 - * Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
 - * Limits supply to MD offices to 72 hour supply of compounded medications.
- Sterile Injectable Compounding Changes (in addition to those above)
- * Written policies/procedures on disposal of infectious materials and cytotoxics.
 - * Labeling of each compounded product to include route and rate of administration.
 - * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Dharma Naidu, Pharm.D

Pharmacy Supervisor

Community Hospital of the Monterey Peninsula

P Please consider the environment before printing this e-mail

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Thank you.



"Jones, Kimberly J"
<Kimberly.Jones@chomp.org>

09/20/2008 11:00 AM

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

bcc

Subject Proposal for medication compounding

September 20, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
- * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
- * Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
- * Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
- * Records of all supplies and ingredients purchased, used or destroyed are maintained.
- * All records and logs are maintained for a minimum of 3 years.
- * Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
- * Limits supply to MD offices to 72 hour supply of compounded medications.
- * Sterile Injectable Compounding Changes (in addition to those above)
- * Written policies/procedures on disposal of infectious materials and cytotoxics.
- * Labeling of each compounded product to include route and rate of administration.
- * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Kimberly Jones, PharmD

Clinical Pharmacist at the Community Hospital of the Monterey Peninsula
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Thank you.



"Berger, Alex \(\OCHV)"
<AlexBerger@dochs.org>
09/18/2008 09:48 PM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Action Requested: New Compound Sterile Injectable
Products Regulations

Hello Karen Cates,

This is a TERRIBLE new regulation that will jeopardize patient's care! We do not have time to for more documentation when an IV medication is needed STAT. STAT means medication is needed now, or the patient will die.

This regulation should exempt IVs for immediate /STAT administration.

Alexander Berger,

Staff pharmacist O'Connor Hospital, San Jose



"Fukano, Robert"
<Robert.Fukano@chomp.org>
>

09/17/2008 03:08 PM

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

bcc

Subject

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
- * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
- * Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
- * Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
- * Records of all supplies and ingredients purchased, used or destroyed are maintained.
- * All records and logs are maintained for a minimum of 3 years.
- * Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
- * Limits supply to MD offices to 72 hour supply of compounded medications.
- * Sterile Injectable Compounding Changes (in addition to those above)
- * Written policies/procedures on disposal of infectious materials and cytotoxics.
- * Labeling of each compounded product to include route and rate of administration.
- * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, there are dozens of hospital in California without 24 hour pharmacy services in which nurses are compounding and mix intravenous products

without the aid of any sterile preparation area or laminar flow hood/biological safety cabinet. Why the separation of record-keeping of pharmacy-prepared versus nurse-prepared or physician-prepared (thinking of anesthesiologists who prepare medication in the operating room)?

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Robert M. Fukano, PharmD
Intensive Care Unit/Critical Care Unit Clinical Pharmacist
Community Hospital of the Monterey Peninsula
Monterey, California



"Yi, Man"
<Man.Yi@chomp.org>
09/17/2008 09:10 AM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject Proposed changes for medication compounding

September 17, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
 - * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
 - * Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
 - * Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
 - * Records of all supplies and ingredients purchased, used or destroyed are maintained.
 - * All records and logs are maintained for a minimum of 3 years.
 - * Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
 - * Limits supply to MD offices to 72 hour supply of compounded medications.
- Sterile Injectable Compounding Changes (in addition to those above)
- * Written policies/procedures on disposal of infectious materials and cytotoxics.
 - * Labeling of each compounded product to include route and rate of administration.
 - * Quality Assurance to include sterility testing of any batch prepared products.

"I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful."

I totally agree with my colleague's concerns above.
Thank you for your consideration,

Man Yi

R.ph, MS.

Clinical Pharmacist at the Community Hospital of the Monterey Peninsula

North Coast Society of Health-System Pharmacists



C/O

Michael W. Sanders, Chapter President
128 Alderbrook Drive
Santa Rosa, CA 95405-4602
(707) 545-0742

September 15, 2008

Board of Pharmacy
Attn: Karen Cates (Proposed Compounding Regulation)
1625 N. Market Blvd. N219
Sacramento, CA 95834
Fax: (916) 574-8618

RE: Proposed changes to 16-CCR 1716.1 and 1716.2

Dear Karen,

On behalf of the members of our C.S.H.P.-affiliated chapter, I wish to voice my objection to certain language changes or omissions pertaining to your proposed revisions to these regulations.

Health system pharmacies, especially in hospitals, must prepare numerous 'stat' or 'now' compounded IV and other products for acutely ill patients. Without exempting immediate or one time use compounded products from §1735.1, Compounding Definitions, the board is placing unreasonable and unnecessary recordkeeping and labeling requirements on already overburdened health care systems in California.

We pharmacists and pharmacy technicians of the North Coast Chapter of C.S.H.P. therefore ask you to rescind these regulatory changes without first making accommodation for immediate and one time use compounded products. Your affirmative action in response would be much appreciated.

Michael W. Sanders, Pharm.D. President, North Coast Society of Health-System Pharmacists
CC: 1) Board of Directors, 2) CSHP, 3) File



"Hayashi, Joanne S"
<Joanne.Hayashi@chomp.org>

09/16/2008 12:54 PM

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

bcc

Subject FW: Proposed changes for medication compounding

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
- * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
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- * Written policies/procedures on disposal of infectious materials and cytotoxics.
- * Labeling of each compounded product to include route and rate of administration.
- * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful. It may also compromise patient safety since the focus will be shifted from the real task at hand - safe, aseptic compounding of CSPs to the task of record keeping!!

Thank you for your consideration,

Joanne Hayashi, PharmD
Clinical Pharmacist at the Community Hospital of the Monterey Peninsula
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Thank you.



"Hendrick, Lynn"
<Lynn.Hendrick@chomp.org>

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

09/16/2008 10:26 AM

bcc

Subject Proposed changes for medication compounding

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
 - * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
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- * Written policies/procedures on disposal of infectious materials and cytotoxics.
 - * Labeling of each compounded product to include route and rate of administration.
 - * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Lynn Hendrick, PharmD

Clinical Pharmacist at the Community Hospital of the Monterey Peninsula
Confidentiality Notice:

This is a transmission from Community Hospital of the Monterey Peninsula. This message and any attached documents may be confidential and contain information protected by state and federal medical privacy statutes. They are intended only for the use of the addressee. If you are not the intended recipient, any disclosure, copying, or distribution of this information is strictly prohibited. If you received this transmission in error, please accept our apologies and notify the sender.

Thank you.



"Miller, Ray - SFMH"
<Ray.Miller@chw.edu>
09/15/2008 05:39 PM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>, "Yee, William - SJMC"
<William.Yee@chw.edu>
bcc
Subject Proposed Compounding Regulations

Dear Ms. Cates:

The CSHP has alerted hospital pharmacists that the BOP is considering amending the California Code of Regulations by adding and/or amending sections 1735 thru 1751.8 of Division 17 of Title 16.

A careful reading of the proposed language does not make it clear to me whether it is the intention of the BOP to include hospital pharmacies who compound admixtures for immediate use on inpatients in these changes. The proposed self assessment that was distributed is titled "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" which implies that it is not intended for hospitals that are accredited by TJC.

Please make sure that the language of these revisions makes it clear that hospital pharmacies accredited by TJC are not bound by these provisions. Although, we comply with many of the quality initiative suggested, the volume of work done in a hospital, as well as the immediate nature of our work would make it difficult to comply with any requirement that every ingredient's lot number, manufacturer etc. be recorded.

Thank you for your consideration.

Ray Miller, Pharm. D.
Director of Pharmacy
St. Francis Memorial Hospital
900 Hyde Street
San Francisco, Ca 94109
(415) 353-6451



"Ghomeshi, Mona - MSJ"
<Mona.Ghomeshi@chw.edu>

10/06/2008 07:53 PM

To <karen_cates@dca.ca.gov>

cc

bcc

Subject Against Proposed IV Compounding Regulations

Dear Ms. Cates,

I am writing to let you know I am against the new proposed regulation to require pharmacists to record in a log each IV compounded. I feel there must be exemptions in life-threatening and emergent situations. To require a delay in services to log a medication prepared during a cardiac arrest or other emergent situation could be detrimental to the patient. As a pharmacist who attends code blues on a regular basis, this would create unnecessary stress, and would not provide any added safety benefit to the dying patient.

I am requesting that all proposed additional pharmacy record keeping requirements for the preparation of one-time and immediate use IV products in the acute care hospital be exempted.

I am also requesting an exemption from having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.

Thank you for taking my concerns for our profession and our patients' safety into consideration.

Mona Ghomeshi, Pharm. D.
Mercy San Juan Medical Center
Carmichael, CA



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

October 6, 2008

Virginia Herold
California Board of Pharmacy
1625 N Market Blvd, Ste. N219
Sacramento, CA 95834

Dear Ms. Herold:

On behalf of the California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS), we would like to submit the following comments regarding the California Board of Pharmacy's proposed Compounding Rules.

Our members thank the Board for addressing some of the concerns we commented on in March 2007 for rules that were proposed in early 2007. Specifically we appreciate that the Board clarified that adding a flavoring agent to a commercially available product is not considered "compounding." As you know, many patients prefer to have the flavor of an oral liquid medication changed to better suit their tastes; pharmacists oblige, recognizing that doing so will increase patient adherence to their medication therapy. It is certainly logical that changing the flavor of a medication is not considered "compounding," as doing so does not change the therapeutic effect of the medication and can positively affect patient adherence. We believe that considering this service to be compounding would only act as a deterrent for pharmacists to provide this service, as having to comply with compounding requirements would be unnecessarily burdensome.

Additionally, Our members appreciate that the Board will not require a pharmacist to establish a professional relationship with both a prescriber and a patient prior to compounding a drug. We believe that this will allow pharmacists to compound drugs ahead of time based upon routine prescribing habits, so they can plan ahead and have commonly prescribed compounded products readily available for patients.

However, our members believe that some of the proposed requirements would prevent pharmacies from engaging in "non-sterile basic" compounding.

As you know, "nonsterile basic" compounding is defined by PCAB (Pharmacy Compounding Accreditation Board) as "compounding which involves the preparation of a formulation containing two or more nonsterile commercially available products employing basic pharmacy training skill sets, as well as, defined policy, procedures and processes necessary to ensure quality and consistency of the completed compounded preparation." Nonsterile basic compounding includes only nonsterile products that are already commercially available, and require only basic pharmacy training skill sets. As such, we question the need for pharmacies

that engage only in this type of compounding to meet the same requirements as for more complex types of compounding.

Our members thank the Board for breaking the self-assessment form into two parts: one for sterile compounding, and another for non-sterile. But, our members still question the need for a pharmacy that engages only in nonsterile basic compounding to have to complete a self-assessment.

Additionally, we thank the Board for allowing pharmacies to record the master formula on the prescription document for preparations that pharmacies do not routinely compound. However, for pharmacies that only engage in nonsterile basic compounding, and do so on a non-routine basis, we question whether these pharmacies should have to comply with requirements for a compounding policy and procedure manual, documentation of the facilities and equipment necessary for compounding, documentation of pharmacy staff training and on-going competency evaluation and a written quality assurance plan.

Our members believe that non-sterile basic compounding employs basic pharmacy skill sets that any registered pharmacist should possess. As such, we believe that these requirements are unnecessary and will act as a hindrance to pharmacies providing nonsterile basic compounding services to patients.

Thank you for your consideration of our position.

Sincerely,

Heidi Barsuglia
California Retailers Association

Mary Staples
National Association of Chain Drug Stores

cc: Anne Sodergren



American Society of
Health-System Pharmacists[®]
7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-664-8892
www.ashp.org

October 6, 2008

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

RE: Proposed Regulatory Changes Regarding Compounding

Dear Ms. Herold:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit the following comments regarding the proposed regulatory changes in Article 4.5, Compounding, of the California Code of Regulations. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

Compounding medications is a significant facet of the practice of pharmacy and we applaud the Board of Pharmacy's desire to ensure that patient safety is protected. ASHP also recognizes the importance of developing regulatory language that provides necessary parameters while avoiding potentially significant barriers to providing patient care. As such, having reviewed the proposed regulatory changes, ASHP does have some concerns regarding the labeling and documentation modifications within the proposed regulations.

The proposed regulatory change to labeling is of concern to ASHP. In the United States Pharmacopeial's revised *USP <797>, Guidebook to Pharmaceutical Compounding - Sterile Preparations*, it states that "unless immediately and completely administered...the [compounded sterile preparation (CSP)] shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour beyond-use date (BUD) and time."¹ This revision allows for less stringent labeling, as long as the compounded product meets all of the stated criteria.

Current ASHP practice guidelines recognize that states have the right to require specific labeling. Enclosed is a copy of the guideline's labeling requirements for sterile

¹ *USP <797> Pharmaceutical Compounding – Sterile Preparations*. Revised 2008. Pg. 13.

preparations. These labeling requirements are more detailed than the current USP revision; however, these guidelines specifically exclude the compounding of sterile preparations for emergency treatments from its scope, a vital distinction that we believe is necessary:

“These ASHP guidelines *do not* apply to the manufacture of sterile pharmaceuticals as defined in state and federal laws and regulations, *nor* do they apply to the preparation of medications by pharmacists, nurses, or physicians in emergency situations for *immediate* administration to patients (e.g., cardiopulmonary resuscitation)... It is recognized that, in certain emergency situations, a pharmacist may be requested to compound products under conditions that do not meet these guidelines. In such situations, it is incumbent upon the pharmacist to employ professional judgment in weighing the potential patient risks and benefits associated with the compounding procedure in question.”²

ASHP believes that the compounding of sterile preparations in emergency situations should be governed by the professional judgment of pharmacists and the policies of the institutions they practice in, as those situations demand that health care professionals have the utmost flexibility to decide what is best for the patient. We would, therefore, strongly encourage the Board to reconsider the current proposed language. While labeling requirements during normal events are beneficial to both the pharmacy and the patient, such strict requirements during emergency situations could negatively impact patient care and introduce delays in medication delivery. As currently proposed, the labeling requirement could in fact create the opposite effect than intended – delays in patient care that places patient health and safety in jeopardy.

In terms of the proposed changes to documentation, there may be some confusion as to whether the documentation requirement applies to every product that is prepared, including those for an individual patient, or if the new requirement will apply solely to those products that are prepared in batch for a yet-to-be determined patient. As pharmacies typically do not record such detailed information for patient-specific items, such a proposed regulation could create an extraordinary burden for pharmacies. Further, not only could this new requirement exist for emergency drugs, it could impact all products prepared for routine care. This added documentation requirement has the potential to delay the preparation and delivery of one-time and immediate-use medications. We would urge the Board to consider the potential implications of such a regulatory change.

We appreciate the opportunity to provide these comments and would be happy to work with you as you continue to develop appropriate guidelines and requirements that affect

² American Society of Health-System Pharmacists. ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products. *Am J Health-Syst Pharm.* 2000; 57:1150–69. pg. 54. (available at: <http://www.ashp.org/DocLibrary/BestPractices/QualityAssurance.aspx>)

California State Board of Pharmacy
Proposed Requirements on Compounding
October 6, 2008
Page 3

the pharmacy profession. If you have any questions or comments, please do not hesitate to contact me at 301-664-8687 or gtrujillo@ashp.org.

Sincerely,



Gerilyn Trujillo, MPP
Director, State Government Affairs

cc: Philip Swanger, California Society of Health-System Pharmacists

Enclosure

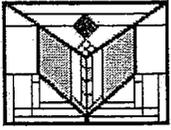
ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products

RL 1.9: Labeling.

Sterile products should be labeled with at least the following information:

1. For patient-specific products: the patient' name and any other appropriate patient identification (e.g., location, identification number); for batch-prepared products: control or lot number,
2. All solution and ingredient names, amounts, strengths, and concentrations (when applicable),
3. Expiration date and time, when applicable,
4. Prescribed administration regimen, when appropriate (including rate and route of administration),
5. Appropriate auxiliary labeling (including precautions),
6. Storage requirements,
7. Identification (e.g., initials) of the responsible pharmacist (and technician),
8. Device-specific instructions (when appropriate), and
9. Any additional information, in accordance with state or federal requirements; for example, a prescription number for products dispensed to ambulatory care, long-term-care, and home care patients.

The label should be legible and affixed to the final container in a manner enabling it to be read while the sterile product is being administered (when possible). Written policies and procedures should address proper placement of labels on containers.



Robert
Ratcliff/Pharmacy/DCANotes
09/30/2008 10:29 AM

To reid.toda@cpspharm.com
cc Anne Sodergren/Pharmacy/DCANotes@DCANotes, Karen
Cates/Pharmacy/DCANotes@DCANotes
bcc
Subject Fw: Board of Pharmacy New Compounding Regulations

Ms. Toda:

Your e-mail has been forwarded to me for a response.

Below is an excerpt from Business and Professions Code section 4127.1 which was the statute that mandated board licensure for those pharmacies compounding sterile injectable products.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

- (1) The sterile powder was obtained from a manufacturer.
- (2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

As you can see reconstituting by health care professionals (RN's) is exempt from licensure. Also, currently there are no regulations requiring documenting the admixing, nor are there any planned regulations requiring this.

I hope I have answered your question

Sincerely,
Bob Ratcliff, Pharm.D.
Supervising Inspector
CA Board of Pharmacy
(661) 943-4775



"Toda, Reid"
<reid.toda@cpspharm.com>
09/25/2008 06:31 AM

To <karen_cates@dca.ca.gov>
cc
Subject Board of Pharmacy New Compounding Regulations

How does this affect pharmacies where nursing reconstitutes and administers a medication on the floors?

Thank you,

Reid Toda, MS, RPh
(925) 200-5517
(413) 451-7170 fax

Confidentiality Notice: *This e-mail communication and any attachments may contain*

Karen Cates
California Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento, CA 95834

Subject: Proposed changes to regulation regarding Article 7 Sterile Injectable Compounding.

In reviewing the document it was notice that there were item needing to be addressed as follows.

last sentence of 1751(b)(7) was omitted.

1751.4 (e) As reference to Title 24 section 4-1106(b) is not readily available to all persons it would be nice to have it included to the paragraph 1751(b)

1751.4(e) some of the information contained has been superseded with up to date releases and there is a grouping of requirements not covered by those referenced in the paragraph.

Example: where reference is: "requiring a laminar air flow hood" it should be changed to read "requiring a Class II (laminar flow) biosafety cabinet and must be certified annually by a qualified technician in accordance with NSF/ANSI 49-2002 available from Techstreet at www.techstreet.com or manufacturers specification.

(f) Clean rooms, Barrier Isolators and Laminar flow hoods should be certified annually by a qualified technician in accordance with International Standards Organization ISO 14644 available from Techstreet at www.techstreet.com or manufacturer specification.

(g) All Certification records must retained for at least 3 years by Certifying Organization and pharmacies being certified.

I hope these changes can reviewed by your committee and included to the regulations.

Sincerely,

Ernest M. Aldama
Adapt Consulting
419 Kaneeta Lane
Grants Pass, OR 97526
510-301-2274 Cell#

Kevin R. Brown, Pharm.D.
2001 Madera Vista Lane
Rescue, CA 95672

BOARD OF PHARMACY
2009 MAR 17 AM 8:50

March 9, 2009

Board of Pharmacy
Attn: Carolyn Klein, Manager, Legislation and Regulation
1625 N. Market Blvd. N219
Sacramento, CA 95834
carolyn_klein@dca.ca.gov

Re: Proposed Regulations - Article 4.5 General Compounding

Dear Ms Klein:

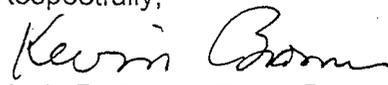
I am very concerned with the sweeping changes proposed to the compounding and documentation of **sterile injectable** products. Current regulations regarding **sterile injectable** compounding are very specific and detailed from both the United States Pharmacopeia (USP) Convention guidelines at the federal level and current state BOP regulations. Adding additional regulations requires assessment of the patient benefits and risks. I am concerned the Board has not adequately assessed this balance.

There has been no documentation offered to show changing compounding regulations for **sterile injectable** products will have a beneficial impact to patient care. Current regulations in California code and USP provide adequate safeguards and documentation. Adding regulations for additional documentation to **sterile injectable** products that will be administered within the next 24 hours is not only labor intensive but offers no benefits or clear value. The addition of thousands of records per day per site will have NO impact to patient safety or any recall process.

In contrast to the lack of patient benefit from the proposed regulations, patient care is likely to be jeopardized by the additional documentation. The added workload produced by this documentation requirement will reassign pharmacy staff away from other patient care functions and clinical programs. As a result, patient care activities with documented patient benefit will be decreased or eliminated.

Current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) to assure patient safety. In addition, the Board requires additional licensure or accreditation of pharmacies to perform the functions of **sterile injectable** compounding. Changes or additional regulations to these sections are NOT needed.

Respectfully,


Kevin R. Brown, PharmD



"Margaret Bradshaw"
<mbradshaw@mcdh.net>

03/12/2009 03:11 PM

To <carolyn_klein@dca.ca.gov>

cc

bcc

Subject Comments about proposed modifications to Section
1735.3(a)(6)

I am submitting the attached comments concerning the proposed modifications to the text of Section 1735.3(a)(6) of Title 16, California Code of Regulations. I have already submitted these comments to you via facsimile, but I feel strongly about this subject, so I am resubmitting my comments in this email communication.

I have limited my comments to the above Section as directed. However, my concerns include the entire section on compounding. Will the Final Statement of Reasons include a discussion of all comments made previously to the proposed rule changes as well as to comments submitted for Section 1735.3(a)(6)?

Thank you,

Margaret C. Bradshaw, R.Ph.



Comments about Section 1735.3(a)(6) to State board on the proposed modifications to the text of section 1735.doc

March 9, 2008

To: Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, California 95834

From: Margaret Bradshaw, R.Ph.
P.O. Box 836
Albion, California 95437
(707) 964-5245

Re: Comments Regarding Proposed Modifications of the Text of Section 1735.5 (a)(6) of Title 16, California Code of Regulations

Thank you for the opportunity to comment on the proposed modifications to the text of Section 1735.5 in Title 16 of the California Code of Regulations. I understand that comments are limited to Section 1735.3(a)(6) providing an exemption to the requirements of the proposed paragraph. I would like to comment on two aspects of the proposed exemption.

(1) The restriction of the exemption to sterile products compounded on a one-time basis for administration within two hours:

I am a pharmacist employed in a critical access hospital in rural northern California. Pharmacies in small hospitals, such as mine, are not staffed 24 hours a day. Some hospital pharmacies are closed on weekends. We are not involved in compounding large batches of sterile products. We prepare limited quantities of sterile products for small populations of patients.

Please consider the following examples:

- (1) A patient receives one dose of an antibiotic once every 24 hours. The dose of the drug is based on the patient's weight, renal function and other factors and will not be used for any other patient. The dose is due at 2 am and the pharmacy closes at 6pm.
- (2) Another patient is receiving a continuous infusion of a drug. The doses prepared are patient specific and will not be used for any other patient. All doses will have been used by the time the pharmacy opens the next day.
- (3) Most hospitals prepare sterile products for less than a 24- hour period, but cannot afford to prepare each sterile product on an as needed basis. Some hospitals because of staffing issues or low patient census may not have a pharmacist available on weekends and thus prepare a 2 day supply of medications before the pharmacist leaves on Friday. In each of these scenarios, the medications will have been used within a few days.

There would not be any greater benefit from the required record keeping for these products than products that were used within 2 hours of preparation. The volumes of records that will result from this requirement taxes already scarce personnel time and

financial resources without any added benefit to patients. Utilizing limited financial, personnel and time resources for training and process validation, including focusing on accuracy and aseptic technique is much more important for achieving the goal of improving patient safety.

Small hospitals, especially, are negatively impacted because we cannot afford to invest in proprietary premixed products that would be more widely available at larger institutions with bigger drug budgets. Even if we could afford to purchase these products, our volumes are so small that we often cannot meet the minimum quantities without generating waste from products that expire before we can use them. **I reject the implication that we cannot provide safe products for our patients without the added requirements for the voluminous records that will result from maintaining batch records for individualized compounded sterile products.**

(2) The restriction of the exemption to compounded sterile products for inpatients.

Most hospitals provide compounded sterile products to their outpatient departments on an individual, as needed basis. These products are not prepared until the patient is at the facility and is ready for the treatment. Hospital personnel administer these products; the patient never takes possession of them. These departments include, but are not limited to, oncology departments, infusion departments, outpatient surgery departments, emergency departments and recovery rooms. These patients are not considered to be inpatients. In some situations these may be STAT medications given in life or death situations. **The emphasis should be on providing accurate, aseptic products to these patients in a timely manner, not on generating compounding drug records.** Even in this situation, small hospitals will be more negatively impacted. We do not have staff dedicated to compounding sterile products. Preparing to make the sterile product takes time. Completing a compounding record will only increase turn around time. **The exemption to the compounding records requirements should at least extend to outpatients in health care facilities licensed under Section 1250 of the Health and Safety Code.**

If you have any questions, I am willing to discuss my comments.

Thank you,

Margaret C. Bradshaw, R.Ph.

March 12, 2008

Virginia Herold
California State Board of Pharmacy
1625 North Market Blvd., Suite N219
Sacramento, CA 95834



Dear Ms. Herold,

We are submitting comments to the 16 proposed changes to the California Code of Regulations beginning with section 1716.1 related to the requirements for pharmacies that compound medications.

In addition, we are submitting comments to the Initial Statement of Reasons to these changes.

If you have any questions, I would be glad to discuss our comments with you or your staff.

Very best wishes,

McGuff Compounding Pharmacy Services, Inc.

William J. Blair, Pharm. D., MBA
Director of Pharmacy Services

McGUFF
COMPOUNDING
PHARMACY
SERVICES

2921 W. MacArthur Blvd.
Suite 142
Santa Ana, CA 92704-6929

TOLL FREE: 877.444.1155

TEL: 714.438.0536

TOLL FREE FAX:

877.444.1155

FAX: 714.438.0520

EMAIL: answers@mcguff.com

WEBSITE: www.mcguff.com

DEPARTMENT OF CONSUMER AFFAIRS BOARD OF PHARMACY
To Repeal Title 16 CCR §§ 1716.1 and 1716.2, Adopt Title 16 CCR §§ 1735 –
1735.8 And Amend Title 16 CCR §§ 1751 – 1751.8 Regarding Requirements for
Compounding

Repeal Section 1716.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

~~As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:~~

~~(a) "Reasonable quantity" means that quantity of an unapproved drug which:~~

~~(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and~~

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

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

~~(b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.~~

~~(c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.~~

~~Repeal Section 1716.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:~~

§1716.2. Record Requirements--Compounding for Future Furnishing.

~~(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:~~

~~(1) The date of preparation.~~

~~(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.~~

~~(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~

~~(4) The signature or initials of the pharmacist performing the compounding.~~

~~(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.~~

~~(6) The name(s) of the manufacturer(s) of the raw materials.~~

~~(7) The quantity in units of finished products or grams of raw materials.~~

Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

~~(8) The package size and the number of units prepared.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.~~

Article 4.5 Compounding

Add Section 1735 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735. Compounding in Licensed Pharmacies

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a drug product from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).

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

Add Section 1735.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.1. Compounding Definitions

- (a) "Integrity" means retention of potency until the expiration date noted on the label.
- (b) "Potency" means active ingredient strength within +/- 10% of the labeled amount.
- (c) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.
- (d) "Strength" means amount of active ingredient per unit of a compounded drug product.

Comment 1881: Delete reference to injectable throughout the document. Compounding practices involving solutions, emulsions, and other dosage forms are permitted by statute. By deleting injectable, all sterile compounding will be included.

Deleted: injectable

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:
Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.
Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions
to the regulatory text are indicated by a double underline, thus: added language.

Add Section 1735.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.2. Compounding Limitations and Requirements

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

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

(c) Pursuant to Business and Professions Code section 4052(a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:

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

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

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

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

(1) Active ingredients to be used.

(2) Inactive ingredients to be used.

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

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

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

(6) Expiration dating requirements.

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

(f) The pharmacist-in-charge is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

Comment (B62): Where is "pharmaceutical standards" defined? Replace with "that will assure."
Deleted: in compliance with pharmaceutical standards for

Comment (B63): This eliminates both "not being responsible." Replace with "The pharmacist-in-charge is responsible."
Deleted: performing or supervising
Deleted: compounding

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

Deleted: compendial

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist-in-charge, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and

Comment [234]: This eliminates both from being responsible. Replace with pharmacist-in-charge

Deleted: pharmacist performing or supervising

Deleted: the compounding

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packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the pharmacist-in-charge.

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

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). That form contains a first section applicable to all compounding, and a second section applicable to sterile compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code. Add Section 1735.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.3. Records of Compounded Drug Products

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

- (1) The master formula record.
- (2) The date the drug product was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug product.
- (4) The identity of the pharmacist reviewing the final drug product.
- (5) The quantity of each component used in compounding the drug product.
- (6) The manufacturer and lot number of each component. If the manufacturer's name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
- (7) The equipment used in compounding the drug product.
- (8) A pharmacy assigned reference or lot number for the compounded drug product.
- (9) The expiration date of the final compounded drug product.

Comment (B&S): Replace with pharmacy in-charge

Deleted: responsible pharmacist

Comment (B&S): Need to propose amendment by committee or change to pharmacist performing of compounding. Pharmacist responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

Deleted: The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product

Deleted: injectable

Deleted: injectable

(10) The quantity or amount of drug product compounded.

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

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

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

Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

Comment [BB7]: ~~Proper disposition, storage, acquisition and destruction.~~
~~Discretionary important in order to make in case of recall.~~
Deleted: ~~and destruction~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code. Add Section 1735.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.4. Labeling of Compounded Drug Products

- (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy assigned reference, or lot number, and expiration date.

Comment [888]: Use "pharmacy assigned reference or lot number" as in (c) above for consistency.

Deleted: pharmacy reference

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code. Add Section 1735.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.5. Compounding Policies and Procedures

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include the following
 - (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
 - (2) Documentation of a plan for recall of a dispensed compounded drug product.
 - (3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
 - (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

Comment [889]: A plan for recall should be required and not be qualified with "where subsequent verification demonstrates"

Deleted: where subsequent verification demonstrates

Deleted: the

Deleted: potential for adverse effects with continued use of a compounded drug product.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:

Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

Add Section 1735.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.6. Compounding Facilities and Equipment

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturer's specifications.

(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained in a readily retrievable form, in the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code. Add Section 1735.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.7. Training of Compounding Staff

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code. Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

Comment (8810): change wording to maintained in a readily retrievable form as previously used
Deleted: maintained and retained

Add Section 1735.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.8. Compounding Quality Assurance

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

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

Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

Article 7 Sterile, Compounding

Amend Section 1751 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751. Sterile, Compounding; Compounding Area.

(a) Any pharmacy engaged in compounding sterile drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding.

(b) The Any pharmacy doing sterile compounding shall have a designated area for the preparation of sterile products which shall meet the following standards:

- (1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
- (2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
- (3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
- (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
- (5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- (6) A sink shall be included in accordance in with Section 490A.3.4 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
- (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(c) Any pharmacy compounding a sterile product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

Comment [BB11]: Delete reference to injectable throughout the document. Ophthalmic products, irrigation solutions, ointments, and other dosage forms are intended to be sterile. By deleting injectable, all sterile compounding will be included.

Deleted: injectable

Comment [BB12]: same as BB11

Deleted: injectable

Renumber section 1751.3 to new section 1751.1 and amend section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.3-1751.1. Sterile Recordkeeping Requirements.~~

Deleted: injectable

(a) Pharmacies compounding sterile products for future use pursuant to section 1716.1 1735.2 shall, in addition to those records required by section 1716.2 1735.3, have make and keep records indicating the name, pharmacy assigned reference or lot number, amount, and date on which the products were provided to a prescriber.

Deleted: injectable

(b) In addition to the records required by section 1735.3 and subdivisions-(a), for sterile products compounded from one or more non-sterile ingredients, the following records must be maintained for at least three years made and kept by the pharmacy:

- (1) The training and competency evaluation of employees in sterile product procedures.
- (2) Refrigerator and freezer temperatures.
- (3) Certification of the sterile compounding environment.
- (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(5) Documentation of all nonconforming compounded products, nonconforming raw materials, and recalled products shall include item identification, reason for nonconformance, evaluation and disposition.

Comment [2813]: Reword as: Documentation of all nonconforming compounded products, nonconforming raw materials, and recalled products to include item identification, reason for nonconformance, evaluation and disposition. All of this record keeping is important.

(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

(c) Pharmacies shall maintain records of validation processes as required by Section 1751.7

Deleted: Inspection for expired or recalled pharmaceutical products or raw ingredients

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

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code. Amend Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.2. Sterile Labeling Requirements.

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

Deleted: injectable

(a) Telephone number of the pharmacy, except for sterile products dispensed for inpatients of a hospital pharmacy.

Deleted: injectable

(b) Name and concentrations of principle active ingredients contained in the sterile product. (Adding "Principal active" ingredients will make this consistent with section 1735.4. Labeling of Compounded Drug Products)

Deleted: Injectable .

(c) Instructions for storage and handling.

(d) All cytotoxic agents shall bear a special label which states "Chemotherapy -Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code. Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

Renumber section 1751.02 to new section 1751.3 and amend section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.02~~ 1751.3. Sterile Policies and Procedures.

Deleted: injectable

~~(a) Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to: Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements~~

(1) Compounding, filling, and labeling of sterile compounds.

Deleted: injectable

(2) Labeling of the sterile product based on the intended route of administration and recommended rate of administration.

Deleted: injectable

(3) Equipment and supplies.

(4) Training of staff in the preparation of sterile products.

Deleted: injectable

(5) Compounding and handling of cytotoxic agents.

(6) Quality assurance program.

(7) Record keeping requirements.

(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

~~(c) Pharmacies compounding sterile products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

Deleted: injectable

(d) Pharmacies compounding sterile products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

Deleted: injectable

(1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.

(2) All personnel involved must read the policies and procedures before compounding sterile products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.

Deleted: injectable

(3) Policies and procedures must address at least the following:

(A) Staff competency evaluation.

Comment: [BB14] Change to: "Staff competency evaluation for sterile"

(B) Storage and handling of products and supplies.

Deleted: Competency evaluation

(C) Storage and delivery of final products.

(D) Process validation.

(E) Personnel access and movement of materials into and near the controlled area.

(F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).

(G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.

(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

(I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.

(J) Sterilization.

(K) End-product evaluation and testing.

Authority cited: Sections 4006 and 4107, Business and Professions Code. Reference: Sections 4005, 4008, 4007, 4051, 4052, and 4127, Business and Professions Code. Renumber section 1751.01 to new section 1751.4 and amend section 1751.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.01-~~ §1751.4. Facility and Equipment Standards for Sterile Compounding from Non-Sterile Ingredients.

(a) ~~No sterile product shall be prepared, compounded, or~~ No sterile product shall be prepared, 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 for the safe compounding of sterile drug products.

Deleted: injectable

Deleted: injectable

Deleted: injectable

(b) During the preparation of sterile products, access to the designated area or cleanroom must be limited to those individuals who are properly trained and attired.

Deleted: injectable

Comment: BOTS: who are properly trained and attired

(c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.

Deleted: who are properly attired

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

(e) Pharmacies preparing parenteral cytotoxic agents shall be do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Authority cited: Sections 4006 and 4107, Business and Professions Code. Reference: Sections 4005, 4008, 4007, 4051, 4052, and 4127, Business and Professions Code; and Sections 4-1106, 4-1107, 4-1108, 4-1109, 4-1110, 4-1111, 4-1112, 4-1113, 4-1114, 4-1115, 4-1116, 4-1117, 4-1118, 4-1119, 4-1120, 4-1121, 4-1122, 4-1123, 4-1124, 4-1125, 4-1126, 4-1127, 4-1128, 4-1129, 4-1130, 4-1131, 4-1132, 4-1133, 4-1134, 4-1135, 4-1136, 4-1137, 4-1138, 4-1139, 4-1140, 4-1141, 4-1142, 4-1143, 4-1144, 4-1145, 4-1146, 4-1147, 4-1148, 4-1149, 4-1150, 4-1151, 4-1152, 4-1153, 4-1154, 4-1155, 4-1156, 4-1157, 4-1158, 4-1159, 4-1160, 4-1161, 4-1162, 4-1163, 4-1164, 4-1165, 4-1166, 4-1167, 4-1168, 4-1169, 4-1170, 4-1171, 4-1172, 4-1173, 4-1174, 4-1175, 4-1176, 4-1177, 4-1178, 4-1179, 4-1180, 4-1181, 4-1182, 4-1183, 4-1184, 4-1185, 4-1186, 4-1187, 4-1188, 4-1189, 4-1190, 4-1191, 4-1192, 4-1193, 4-1194, 4-1195, 4-1196, 4-1197, 4-1198, 4-1199, 4-1200, 4-1201, 4-1202, 4-1203, 4-1204, 4-1205, 4-1206, 4-1207, 4-1208, 4-1209, 4-1210, 4-1211, 4-1212, 4-1213, 4-1214, 4-1215, 4-1216, 4-1217, 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Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769 8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code, and Section 18944(a), Health and Safety Code.

Repeal Section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.3. Recordkeeping Requirements.~~

~~(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.11735.2 shall, in addition to those records required by section 1716.2-1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:~~

~~(1) The training and competency evaluation of employees in sterile product procedures.~~

~~(2) Refrigerator and freezer temperatures.~~

~~(3) Certification of the sterile compounding environment.~~

~~(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~

~~(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.~~

~~(6) Preparation records including the master work sheet, the preparation work sheet, and records of end product evaluation results.~~

~~(c) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.~~

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

Renumber section 1751.4 to new section 1751.5 and amend section 1751.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.4-1751.5. Sterile Compounding Attire.~~

(a) When preparing cytotoxic agents, gowns and gloves shall be worn.

(b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:

(1) Cleanroom gowning attire, consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.

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Comment [BB15]: Webster says a gown is a style of apparel. Replace with cleanroom gowning attire.

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(2) Cleanroom gowning attire, ~~must~~ be donned and removed outside the designated area.

Comment: PBI 1734 used

(3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.

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Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

(4) Head and facial hair must be kept out of the critical area or be covered.

(5) Gloves made of low-shedding materials are required.

(c) The requirements of this subdivision (b) do not apply if a barrier isolator is used to compound sterile products from one or more non-sterile ingredients.

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Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections

4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.5 to new section 1751.6 and amend section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.5-1751.6. Training of Sterile Compounding Staff, Patient, and Caregiver.~~

Comment [BB18]: Compounding staff, patient and caregiver

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile products and related supplies furnished by the pharmacy.

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(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile drug products shall have training and demonstrated competence in the safe handling and compounding of sterile products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.

Comment [BB19]: title of paragraph should follow title b and c title to match order of other staff

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(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

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(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile products.

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(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

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(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile product compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper gowning and gloving technique.

(G) General conduct in the controlled area.

(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.

(I) Sterilization techniques.

(J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs shall be reassessed every 12 months.

Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

Comment [18820]:

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Results of these assessments must be documented and retained in the pharmacy for three years.

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

Repeal Section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.6. Disposal of Waste Material.

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

~~Authority cited: Section 4005 Business and Professions Code. Reference: Section 4005 Business and Professions Code.~~

Amend 1751.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.7. Sterile Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, There shall be a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

- (1) Cleaning and sanitization of the sterile preparation area.
- (2) The storage of compounded sterile products in the pharmacy and periodic documentation of refrigerator temperature.
- (3) Actions to be taken in the event of a drug recall.
- (4) Written justification of the chosen expiration dates for compounded sterile products.

(b) Each individual involved in the preparation of sterile products must first successfully complete a validation process on technique before being allowed to prepare sterile products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, the sterile preparation process must be reevaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months and whenever the quality assurance program yields an unacceptable

~~Deleted: injectable~~
~~Deleted: injectable~~

~~Comment [BB21]: As written, this limits the section to only products that are injected or infused.~~
~~Deleted: parenteral medication~~
~~Comment [BB22]: n/d.~~
~~Deleted: injectable~~

~~Deleted: injectable~~

~~Deleted: injectable~~
~~Deleted: injectable~~

Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

Result. When the compounding process changes, or whenever improper aseptic techniques are observed, Revalidation of personnel must be documented.

(c) When the equipment used in the compounding of sterile drug products is repaired or replaced, the equipment must be recalibrated. When the facility is modified in a manner that affects airflow or traffic patterns change, the equipment and/or facility shall be recertified.

(d) Batch-produced sterile drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

(e d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code. Renumber section 1751.9 to new section 1751.8 and amend section 1751.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.9.~~ 1751.8. Sterile Compounding Reference Materials.

All pharmacies engaged in compounding sterile drug products shall have current and appropriate reference materials regarding the compounding of sterile products located in or immediately available to the pharmacy.

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

Deletions to the regulatory text are indicated by double strike-through, thus: deleted language. Additions to the regulatory text are indicated by a double underline, thus: added language.

Comment (BB27): It is the individual aseptic process used that undergoes validation of being able to successfully produce sterile products. Equipment, facility modifications, and traffic patterns do not affect the operator. Equipment and facility modifications need to be recertified when changes occur. See paragraph for appropriate revision.

Deleted: equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, o

Deleted: injectable

Deleted: Insectible

Comment (BB24): Replace with: "All pharmacies engaged in sterile compounding shall have current and appropriate reference materials readily available to compounding staff."

Deleted: In any pharmacy engaged in compounding sterile injectable drug products there shall be

Deleted: injectable

Board of Pharmacy**Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Requirements for Pharmacies that Compound

Medications

Sections Affected: Repeal sections

16 CCR 1761.1

16 CCR 1761.2

Add sections

16 CCR 1735

16 CCR 1735.1

16 CCR 1735.2

16 CCR 1735.3

16 CCR 1735.4

16 CCR 1735.5

16 CCR 1735.6

16 CCR 1735.7

16 CCR 1735.8

Amend sections

16 CCR 1751

16 CCR 1751.1

16 CCR 1751.2

16 CCR 1751.3

16 CCR 1751.4

16 CCR 1751.5

16 CCR 1751.6

16 CCR 1751.7

16 CCR 1751.8

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes to repeal sections 1716.1 and 1716.2,

1751.01,

1751.02; add sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6,

1735.7,

1735.8; and amend sections 1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5,

1751.6,

1751.7, and 1751.8 of Division 17 of Title 16 of the California Code of

Regulations.

The purpose for repealing the above sections is to remove duplication between Article 4.5

and Article 7 and to reorganize Article 7 to make it consistent with Article 4.5.

These

requirements are incorporated into section 1735.2

The purposes for adding the above sections is to address, among other items, the

strength, efficacy and quality in compounding, as well as to require a quality assurance

program for general compounding. Currently, there are no provisions that either define

these items for general compounding or set any parameters established in the Pharmacy

law (Business and Professions Code §§ 4000 and following) detailing general compounding by a pharmacy.

The purpose for amending the above sections is to remove redundancies between the

requirements for general compounding and sterile injectable compounding as well as to

ensure consistent sequencing of related requirements contained in both Articles.

This proposal will provide uniformity in compounding for California consumers.

Below is a

summary of each change as well as a brief justification for each change.

Repeal 16 CCR 1716.1 – Compounding Unapproved Drugs for Prescriber Office Use.

The provisions in 1716.1 are now included within other sections including 1735 & 1735.2

of the regulation proposal.

Repeal 16 CCR 1716.2 – Records Requirement – Compounding for Future Furnishing.

The provisions in 1716.2 are now included in other section 1735.3 of the regulation

proposal.

Add 16 CCR 1735 – Compounding in Licensed Pharmacies

This new section will define the activities that constitute. These activities were defined by

the workgroup, which included members of industry, board staff and board members.

Add 16 CCR 1735.1 – Compounding Definitions

This new section defines the terms "integrity", "potency", "quality", and "strength" referenced throughout the regulation proposal for clarity and ease-of-reference.

Add 16 CCR 1735.2 – Compounding Limitations and Requirements

This new section places limitations on the conditions for compounding including anticipatory use. In addition, this section allows for anticipatory compounding under

specified conditions. This section contains the provisions previously contained in section

1716.1 and section 1716.2, which is being repealed in this proposal and specifies the

general requirements for compounding. Those requirements include the requirement to

maintain a master formula, storage requirements and expiration date requirements. In

addition this section now requires the completion of a self-assessment form, which is

Incorporated by reference in this section. This self-assessment form is to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the proposal would

make the pharmacy inspection process more meaningful and provide relevant information to pharmacies and their pharmacist-in-charge (PIC).

Add 16 CCR 1735.3 – Records of Compounded Drug Products

This new section details the pharmacy records requirements for each compounded drug,

record requirements for acquisition, storage and destruction for products used in compounding, specifies that all drug products must be obtained from reliable suppliers and

specifies that all records required must be maintained for at least three years.

Some of

these requirements were previously included in section 1716.2 which is being repealed in

this proposal. It is necessary to require the pharmacy to maintain records for acquisition,

storage and destruction of products to confirm that drug products are obtained from

reliable suppliers, and in the event of a product recall, allow the pharmacy to identify

products affected and remove them from inventory. The records retention period of three

years is consistent with all other pharmacy related records retention throughout pharmacy

law.

Add 16 CCR 1735.4 – Labeling of Compounded Drug Products.

This new section requires that the labeling of the product comply with Business and

Professions Code section 4076 as well as specifies that the labeling requirements for

compounded drugs must include the generic name of the principle active ingredients as

well as a statement that the product is compounded. This requirement provide for full

consumer notification and will enable the consumer to identify any potential allergies to

ingredients used.

Add 16 CCR 1735.5 – Compounding Policies and Procedures

This new section establishes and defines the content of the policy and procedure manual

that must be maintained by a pharmacy that compounds medications. The procedure

manual is necessary to ensure that the pharmacy has established procedures for

procurements, methodologies of the formulation and compounding of drugs as well as

procedures for facilities and equipment cleaning, maintenance and operation.

Add 16 CCR 1735.6 – Compounding Facilities and Equipment

This new section requires that the pharmacy maintain written documentation regarding the

facilities and equipment used and specifies that all equipment (where applicable) shall be

calibrated and the results documented in accordance with the manufacturers' specifications. This is necessary to ensure that equipment used in compounding is used

and maintained appropriately.

Add section 16 CCR 1735.7 – Training of Compounding Staff

This new section requires that the pharmacy maintain written documentation and an

ongoing evaluation process to demonstrate that pharmacy personnel assigned compounding duties are trained and possess the necessary skills. This requirement will

ensure that only qualified personnel compound medicine for California consumers.

Add section 16 CCR 1735.8 – Compounding Quality Assurance

This new section requires that the pharmacy include a written quality assurance plan

designed to monitor and ensure the integrity, potency, quality and labeled strength of

compounded drug products. This section also specifies the required elements of the plan.

This requirement will protect consumers by ensuring that a pharmacy that compounds

medications has an appropriate quality assurance plan in place.

Amend 16 CCR 1751 – Sterile Injectable Compounding – Compounding Area

This section is amended to clarify that pharmacies that compound sterile injectable

products must comply with Article 4.5 and Article 7. This amendment is necessary as

relevant requirements were consolidated into Article 4.5 to remove redundancies within

the two articles.

Amend 16 CCR 1751.1 – Sterile Injectable Recordkeeping Requirements

This section is renumbered from 16 CCR 1751.3 to 1751.1 to conform with the sequence

of similar subject areas of Article 4.5 (16 CCR 1735 – 1735.8).

Amend 16 CCR 1751.2 – Sterile Injectable Labeling Requirements

This section is amended to include the specific labeling requirements contained in

Business and Professions Code section 4076 as well as the labeling requirements

specified in 16 CCR 1735.4 to ensure consistency.

Amend 16 CCR 1751.3 – Sterile Injectable Policies and Procedures

This section is renumbered from 16 CCR 1716.02 and is consolidated to reduce confusion. In addition it was reordered to conform with the sequence of similar subject

areas in Article 4.5. Subsection (c) was moved and slightly modified from former section

16 CCR 1751.1, to consolidate similar provisions.

Amend 16 CCR 1751.4 – Facility and Equipment Standards for Sterile Injectable Compounding

This section is renumbered from 16 CCR 1751.01 and is consolidated with 16 CCR

1751.1. In addition subsection (d) was moved and is slightly modified from former section

16 CCR 1751.1, to consolidate similar provisions.

Amend 16 CCR 1751.5 – Sterile Injectable Compounding Attire

This section is renumbered from former section 16 CCR 1751.4.

Amend 16 CCR 1751.6 – Training of Sterile Injectable Compounding Staff,

Patient and

Caregiver

This section is renumbered from former section 16 CCR 1751.5.

Amend 16 CCR 1751.7 – Sterile Injectable Quality Assurance and Process Validation

This section specifies that any pharmacy engaged in sterile injectable compounding must

include a written quality assurance plan as part of its written policies and procedures and

that batch-produced sterile to sterile transfers are subject to periodic testing through

process validation for sterility as determined by the pharmacist-in-charge and described

in the written policies and procedures. This is necessary to ensure the integrity of compounded product and is an important patient safety measure.

Amend 16 CCR 1751.8 – Sterile Injectable Compounding Reference Materials.

This section is renumbered from former section 16 CCR 1751.9 and was slightly modified

to use consistent language throughout Article 7.

Factual Basis

In 2004 the Board of Pharmacy formed a Workgroup on Compounding comprised of

board members, board staff and industry representatives. The workgroup recognized

that current pharmacy regulations addressing compounding only govern the physical

circumstances, procedures and record keeping requirements for general compounding

and do not address quality, strength or purity.

The Board adopted regulations in Article 7 of Division 17 of Title 16 of the California

Code of Regulations (commencing with Section 1751) to implement provisions for

pharmacies that compound sterile injectable products as required in Business and

Professions (B&P) Code Section 4127. As there are no similar provisions in regulation

for general compounding, this amendment would establish the parameters and provide

uniformity for pharmacies that complete general compounding.

Records, labeling and quality assurance are needed for any product a pharmacy compounds, even if the pharmacy rarely compounds medications. The level of

recordkeeping and quality assurance required, as specified in these regulations, depends upon the frequency and volume of medicine compounded. The

pharmacy that

rarely compounds medicine or does so to a limited extent may provide most of the

recordkeeping on the prescription document itself. When larger volumes of medicine

are compounded, the Board expects more recordkeeping and higher quality assurance.

This proposal distinguishes between the two levels.

The current practice of compounding pharmacies includes the maintenance and documentation of records. This regulation standardizes these general practice

standards for recordkeeping and procedures. This regulation also specifies the quality

assurance process that must be completed to ensure each product meets acceptable

quality, purity, and strength requirements.

Completing the self-assessment form would allow the pharmacist-in-charge (PIC) to

increase the pharmacy's compliance with legal requirements without awaiting board

inspection. The benefit to the public when a pharmacy is in compliance with the law is

significant. ("Wholesaler" is inappropriate)

An inspector conducting an inspection is frequently asked questions regarding aspects of

the inspections as well as clarifications and requirements of pharmacy law. This selfassessment

form would provide an easy reference guide to the PIC when an inspector is not available.

Deleted: wholesaler

Deleted: is

Below is a brief description of the relevant sections of state and federal law. Business and Professions Code section 4005 provides that board with the authority to adopt rules and regulations.

Business and Professions Code section 4036 defines the term "pharmacist".

Business and Professions Code section 4037 defines the term "pharmacy".

Business and Professions Code section 4051 specifies that it is unlawful for any person to manufacture, compound, furnish, sell or dispense any dangerous drug or device or to dispense or compound any prescription pursuant to a prescriber unless he or she is a pharmacist.

Business and Professions Code section 4052 specifies permissible procedures by a pharmacist.

Business and Professions Code section 4059 specifies the conditions for furnishing dangerous drugs and devices upon a prescription as well as exemptions to the requirement.

Business and Professions Code section 4076 specifies the labeling requirements for prescription containers.

Business and Professions Code section 4081 specifies the requirements for records of dangerous drugs and devices.

Business and Professions Code section 4127 requires the board to adopt regulations establishing standards for sterile injectable compounding.

Business and Professions Code section 4127.7 specifies the requirements for compounding sterile injectable products from nonsterile ingredients.

Business and Professions Code section 4332 specifies that it is a misdemeanor to fail or refuse to maintain or produce records.

Health and Safety Code section 18944 requires state agencies to adopt regulations for

publication in titles of the CCR containing other regulations of that agency to identify, the

appropriate sections of the California Building Standards Code.

Underlying Data

This proposal is based upon recommendations from the Workgroup on Compounding as

well as public comment to those recommendations at several board meetings and

Licensing Committee Meetings:

(1) Minutes from Compounding Workgroup Meeting - March 3, 2004

- (2) Minutes from Compounding Workgroup Meeting - June 9, 2004
- (3) Minutes from Compounding Workgroup Meeting - September 22, 2004
- (4) Minutes from Compounding Workgroup Meeting - December 1, 2004
- (5) Minutes from Board Meeting - January 19 & 20, 2005

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 Board of Pharmacy is aware that pharmacies that compound medicine will incur the

cost of end-product testing. The estimated costs for such testing are about \$100.00 per

test. This is a one-time cost as long as the compounding process remains the same. The economic impact on pharmacies can be significant. A cost of \$100 per test may be a close approximation. However, in order to establish a valid Beyond Use Date multiple tests will need to be performed. At a minimum, potency will need to be determined at time zero and at the end of the Beyond Use Date established by the pharmacist. For a pharmacy that compounds 100-200 significantly different preparations, the economic impact on a pharmacy will amount to tens of thousands of dollars.

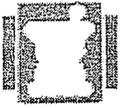
Specific Technologies or Equipment

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.



Virginia
Herold/Pharmacy/DCANotes
03/09/2009 12:39 PM

To Carolyn Klein/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Fw: Comments Regarding Compounding Regulations

----- Forwarded by Virginia Herold/Pharmacy/DCANotes on 03/09/2009 12:42 PM -----



"Alan Endo"
<AEndo@pih.net>
03/09/2009 11:35 AM

To <virginia_herold@dca.ca.gov>
"Philip Swanger" <philip@swangermanagement.com>,
"Dawn Benton" <dbenton@cshp.org>, "William Yee"
cc <william.yee@chw.edu>, <Scott.H.Takahashi@kp.org>,
"Nancy Korman" <nancy.korman@va.gov>
Subject Comments Regarding Compounding Regulations

Hi Virginia,

I have reviewed the document with the changes to the Compounding Regulations and made the following comments and suggestions. I have also attached my previous letter as a reference.

I have also CC'ed CSHP in my response only for follow up. The comments that are made are totally my own as a concerned practicing pharmacist.

Thank you for your consideration,

Alan Y. Endo, Pharm.D., FCSHP

Pharmacy Director

PresbyterianIntercommunityHospital

12401 Washington Blvd.

Whittier, CA90602

(562) 698-0811, Ext. 2804

Email: aendo@pih.net



12401 Washington Boulevard
Whittier, California 90602-1099
(562) 698-0811
Hearing Impaired TDD (562) 696-9267

Board of Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834

March 9, 2009

Dear Sir or Madame:

This is in response to the proposed revision of the Requirements for Compounding, Article 4.5. Please see my initial recommendations to this rule change and I have included some additional comments.

Section 1735.c, has included an exception which is not clear. If the drug is commercially available or a copy of a commercially available drug, why should it be excepted? What specific circumstances is this referring to?

Section 1735.2, f, refers to a pharmacist supervising compounding but does not refer to who they would be supervising. I would like to recommend that the regulation specifically identify trained pharmacy technicians into the language of this regulation.

Section 1735.3,c, states "Certificates of purity or analysis are not required for drugs products that are approved by the Food and Drug Administration". Can you clarify this, since chemicals are approved for compounding by the United States Pharmacopeias or the Nation Formulary. Does this qualify as an approved drug by the FDA?

Section 1735.4, b, has language that "A statement that the drug has been compounded by the pharmacy" be included in the labeling. This should not apply for compounded agents made specifically for patient in the inpatient setting with the exception to read "except for sterile injectable products dispensed for inpatients of a hospital pharmacy".

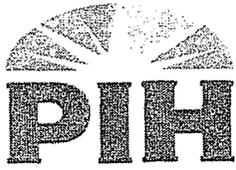
Section 1751.7, c, the term "Batch-produced sterile injectable drug products" needs to be defined. If this means product that will be used in the future, I would agree. If this refers to product that will be use the next day for specific patient in the hospital, I don't think this is necessary.

I hope that you will consider my concerns and I would be happy to discuss any of my comments with you if you would like to contact me.

Thank you for the consideration,

Sincerely,

Alan Endo, Pharm. D., (RPh 27276)
Pharmacy Director
(5620 698-0811, Ext. 2804



Presbyterian
Intercommunity
Hospital

12401 Washington Boulevard
Whittier, California 90602-1099
(562) 698-0811
Hearing Impaired TDD (562) 696-9267

September 30, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento, California 958834

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Herold:

I have commended and supported the California Board of Pharmacy for their previous and current efforts to strengthen the regulations surrounding pharmacists that compound medications. However, I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to compounded IV medications in acute care hospitals.

In the past, there has always been a clear distinction between prescription compounding and manufacturing. Trying to apply manufacturing practices to an acute care setting can seriously jeopardize the hospital pharmacist's ability to respond to the acute needs of their patients. Clearly, the workflow process to manufacturer in bulk versus the compounding of sterile products for individual patient prescriptions are distinctly different in their response time and the need for timely administration to the patient.

I would highly recommend that the Board accept the recommended changes of the California Society of Health-System Pharmacists or create a working group of practicing hospital pharmacists and create a safe and workable process that will insure the ability of the hospital pharmacists to be responsive and responsible to safe guarding the protection of the patient. Creating regulations that mandate the same practice in all pharmacy practice arenas does not serve the specific needs of all of our patients.

If you have any questions, please do not hesitate to contact me at (562) 698-0811, Extension 2804.

Respectfully,

Alan Y. Endo, Pharm. D.
Pharmacy Director
RPh 27276



Virginia
Herold/Pharmacy/DCANotes
03/12/2009 02:18 PM

To Carolyn Klein/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Fw: Proposed Change in Sterile Compounding Language

----- Forwarded by Virginia Herold/Pharmacy/DCANotes on 03/12/2009 02:20 PM -----



Steve.W.Gray@kp.org
03/12/2009 02:17 PM

To Virginia_Herold@dca.ca.gov
cc Anne_Sodergren@dca.ca.gov
Subject Fw: Proposed Change in Sterile Compounding Language

Ginny

I completely agree with Don's assessment. Weekly cleaning of that intensity is NOT necessary when the pharmacist is NOT compounding from NON-sterile ingredients.

We are sorry we did not emphasize this point enough in our earlier submissions but we feel strongly that it would not add significantly to patient safety to have weekly vs. monthly intense cleanings unless the compounding includes non-sterile ingredients. Further, its inclusion will cause substantial unnecessary costs, delays and frustration to the care of hospital and other patients. Otherwise this would be a four+ fold increase in the necessary intense cleanings.

Such cleanings have to be done when the area is "shut down". Since it is inside a pharmacy, a pharmacist must be on duty when environmental services personnel perform such work. Such requirements could even stimulate some less-than-100 bed hospitals to eliminate pharmacist services.

Please ask the Board to make this change. Perhaps it was just a clerical change omission that could be incorporated without another comment period. If not, it is well worth the effort and delay to have it changed.

Steven W Gray, PharmD, JD
Kaiser Permanente, California Pharmacy Regulatory Compliance and Professional Affairs Leader

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----- Forwarded by Steve W Gray/CA/KAIPERM on 03/12/2009 02:05 PM -----

Donald R Kaplan/CA/KAIPERM

03/04/2009 08:41 AM

To Steve W Gray/CA/KAIPERM@KAIPERM
cc
Subject Fw: Proposed Change in Sterile Compounding Language
ct

Steve -

Here is the proposed change in compounding language I mentioned to you on the phone yesterday. This is language

that is supposedly not subject to further review, because it was not double underlined or double crossed out - but represents a serious error in the Board's efforts to consolidate some compounding language. Virginia Herold indicated to me after the BOP meeting on Mon. 3/2 that the Board could reconsider this. Please forward this to her.

Thanks,
Don K.

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----- Forwarded by Donald R Kaplan/CA/KAIPERM on 03/04/2009 08:37 AM -----

Doug C O'brien/CA/KAIPERM

03/03/2009 07:44 PM

To Donald R Kaplan/CA/KAIPERM@KAIPERM
cc
Subject Re: Proposed Change in Sterile Compounding Language
[Link](#)

Thanks Don,

It looks Great.

Doug

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Donald R Kaplan/CA/KAIPERM

03/03/2009 04:04 PM

To Doug C O'brien/CA/KAIPERM@Kaiperm
cc
Subject Proposed Change in Sterile Compounding Language

Doug - Check this out. Your thoughts before I send this to Steve Gray?

Don

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- Proposed Changes BOP Cmpding Language 3-09.doc

Proposed Language Citation # & Page #	Concern	Recommended Language Change
1751.4 (d)	<p>According to the Initial Statement of Reasons published by the Board, this section was renumbered from CCR 1751.01 and was consolidated with CCR 1751.1.</p> <p>Consolidating this language is incorrect.</p> <p>CCR 1751.01 applied to Sterile Injectable Compounding from Non-Sterile Ingredients. The importance of more stringent facility and equipment standards for compounding sterile products from non-sterile ingredients is well established. The proposed 1751.4 applies to all sterile injectable compounding, regardless of whether the ingredients were sterile or non-sterile. This proposed language applies these stringent standards to compounding sterile products from sterile ingredients, which is not supported by USP <797>.</p> <p>We are therefore proposing that the frequency of surface cleaning correspond to the risk level of sterile compounding being performed. We are using language adapted from USP <797>.</p>	<p>Proposed change to language:</p> <p>(d) Counters and easily cleanable work surfaces and floors must be disinfected daily. Walls, ceilings and storage shelving must be disinfected monthly. These surfaces must also be disinfected after any unanticipated event that could increase the risk of contamination.</p> <p>(e) When preparing sterile products from non-sterile ingredients, counters and easily cleanable work surfaces and floors must be disinfected daily. Walls, ceilings and storage shelving must be disinfected weekly. These surfaces must also be disinfected after any unanticipated event that could increase the risk of contamination.</p> <p>Move existing item regarding preparing cytotoxic agents to be new item (f)</p>



St. Joseph's Medical Center

A member of CHW

BOARD OF P

2009 MAR 17 10:40

Pharmacy Department
1800 N. California St.
Stockton, CA 95204
(209) 467-6518
(209) 461-6890 fax

March 12, 2009

Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Klein,

I am writing to you regarding the proposed text of Section 1735 of Division 17 of Title 16 of the California Code of Regulations. As a pharmacist practicing in a busy inpatient hospital setting, I am concerned that there is unclear language in the proposed regulation and request that the following issues be addressed.

I believe the intent of the regulation is to define and set quality assurance parameters for compounding in an outpatient setting, but the current proposal language does not make that distinction. The proposed self-assessment tool is titled "Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment," suggesting that the regulation applies only to outpatient pharmacies in hospitals. The language in the regulation itself, however, suggests any licensed pharmacy. It would be preferred that the language be made specific to hospital outpatient pharmacies and exclude inpatient hospital pharmacies.

In Section 1735(a) and 1735(b), the definition of compounding includes "Altering the dosage form or delivery system of a drug" and "Altering the strength of a drug." Would attaching a vial to a piggyback using a device such as the Add-Ease connector be considered compounding? Does adding the entire contents of a vial of drug to a piggyback in accordance with the manufacturer's guidelines equate to altering the strength of a drug? I would suggest that these practices are not compounding and should be exempted from the definition of compounding.

Section 1735.3(a)(7) sets a requirement for documenting all equipment used in compounding the drug product. It is unclear whether equipment such as needles, syringes, dispensing pins, alcohol swabs, etc., are considered equipment that needs to be documented. If so, this sets a very unrealistic expectation that is of questionable benefit.

Section 1735.3(d) requires pharmacies to maintain records the compounded products for at least three years. In an average hospital inpatient pharmacy, hundreds of IVs are made daily and used within 24 hours. Adding this level of documentation to the inpatient workflow would be daunting. While an electronic file system may alleviate storage issues, it does not address the sheer quantity of documentation required by the proposed regulation.



St. Joseph's Medical Center

A member of CHW

Pharmacy Department
1800 N. California St.
Stockton, CA 95204
(209) 467-6518
(209) 461-6890 fax

I urge the Board of Pharmacy to consider these issues before finalizing this regulation. The current language in the regulation makes no distinction between inpatient and outpatient pharmacies, and the definition of compounding is broad enough to be interpreted several ways. To reiterate, the proposed regulation as currently worded adds a great deal of additional work with little to no benefit in terms of protecting the public.

Sincerely,

Katherine Lee, Pharm.D.
Clinical Pharmacist
St. Joseph's Medical Center



California Pacific
Medical Center

A Sutter Health Affiliate

STATE BOARD OF PHARMACY

2009 MAR 13 PM 3:51

Gary Louie, Pharm.D.
2333 Buchanan St.
San Francisco, California 94115
louieg@sutterhealth.org

March 10, 2009

Board of Pharmacy
Attn: Carolyn Klein, Manager, Legislation and Regulation
1625 N. Market Blvd. N219
Sacramento, CA 95834
carolyn_klein@dca.ca.gov

Re: Proposed Regulations - Article 4.5 General Compounding

Dear Ms Klein:

I am very concerned with the sweeping changes proposed to the compounding and documentation of **sterile injectable** products. As I understand it, the California Board of Pharmacy was originally tasked to strengthening compounding practice and safety for **"traditional"** compounding. This area of pharmacy practice lacks specific regulation to adequately protect patients. Additional regulation is needed in the area of "traditional" compounding. Unfortunately, the proposed regulations have crept into an area that is out of scope and fully regulated. My concern is that **sterile injectable** compounding should not be lumped together with the **"traditional"** form of compounding. Current regulations regarding **sterile injectable** compounding are very specific and detailed from both the United States Pharmacopeia (USP) Convention guidelines at the federal level and current state BOP regulations.

There has been no documentation offered that shows changing compounding regulations for **sterile injectable** products will have any impact to patient care. Current regulations in California code and USP provide adequate safeguards and documentation. Adding regulations for additional documentation to **sterile injectable** products that will be administered within the next 24 hours is not only labor intensive but offers no benefits or clear value. The addition of thousands of records per day per site will have NO impact to patient safety or any recall process.

I am additionally concerned patient care may be jeopardized by the additional documentation requirements suggested for **sterile injectable** compounding if lumped together with **"traditional" non-sterile** compounding. The added workload of this documentation will reassign pharmacy staff away from other patient care functions. Unfortunately this new workload has not been shown to benefit the patient, while other clinical programs and patient care activities with clear documented patient benefit would be decreased or eliminated.

I suggest **sterile injectable** and **non-sterile** compounding remain in separate regulations. Current California regulations, Article 7 Section 1751 (Sterile Injectable Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug

California Campus
3700 California Street

Castro & Duboce Streets

San Francisco, California 94127
415.600.6000

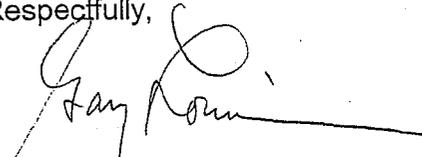
Pacific Campus
2333 Buchanan Street

Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug Products) cover the issues related to **sterile injectable** compounding. These current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) to assure patient safety. In addition, the Board requires additional licensure or accreditation of pharmacies to perform the functions of **sterile injectable** compounding. Changes or additional regulations to these sections are NOT needed.

The requirements for the safe preparation of **sterile injectable** and "**traditional**" **non-sterile** products are distinctly different. The United States Pharmacopeia (USP) regulates these processes separately in 2 distinct chapters. USP 797 deals with Pharmaceutical Compounding – Sterile Preparations and USP 795 deals with Pharmaceutical Compounding – Nonsterile Preparations.

Thank you for considering these issues. I ask that the Board address the patient safety needs of "**traditional**" **non-sterile** compounding and move forward on those regulations. This is urgently needed. There is no need to change the current status and regulations for **sterile injectable** compounding.

Respectfully,



Gary Louie, PharmD
Director of Pharmacy Services
California Pacific Medical Center



California Pacific
Medical Center

A Sutter Health Affiliate

BOARD OF PHARMACY

2009 MAR 11 PM 3:23

Andrée S. Hest, RPh, MScPharm
2333 Buchanan Street
San Francisco, CA 94115
hesta@sutterhealth.org

March 10, 2009

Board of Pharmacy
Attn: Carolyn Klein, Manager, Legislation and Regulation
1625 N. Market Blvd. N219
Sacramento, CA 95834
carolyn_klein@dca.ca.gov

Re: Proposed Regulations - Article 4.5 General Compounding

Dear Ms Klein:

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There has been no documentation offered that shows changing compounding regulations for **sterile injectable** products will have any impact to patient care. Current regulations in California code and USP provide adequate safeguards and documentation. Adding regulations for additional documentation to **sterile injectable** products that will be administered within the next 24 hours is not only labor intensive but offers no benefits or clear value. The addition of thousands of records per day per site will have NO impact to patient safety or any recall process.

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I suggest **sterile injectable** and **non-sterile** compounding remain in separate regulations. Current California regulations, Article 7 Section 1751. (Sterile Injectable Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug Products) cover the issues related to **sterile injectable** compounding. These current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) to assure patient safety. In addition, the Board requires additional licensure or accreditation of pharmacies to perform the functions of **sterile injectable** compounding. Changes or additional regulations to these sections

California ~~are NOT needed.~~
3700 California Street

Davies Campus
Castro & Duboce Streets

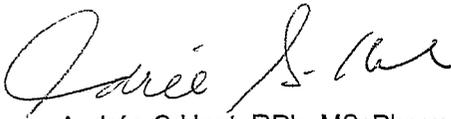
P. O. Box 7999
San Francisco, California 94120
415.600.6000

Pacific Campus
2333 Buchanan Street

The requirements for the safe preparation of **sterile injectable** and "**traditional**" **non-sterile** products are distinctly different. The United States Pharmacopeia (USP) regulates these processes separately in 2 distinct chapters. USP 797 deals with Pharmaceutical Compounding – Sterile Preparations and USP 795 deals with Pharmaceutical Compounding – Nonsterile Preparations.

Thank you for considering these issues. I ask that the Board address the patient safety needs of "**traditional**" **non-sterile** compounding and move forward on those regulations. This is urgently needed. There is no need to change the current status and regulations for **sterile injectable** compounding.

Respectfully,



Andrée S. Hest, RPh, MScPharm
Director of Pharmacy Services
California Pacific Medical Center

STATE OF CALIFORNIA
BOARD OF PHARMACY

2009 MAR 10 AM 9:14

March 4, 2009

Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd., Suite N 219
Sacramento, CA 95834

Dear Members of the California State Board of Pharmacy:

As a pharmacy director in the Catholic Healthcare West system, I am vitally interested in patient safety. While regulation and mandates from various regulatory organizations have done much to improve our care, I believe your modifications to the text of section 1735.5 in Title 16 Cal. Code Reg. does not improve the care delivered in California's Joint Commission Accredited Hospitals. In addition, the record-keeping required by the changes will add burden and expense to our licensed hospital pharmacies without positively impacting patient care.

It is my assumption that our Board of Pharmacy has re-written these rules to, appropriately, control compounding in the outpatient setting. I have no problem with implementing these rules in that area. However, to expect that every admixture bag mixed in a hospital pharmacy will follow the same rules is time consuming and not productive to the end of improving patient safety.

I ask that you consider excluding Joint Commission Accredited institutions from these rules. Hospitals are already mandated by the Board of Pharmacy, the California Department of Public Health, TJC, USP <797> etc. to utilize high standards in the compounding of admixtures and the absence of literature to support any assertion that hospitalized patients are at risk of infection leads me to conclude that the steps you are about to mandate would add unnecessary cost to an already difficult healthcare environment.

Thank you for your time and consideration.

Inaya Hazime, Pharm.D.

Inaya Hazime, Pharm.D.
Director of Pharmacy
Methodist Hospital of Sacramento
7500 Hospital Drive
Sacramento, Ca 95823



Carolyn
Klein/Pharmacy/DCANotes
03/09/2009 04:16 PM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Fw: Dawn Benton's Letter

I've added the email below to those responses received during the 15-day comment period for Compounding.

Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, California 95834
Phone (916) 574-7913
Fax (916) 574-8618
Carolyn_Klein@dca.ca.gov

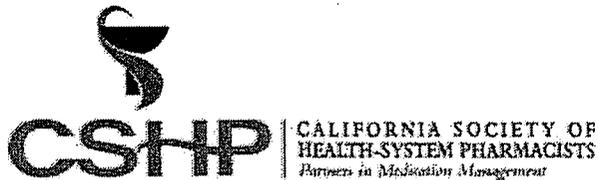
----- Forwarded by Carolyn Klein/Pharmacy/DCANotes on 03/09/2009 04:18 PM -----



"Maurino, Ed"
<Ed.Maurino@bannerhealth.com>
03/09/2009 04:09 PM

To <carolyn_klein@dca.ca.gov>
cc <dawn@cshp.com>
Subject Dawn Benton's Letter

Dawn's letter about the Board of Pharmacy's proposed record keeping for compounded sterile products is right on track. The record keeping would be immense for very little, if any, benefit to the patient. This is clearly further example of our health care system on the brink of financial disaster. A retrospective look after the fact? What benefit is that? Most hospitals do a very good job compounding sterile IV's. What percentage of harm comes knowing that California make millions of CSP's every day? Please heed the points made in Ms. Benton's letter and stop the madness. Thank you.
Ed Maurino RPh. FCSHP, Pharmacy Manager, Banner Lassen Medical Center, Susanville, California, 96130, 530-252-2161 I am a California Pharmacy license holder for 30 years.



1314 H Street, Suite 200, Sacramento, CA 95814 • Phone: (916) 447-1033 • Fax: (916) 447-2396

March 9, 2009

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834
Virginia_Herold@dca.ca.gov

**Re: 15-Day Comment Period Proposed Requirements
for Pharmacies that Compound Medications**

Dear Ms. Herold:

The California Society of Health-System Pharmacists (CSHP) would like to thank the California Board of Pharmacy (board) for the changes made to section 1735.3(a)(6) that exempts the manufacturer and lot number of each component if the sterile product is compounded "on a one-time basis for administration within two hours to an inpatient in a health care facility..." CSHP believes this exemption will help to prevent delay of medications to patients with immediate and urgent needs, but nonetheless still questions the **necessity** of including any inpatient pharmacy currently covered by Article 7: Sterile Injectable Compounding also under the proposed Article 4.5: Compounding regulations. Furthermore, there are additional concerns our membership has raised in regards to the compounding regulations.

It should be noted that CSHP has been extremely active throughout the multiple rulemaking files the board has opened in regards to the proposed compounding language. Below you will find a brief history of action taken by CSHP with regard to this issue:

- **June 8, 2007** – CSHP submitted a letter and provided comment requesting that sterile and non-sterile compounding regulations be contained in separate regulatory sections. The primary reason for this request was to ensure clarity between these two very different compounding practices and imitate the current compounding requirement standards set forth by the United States Pharmacopeia (USP) 797, which contains sterile and non-sterile compounding information in two different chapters.
- **December 20, 2007** – CSHP submitted a letter and provided public comment requesting an exemption of immediate and one-time use (STAT) compounded drugs from the recordkeeping requirements in proposed Article 4.5, Section 1751.1: Sterile Injectable Recordkeeping Requirements. CSHP's primary concerns were that the additional recordkeeping requirements, with little benefit to improving patient safety, would delay patient care for individuals in need of immediate and one-time use medications.
- **September 17, 2008** – CSHP submitted a letter and provided public comment requesting an exemption of immediate and one-time use (STAT) compounded drugs from the recordkeeping and labeling requirements in proposed compounding regulations.

In response to CSHP's concerns, the board formed a 2-person subcommittee in October 2008 to evaluate the requested recordkeeping exemption pertaining to the pharmacy assigned lot number for immediate and one-time use sterile injectable products. In January 2009, the recommendation of the board subcommittee was to exempt the need to track manufacturer and lot number for each immediate and one-time use sterile injectable product; although the pharmacy assigned lot number is still required in immediate and one-time use sterile injectable products. CSHP hopes this is an oversight of the board and can be corrected by also exempting the pharmacy assigned lot number in urgent situations.

Upon further discussion among CSHP members, we have also discovered more issues with regard to the proposed regulatory language and request that the following issues be addressed to both the proposed regulation and the self-assessment:

- In an average hospital inpatient pharmacy, hundreds of IVs are made daily. Adding this level of documentation to the workflow and requiring its storage for 3 years as stated in 1735.3(d) would create a bookkeeping challenge. While an electronic file system would alleviate storage issues, it does not address the sheer quantity of documentation. Obviously, this has a serious impact on small/rural hospitals.
- The self-assessment is titled "COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT." This term hospital outpatient pharmacy suggests that the regulation applies only to outpatient pharmacies in hospitals. However, the language in the regulation suggests any licensed pharmacy. It would be preferred that the language be specific to hospital outpatient pharmacies and exclude inpatient hospital pharmacies.
- Section 1735.3(a)(7) sets a requirement for documenting all equipment to be used in compounding the drug product. It is unclear whether it is mandated that equipment such as needles, syringes, dispensing pins, IV hood, etc. are considered equipment. If so, this sets an unrealistic expectation that would be of questionable benefit. For example, preparing a single IVPB could theoretically require the following elements:

<p>Equipment used: 1-ceftriaxone 1gm vial (Roche) Lot: 1234 Exp: 9/99 1-D5W 50ml IVPB (Baxter) Lot: 1234 Exp: 9/99 1-alcohol swab 1-18 gauge needle 1-10 ml syringe 1-foil seal 1-laminar flow hood</p> <p>Prepared by: John Smith, pharmacy technician 3/5/09 1900. Inspected by: Mary Jones, PharmD. 3/5/09 2000.</p> <p>Internal lot number: 99999</p> <p>Expires: 3/9/09 1900.</p>

- Section 1735(a)(2) and 1735(b) includes the definition of compounding to include "Altering the strength of a drug." CSHP questions whether adding the entire contents of a vial of drug to a piggyback in accordance with manufacturer's guidelines equate to altering the strength of a drug? Does placing the entire contents of a vial into a piggyback suggest reconstitution? CSHP would recommend that this type of practice NOT constitute compounding and that this be exempted from the definition of compounding.

CSHP urges the Board of Pharmacy to consider these exemptions as the proposed requirements add additional work to a hospital pharmacy while providing unclear benefit to the patient.

Additionally, the intent of the proposed rulemaking seems to be documenting the practice of mass compounding in the event of a potential safety recall. However, in the inpatient hospital setting, a substantial majority of IV admixtures involves small batches that are generally used within 24 hours. Any recall of a product would be unlikely to be tracked in these small batches. **To reiterate, this proposed regulation adds additional work to pharmacy staff without justifiable benefit in terms of protection the public.**

Founded in 1962, CSHP is a professional society representing more than 4,000 pharmacists, pharmacy technicians, and associates who serve patients and the public by promoting wellness and the best use of medications. CSHP members practice in a variety of organized health care settings including, but not limited to hospitals, integrated healthcare systems, clinics, home health care and ambulatory settings.

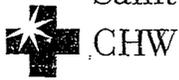
If you have any questions, please do not hesitate to contact me at (916) 447-1033 or CSHP's Legislative Advocate Bryce Docherty at (916) 446-4343.

Respectfully,



Dawn Benton
Executive Vice President, CEO

cc. Bryce Docherty



Saint Francis Memorial Hospital

900 Hyde Street
San Francisco, CA 94109
(415) 353-6000 Telephone

R
B
CALIFORNIA BOARD OF PHARMACY
2009 MAR 10 PM 2:23

March 4, 2009

Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd., Suite N 219
Sacramento, CA 95834

Dear Members of the California State Board of Pharmacy:

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It is my assumption that our retail-focused Board of Pharmacy has re-written these rules to, appropriately, control compounding in the outpatient setting. I have no problem with implementing these rules in that area. However, to expect that every admixture bag mixed in a hospital pharmacy will follow the same rules is busy work, time consuming and not productive to the end of improving patient safety.

I ask that you consider excluding Joint Commission Accredited institutions from these rules. Hospitals are already mandated by the Board of Pharmacy, the California Department of Public Health, TJC, USP <797> etc. to utilize high standards in the compounding of admixtures and the absence of literature to support any assertion that hospitalized patients are at risk of infection leads me to conclude that the steps you are about to mandate would add unnecessary cost to an already difficult healthcare environment.

Thank you for your time and consideration.

Ray Miller, Pharm.D.
Director of Pharmacy
Saint Francis Memorial Hospital
900 Hyde Street
San Francisco, CA 94109
(415) 353-6451
ray.miller@chw.edu

Maria D. Serpa, Pharm.D.
6744 Paseo Del Sol
Elk Grove, California 95758
serpam@sutterhealth.org

March 9, 2009

Board of Pharmacy
Attn: Carolyn Klein, Manager, Legislation and Regulation
1625 N. Market Blvd. N219
Sacramento, CA 95834
carolyn_klein@dca.ca.gov

Re: Proposed Regulations - Article 4.5 General Compounding

Dear Ms Klein:

I am very concerned with the sweeping changes proposed to the compounding and documentation of **sterile injectable** products. As I understand it, the California Board of Pharmacy was originally tasked to strengthening compounding practice and safety for **"traditional"** compounding. This area of pharmacy practice lacks specific regulation to adequately protect patients. Additional regulation is needed in the area of **"traditional"** compounding. Unfortunately, the proposed regulations have crept into an area that is out of scope and fully regulated. My concern is that **sterile injectable** compounding should not be lumped together with the **"traditional"** form of compounding. Current regulations regarding **sterile injectable** compounding are very specific and detailed from both the United States Pharmacopeia (USP) Convention guidelines at the federal level and current state BOP regulations.

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Thank you for considering these issues. I ask that the Board address the patient safety needs of "**traditional**" **non-sterile** compounding and move forward on those regulations. This is urgently needed. There is no need to change the current status and regulations for **sterile injectable** compounding.

Respectfully,

Maria D. Serpa, PharmD



American Society of
Health-System Pharmacists®

7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-664-8892
www.ashp.org

March 13, 2009

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

RE: Proposed Modifications to Title 16, Section 1735.3(a) of the California Code of Regulations

Dear Ms. Herold:

The American Society of Health-System Pharmacists (ASHP) has received notification of the proposed modifications to section 1735.3(a)6 of Title 16 of the California Code of Regulations and is pleased to submit the following comments. We appreciate the Board's efforts to modify the current regulatory language, as we all seek to preserve patient safety and ensure that pharmacy practice continues to evolve and develop. Having reviewed the modified language, we do believe that the proposed exemption is in the best interest of all parties and support the adoption of such language. However, we are concerned that there is an overall focus on documentation that is impractical for inpatient situations, leading to a reduction in patient care and the effective and timely delivery of medication.

As the national professional association representing over 35,000 pharmacists who practice in hospitals and health systems, ASHP offers unique and vital feedback on this important health-care issue. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely, effectively, and in a cost-conscious manner. As an essential duty of the pharmacist, the issue of compounding and its impact on patient safety is one that we consider to be of paramount concern.

The proposed exemption in section 1735.3(a)6, is one that we, along with our affiliate, the California Society of Health-System Pharmacists, support. By exempting "sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility," we believe that the potential delay to patients with

urgent medication needs will be avoided. This is in the best interest of our patients and we applaud the Board's decision to modify the language.

We would urge the Board to continue to be mindful of the potential implications of other proposed modifications to the regulations. While it is imperative to provide appropriate and necessary parameters around the practice of compounding, it is equally vital that the pharmacist continues to be empowered and retains the necessary flexibility to decide what is best for each individual patient. As the medication expert in the health care environment, we need to balance the value of documentation with a recognition that onerous requirements may lead to delay in care and have a negligible impact on patient safety. Especially in hospital settings, compliance with labeling requirements that are more akin to manufacturing best practices would be, at best, time consuming and, at worst, have a direct negative impact on patient care. Such an expectation of documentation could be onerous on any size hospital. When you consider the impact of such regulation on the workforce in smaller and rural hospitals, the ramifications could be not only unreasonable but unmanageable.

Documentation is clearly an important step in the delivery of any medication. Lot numbers are recorded for large batches, a practice that is reasonable. However, recording lot numbers for small or individual compounds that are administered immediately or within 24-hours is a requirement that removes the focus of the pharmacy from patient care and effective delivery to documentation. We would question the value of such language, from both a workforce perspective as well as that of patient safety and delivery of care.

There also continues to be confusion as to whether the documentation requirement applies to every product that is prepared, including those for an individual patient, or if the new requirement will apply solely to those products that are prepared in batch for a yet-to-be determined patient. As pharmacies typically do not record such detailed information for patient-specific items, such a proposed regulation could create an extraordinary burden for pharmacies. Not only could this new requirement exist for emergency drugs, it could impact all products prepared for routine care. This added documentation requirement has the potential to delay the preparation and delivery of one-time and immediate-use medications. We would urge the Board to consider the potential implications of such a regulatory change.

Again, we applaud the Board's intent to modernize the regulations and its recognition to exempt the sterile compounds for immediate use. In principle, documentation is a good thing. We would recommend that the Board continue to assess how documentation is being currently achieved and to seriously consider the consequences of requiring hospitals to rapidly divert scarce resources into documentation, rather than critical patient care services. It may be worthwhile, as this process continues to move forward, to consider a phased-in approach, with defined milestones and deadlines, should you continue to proceed with the current proposed language.

California Board of Pharmacy
Proposed Modifications to Title 16, Section 1735.3(a)6
March 13, 2009
Page 3

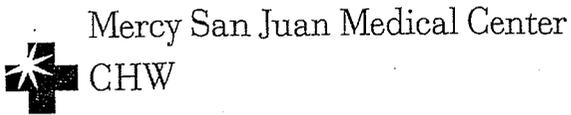
We appreciate the opportunity to provide these comments and would be happy to work with you as you continue to develop appropriate guidelines and requirements that affect the pharmacy profession. If you have any questions or comments, please do not hesitate to contact me at 301-664-8687 or gtrujillo@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Geralyn M. Trujillo". The signature is written in black ink and is positioned above the typed name and title.

Geralyn M. Trujillo, MPP
Director, State Government Affairs

cc: Dawn Benton, California Society of Health-System Pharmacists



Department of Pharmacy Services
6501 Coyle Avenue
Carmichael, CA 95608
Telephone (916) 537-5280

March 10, 2009

Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Klein,

I am a practicing pharmacist in a hospital setting, and I am writing to you to comment on the proposed modifications to the text of section 1735.5 in Title 16 CCR.

I am supportive of the changes made to the proposed regulation to section 1735.3(a)(6), which now exempts the manufacturer and lot number of each component if the sterile product is compounded "on a one-time basis for administration within two hours to an inpatient in a health care facility..."

However, I am concerned that there is still unclear language in the proposed regulation and request that the following issues be addressed in both the proposed regulation and the self-assessment.

- The self-assessment is titled "COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT". The term "hospital outpatient pharmacy" suggests that the regulation applies only to outpatient pharmacies in hospitals. However, the language in the regulation suggests any licensed pharmacy. I believe that the language should be specific to hospital outpatient pharmacies and exclude inpatient hospital pharmacies.
- Section 1735(b)(1) defines compounding as "Alerting the dosage form or delivery system of a drug." This statement is not clear. Does compounding include the use of Add-a-Vials where the vial is attached to a piggyback using a connector? My suggestion would be to clarify the language and specifically exempt the use of Add-a-Vials from the definition of compounding.
- Section 1735(a)(2) and 1735(b) includes the definition of compounding to include "Altering the strength of a drug". Again, this statement is not clear. My recommendation is to clarify the statement and to exempt the practice where the entire content of a drug vial is added to a piggyback.
- Section 1735.3(a)(7) sets a requirement for documenting all equipment to be used in compounding the drug product. It is unclear if equipment such as needles, syringes,

March 11, 2009

Page 2

dispensing pins, IV hood, etc. is considered equipment and must be on the product label. If this is true, the requirement would be an unrealistic expectation with seemingly limited added benefit.

An average hospital inpatient pharmacy produces hundreds of IVs daily. Adding this level of documentation to the workflow and requiring its storage for 3 years as stated in 1735.3(d) would create a bookkeeping challenge. While an electronic file system would alleviate storage issues, it does not address the sheer quantity of documentation.

In conclusion, I am urging the California State Board of Pharmacy to consider these exemptions as the requirements will add additional workload to a hospital pharmacy while providing unclear benefit. I believe that the intent of this regulation is for the documentation within the practice of mass compounding in the event of a potential safety recall. However, in the inpatient hospital setting, the majority of IV admixtures involve small batches that are generally used within 24 hours. The pharmacy profession is dedicated to patient safety; however the proposed regulations will not add significantly to patient safety while dramatically increasing the workload for hospital inpatient pharmacies.

Sincerely,

Tracey Okabe-Yamamura, Pharm.D.
Clinical Pharmacy Specialist
Mercy San Juan Medical Center
Carmichael, CA

UCLA

Health System

Pharmaceutical Services

17-135 CHS
Mail Code: 169516

March 12, 2009

Virginia Herold,
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219 Sacramento, California 95834
Virginia_Herold@dca.ca.gov

Re: 15-Day Comment Period Proposed Requirements for Pharmacies that
Compound Medications

Dear Ms. Herold,

As a UCLA Medical System pharmacist who has been practicing solely in hospitals for over 28 years, I and my colleagues are very concerned with the direction the Board of Pharmacy is taking with these proposed regulations that we believe will negatively affect the ability of hospital pharmacists to safely care for our patients. We are well aware of the problems that have been reported with "compounding pharmacies" over the past few years, however, we feel that this proposal impairs hospital practices without any change in patient safety. In fact, the additional documentation burden could actually be detrimental to hospitalized patients as limited staff capabilities are further stretch with another agency's regulations. We would like to remind you and the Board of the classic anxiety/performance curve principle. This curve demonstrates that as stress is increased past a critical point, performance (i.e. safety) decreases.

To be more specific, we would like to stress that the effect of the above proposed regulations would negatively effect the compounding of medications in every hospital's Intravenous Additive Service (IVAS) in the state of California. Whether this be a separate division within a large institution, or a "room" in a small facility the outcome would be disastrous. You need to delay the decision on these regulations and begin intensive examinations of the real effect they would have on the practice of hospital pharmacy. In our institution alone, we predict that the

MINIMUM effect would be an increase by 30 technician hours a day to perform the tasks required for our volume of IV preparations and an additional number of unknown pharmacists FTE to adequately supervise their activities. In today's economic condition this increase cost to health care cannot be justified. Hospitals will be forced to add additional duties to overworked staff which will negatively affect patient safety.

As we read the regulation, it would apply to every function performed in the typical hospital IVAS area. Most of the changes directly effect manual labor activities and will greatly increase the time to prepare a compounded IV solution for a patient. Your recent change to exempt immediate use compounded products (items to be used within 2 hours) is a first step, but this does not address the whole issue.

In closing we would like to point out that the California Department of Consumer Affairs states that its mission is: "To serve the interests of California consumers by ensuring a standard of professionalism in key industries and promoting informed consumer practices." The mission of the California Board of Pharmacy is: "The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement." I suggest that this proposal, in its current form, does not meet either of these goals. Mandating documentation of manufacturers, lot numbers and expiration dates on products that will be infused into patients within 24 hours of their manufacturer does not promote health or safety, nor does it ensure professionalism. It creates unnecessary paperwork and reams of records that will be stored and never looked at.

As licensed pharmacists we are asking that the Board not pass this proposal without a more intensive evaluation of how it will affect hospital practices. These kinds of massive changes to well established, safe, compounding practices (which by the way have been historically driven not by regulations, but by the professionalism of many) can only increase risk not improve safety.

Sincerely,



Charles A. Reynolds, Pharm.D.,
B.C.P.P. UCLA Health Systems
Ronald Reagan UCLA Medical Center



"Richard Sakai"
<RSakai@childrenscentralcal
.org>

03/09/2009 06:42 PM

To <carolyn_klein@dca.ca.gov>

cc "Dawn Benton" <dbenton@cshp.org>,
<philip@swangermanagement.com>

bcc

Subject Comments on Board of Pharmacy Proposed Compounding
Regulations

I had previously sent in comments and I would like to reiterate my concerns about these new regulations. I think CSHP has provided the Board with many valid concerns and I am supportive of their comments. I would like to add several more.

1. I would like the board to consider exempting hospitals from compliance with any regulation you approve in this area for a period of **five years** at which time full compliance is expected. This will allow organizations to properly budget for the development if needed and plan for the resources (human and/or computerization) to fully comply with the regulations. I believe organizations given sufficient time to procure the financial and human resources can comply. Should organizations not be able to comply, they should be expected to submit something in writing explaining the reason for lack of compliance and the Board would determine the reasonableness of their inability to compliance. Based upon the evidence provided, the Board would take appropriate action from an extreme of closing the pharmacy to fines.

2. I would like the Board to consider exempting the compounding of medications if one is following USP797 guidelines for beyond use dating as a guideline when lot numbers are required. Beyond use dating is when the pharmacy who makes things beyond these defined dates/time and stored under certain conditions (room temp, refrigerated, frozen), stability and sterility testing must be performed.

The reason I would like you to consider this is that in the OR, anesthesiology often prepare medications of critical nature in a case prior to the case. These are medications that are often necessary in an event something goes wrong. Not all cases have this situation. The time frame for which you have set is not within the normal length of time for a complex surgical case. Not preparing these medications for that emergency situation will put patients at risk and/or the anesthesiologist will not comply with the regulations. Then the Board of Pharmacy will hold the PIC ultimately responsible for the physician's actions. Their response "is that it is a patient care issue and not preparing the medication puts my patient at risk".

If these regulations are jointly prepared and/or endorse by the Board of Registered Nurses and the Board of Medicine, pharmacy can help better control the safe use of medications. Please consider getting an endorsement from these organizations.

3. As CSHP, the definition of compounding needs clarity. A single manipulation such as taking a partial amount from a larger vial and putting it into a syringe is not compounding. It is unit dosing of the medication. By your definition since it is not in the original container, it is compounding. When the board as well as other regulatory agencies promote unit dose and unit of use to reduce the chance of the end user making a dosing error because a calculation error,

these simple transfer of a product from a large container to a smaller one should not be considering compounding. If passed, to avoid lack of compliance the pharmacy will send out the larger container and have the end user remove the appropriate amount (hopefully calculate correctly). In my estimation this places the patient at greater risk. Please reconsider.

Thank you very much for your time and consideration in this matter

Richard I. Sakai, Pharm.D., FASHP, FCSHP
Director of Pharmacy Services
Children's Hospital Central California
9300 Valley Children's Place
Madera, California 93638
1-559-353-5505 (w)
1-559-353-5515 (fax)
1-559-262-7743 (pager)

**CEDARS-SINAI MEDICAL CENTER.**

Department of Pharmacy Services
8700 Beverly Blvd, Room A-845
Los Angeles, CA 90048

Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd
N219
Sacramento, CA 95834

Re: Title 16 Board of Pharmacy Proposed Language

Dear Ms. Klein,

Thank you for the opportunity to provide input regarding the Proposed Language which I have provided below. In our organization, we prepare over 1000 compounded products/day. There are a number of requirements that need clarification in the areas of definitions and expectations to ensure that organizations are able to meet the intent of the regulation. Additionally, a number of these requirements entail a significant increase in documentation and new processes which could result in delaying the compounding of products for patients.

Page 3, 1735.2, Section d.4.

The definition of and expectations for a quality review are needed.

Page 4, 1735.2, Section f.

Definitions and expectations of how the pharmacist is to ensure potency and quality are needed.

Page 5, 1735.3, Section a.6.

Maintaining records of lot numbers for each component is a significant requirement. This would require recording for lot numbers for any IV product that is diluted such as antibiotics that are administered IVPB, complex products such as TPN, IVs with multiple electrolytes, chemotherapy with multiple vials, etc.

Page. 5, 17353, Section b.

Hospital pharmacies currently procure medications from a wholesaler, generally daily or twice a day. On the orders placed to the wholesaler, drug products and components used in compounding are dispersed throughout each order. This requirement would require that products and components for compounding would need to be ordered separately. In

some cases, the same medication may be one that is both compounded and dispensed without compounding directly to the patient. Examples include insulin, ranitidine, and hydrocortisone, to name a few. The requirement would require ordering these medications twice: once for dispensing and once for compounding.

Page 6, Section 1735.5, Section c. 4.

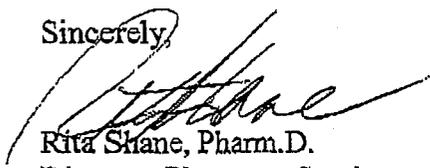
The expectations for testing integrity, potency and quality need to be delineated. Determination of potency and integrity entails a physical examination of the compounded product itself which would need to be conducted by special laboratories that have the ability to verify these requirements. The need to send products to specialized labs would significant delay patient treatment. Note that these requirements are also cited in Section 1735.8, Section a.

Section 1751.2, Section c.

Clarification is needed as to what instructions should appear on the label for medications that do not require refrigeration or any special handling.

Please feel free to contact me should you have any questions. Thank you again.

Sincerely,



Rita Shane, Pharm.D.
Director, Pharmacy Services
310-423-5611
shane@cshs.org

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HEALTH SCIENCES AND SERVICES
DIVISION

OFFICE OF THE PRESIDENT
1111 Franklin Street - 11TH Floor
Oakland, California 94607-5200
(510) 987-9071 Fax 763-4253

March 13, 2009

Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

**Subject: Comment to “Requirements for Pharmacies that Compound Medications”
(Beginning with Section 1716 – Date Released: August 22, 2008)**

Dear Ms. Klein –

Per the 15-day notice period, dated February 26, 2009, for the above titled regulation, the University of California Medical Centers’ (UC Davis, UC Irvine, UC Los Angeles, UC San Diego and UC San Francisco) Department of Pharmacies would like to submit the following comments:

- Regarding the “1716_revised_notice” document, in the section that describes “Fiscal Impact Estimates”, we note:
 - In the “Business Impact” sub-section the notice states there will be “no significant, statewide adverse economic impact”. We respectfully disagree. To provide grounds for our position we cite a study conducted at the University of California Davis using manual labor (no automation) to fulfill the proposed record keeping requirements. In this study it is estimated that there will be additional labor and record storage costs of approximated \$1,000,000 per year for all University of California hospitals.
 - In the “Impact on Jobs” sub-section the notice states “this regulatory proposal will not have a significant impact on the creation of jobs”. Again we respectfully disagree and cite the study performed at the University of California Davis. In this study 16 new jobs would need to be created at the costs stated above for the University of California hospitals.
- Regarding the “1716_statement_rev” document, in the section that describes “Specific Purpose of the Proposed Changes”, we note:
 - The stated purpose of these changes is to “address, among other items, the strength, efficacy, and quality in compounding” and further “there are no provisions that ... define these items for general compounding” in current law. We respectfully disagree in that the statement of reasons does not clearly identify how the public will be protected. It is understood that an improvement in the recall process would increase the protection of the public. However, any additional protections that this law would provide are not apparent. All licensed acute care hospitals in California are required by the FDA to comply with current USP 797 regulations, which mandate appropriate compounding of sterile products. These regulations, which are widely accepted as the most comprehensive and

evidence-based guidance to ensure safe preparation of aseptic products, do **not** require the documentation elements included in 1735.3 (a) (6) and (8).

- Regarding the section titled “ADD 16 CCR 1735.3 Records of Compounded Drugs”, we note:
 - This section would require documentation of waste for compounded sterile products. This task would be very onerous to all acute care hospitals.
- Regarding the section titled “Factual Basis”, we note:
 - The following statement was made: “The workgroup recognized that current pharmacy regulations addressing compounding only govern the physical circumstances, procedures and record keeping requirements for general compounding and do not address quality, strength or purity.” This does not take into consideration USP 797 which does specify quality, strength, and purity. As stated above, compliance with USP 797 is required by all acute care hospitals.
 - The following statement was made: “The benefit to the public when a wholesaler is in compliance with the law is significant.” Assuming the word “wholesaler” in the above statement should be pharmacy, on what factual basis does the Board determine that the benefit of compliance is significant?

In summation, the proposed regulations could incur a large increase in costs for acute care hospitals and increased labor demands. In the midst of difficult financial times and labor shortages for pharmacy technicians, it will be challenging for institutions to meet the proposed regulations. The University of California hospitals appreciates the opportunity to comment on the proposed language of these regulations. Please contact me if I can answer any questions or provide any additional information. I can be reached at 510-987-0586 or michael.thompson@ucop.edu.

Sincerely,



Michael Thompson Ph.D.
Director

March 9, 2009

Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

Re: Comments on proposed amendments to Section 1735.3 of Title 16, California Code of Regulations

My primary concern with the proposed compounding regulations is that preparation of intravenous admixtures for hospital inpatients and outpatients is included in the regulations. I maintain that there is a big difference in needed safeguards between products compounded for extended use in physicians offices or a patient's home and sterile products with short expiration dates compounded for use in hospital inpatients and outpatients.

Regulation of compounded sterile preparations has recently been extensively instituted in the form of USP-797. For the Board of Pharmacy to create additional regulations is unnecessary. In addition, it creates problems when there are deviations between the standards set by USP-797 and the proposed regulations. Why not simply adopt the standards developed by USP-797 as Pharmacy Law? That seems like a much more reasonable approach to me.

Additionally, I feel that the regulations proposed by the Board impose an unreasonable amount of work in their record keeping requirements with no resultant improvement in patient safety. The additional pharmacy logs and records of supplies and ingredients do nothing to improve product preparation and patient safety. While they may help an investigation of what caused an adverse reaction, they will not prevent adverse events. That should be the thrust of our efforts, and USP-797 attempts to do just that. What these record-keeping requirements will do is increase the cost of the IV Admixture Service to hospitals, which are already struggling to keep their doors open.

In conclusion, I believe the Board would do better in protecting the public by adopting USP-797 regulations for compounded sterile preparations instead of adding these proposed regulations to the non-sterile product compounding regulations.

Cordially,

Gerald R. Trindade, Pharm.D.



Dominican Hospital
CHW

BOARD OF PHARMACY
2009 MAR 10 PM 3:46

Dominican Hospital
1555 Soquel Drive
Santa Cruz, CA 95065

Dominican
Rehabilitation Services
610 Frederick Street
Santa Cruz, CA 95062

March 5, 2009

Ms. Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd., Suite N 219
Sacramento CA 95834

Dear Ms. Klein and Members of the California State Board of Pharmacy:

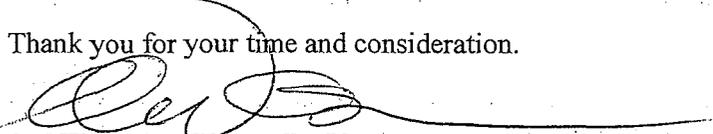
As a pharmacy director in the Catholic Healthcare West system, I want to add my voice to other directors that have written to you. Hospital Pharmacy is reviewed and regulated by many state and national agencies. Their purpose and ours is to achieve the highest level of safe medication practices possible. I believe your modifications to the text of section 1735.5 in Title 16 Cal. Code Reg. does nothing to improve the care delivered in the hospitals accredited by Joint Commission. In addition, the record-keeping required by the changes will add burden and expense without adding improvement to the safety of Pharmacy practice.

Section 1735.5 in title 16 Cal. Code Reg. is retail-focused. The Board of Pharmacy has re-written these rules to, appropriately, control compounding in the outpatient setting. I have no problem with implementing these rules in that area. However, to expect admixtures prepared in a hospital pharmacy to follow the same rules, is busy work, time consuming and not productive to the end of improving patient safety.

Please consider excluding hospitals accredited by Joint Commission from these rules. Hospitals are already mandated by the Board of Pharmacy, the California Department of Public Health, TJC, USP <797> etc. to utilize high standards in the compounding of admixtures and the absence of literature to support any assertion that hospitalized patients are at risk of infection leads me to conclude that the steps you are about to mandate would add unnecessary cost to an already difficult healthcare environment.

I ask that, instead of including hospital pharmacies in the process outlined in Section 1735.5, the Board of Pharmacy utilize existing, well-vetted requirements as mentioned in USP 797 to ensure medication safety.

Thank you for your time and consideration.


Carl Washburn, Pharm. D.; Pharmacy Director
Dominican Santa Cruz Hospital
1555 Soquel Dr.
Santa Cruz, CA. 95065
☎ office 831-462-7815
📞 cell 831-588-0651

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BOARD OF PHARMACY

2009 MAR 16 PM 4:17

Don Willis, CPhT.
2333 Buchanan St.
San Francisco, California 94115
willisdl@sutterhealth.org

March 9, 2009

Board of Pharmacy
Attn: Carolyn Klein, Manager, Legislation and Regulation
1625 N. Market Blvd. N219
Sacramento, CA 95834
carolyn_klein@dca.ca.gov

Re: Proposed Regulations - Article 4.5 General Compounding

Dear Ms Klein:

I am deeply concerned with the sweeping changes proposed to the compounding and documentation of **sterile injectable** products. As I understand it, the California Board of Pharmacy was originally tasked to strengthening compounding practice and safety for "**traditional**" compounding. This area of pharmacy practice lacks specific regulation to adequately protect patients. Additional regulation is needed in the area of "**traditional**" compounding. Unfortunately, the proposed regulations have crept into an area that is out of scope and fully regulated. My concern is that **sterile injectable** compounding should not be lumped together with the "**traditional**" form of compounding. Current regulations regarding **sterile injectable** compounding are very specific and detailed from both the United States Pharmacopeia (USP) Convention guidelines at the federal level and current state BOP regulations.

There has been no documentation offered that shows changing compounding regulations for **sterile injectable** products will have any impact to patient care. Current regulations in California code and USP provide adequate safeguards and documentation. Adding regulations for additional documentation to **sterile injectable** products that will be administered within the next 24 hours is not only labor intensive but offers no benefits or clear value. The addition of thousands of records per day per site will have NO impact to patient safety or any recall process especially since these products will most likely have already been given. It is also arguable that the traditional hospital extemporaneous compounding for immediate use is a quite different practice from sterile injectable batching or compounding (covered under compounding pharmacy licensure). These regulations continue the trend of treating extemporaneous admixture like pharmaceutical style manufacture, and I would take exception that these two practices should have the same or similar style regulations.

I am additionally concerned patient care may be jeopardized by the additional documentation requirements suggested for **sterile injectable** compounding if lumped together with "**traditional non-sterile**" compounding. The added workload of this documentation will reassign pharmacy staff away from other patient care functions. Unfortunately this new workload has not been shown to benefit the patient, while other clinical programs and patient care activities with clear documented patient benefit would be decreased or eliminated. This is even more true in these increasingly difficult economic times.

I suggest **sterile injectable** and **non-sterile** compounding remain in separate regulations. Current California regulations, Article 7 Section 1751 (Sterile Injectable Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug Products) cover the issues related to **sterile injectable** compounding. These current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) to assure patient safety. In addition, the Board requires additional licensure or accreditation of pharmacies to perform the functions of **sterile injectable** compounding. Changes or additional regulations to these sections are NOT needed.

The requirements for the safe preparation of **sterile injectable** and "**traditional**" **non-sterile** products are distinctly different. The United States Pharmacopeia (USP) regulates these processes separately in 2 distinct chapters. USP 797 deals with Pharmaceutical Compounding – Sterile Preparations and USP 795 deals with Pharmaceutical Compounding – Nonsterile Preparations.

Thank you for considering these issues. I ask that the Board address the patient safety needs of "**traditional**" **non-sterile** compounding and move forward on those regulations. This is urgently needed. There is no need to change the current status and regulations for **sterile injectable** compounding.

Respectfully,



Don Willis
Pharmacy Manager
California Pacific Medical Center



St. Joseph's Medical Center

A member of CHW

Pharmacy Department
1800 N. California St.
Stockton, CA 95204
(209) 467-6518
(209) 461-6890 fax

March 5, 2009

Carolyn Klein, Manager
Legislation and Regulations
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Klein,

I am writing to you as a practicing pharmacist commenting on the proposed modifications to the text of section 1735.5 in Title 16 CCR. While I am supportive of the changes made to the proposed regulation to section 1735.3(a)(6), which now exempts the manufacturer and lot number of each component if the sterile product is compounded "on a one-time basis for administration within two hours to an inpatient in a health care facility..." I am concerned that there is still unclear language in the proposed regulation and request that the following issues be addressed to both the proposed regulation and the self-assessment.

- The self-assessment is titled "COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT". This term hospital outpatient pharmacy suggests that the regulation applies only to outpatient pharmacies in hospitals. However, the language in the regulation suggests any licensed pharmacy. It would be preferred that the language is specific to hospital outpatient pharmacies and excluding inpatient hospital pharmacies.
- Section 1735(b)(1) defines compounding as "Altering the dosage form or delivery system of a drug." It is unclear whether compounding includes assembling a vial to a piggyback using a device such as Add-Ease connector constitutes compounding. I would urge that language is clear that this practice is exempted from the definitions of compounding.
- Section 1735(a)(2) and 1735(b) includes the definition of compounding to include "Altering the strength of a drug". Does adding the entire contents of a vial of drug to a piggyback in accordance with manufacturer's guidelines equate to altering the strength of a drug? Does placing the entire contents of a vial into a piggyback suggest reconstitution? I would recommend that this type of practice does NOT constitute compounding and that this be exempted from the definition of compounding.
- Section 1735.3(a)(7) sets a requirement for documenting all equipment to be used in compounding the drug product. It is unclear whether it is mandated that equipment such as needles, syringes, dispensing pins, IV hood, etc. are considered equipment. If so, this sets an unrealistic expectation that would be of questionable benefit. For example, preparing a single IVPB could theoretically require the following elements:



St. Joseph's Medical Center

A member of CHW

Pharmacy Department
1800 N. California St.
Stockton, CA 95204
(209) 467-6518
(209) 461-6890 fax

Equipment used:

1-ceftriaxone 1gm vial (Roche)	Lot: 1234	Exp: 9/99
1-D5W 50ml IVPB (Baxter)	Lot: 1234	Exp: 9/99
1-alcohol swab		
1-18 guage needle		
1-10 ml syringe		
1-foil seal		
1-laminar flow hood		

Prepared by: John Smith, pharmacy technician 3/5/09 1900.
Inspected by: Mary Jones, Pharm.D. 3/5/09 2000.

Internal lot number: 99999

Expires: 3/9/09 1900.

- In an average hospital inpatient pharmacy, hundreds of IVs are made daily. Adding this level of documentation to the workflow and requiring its storage for 3 years as stated in 1735.3(d) would create a bookkeeping challenge. While an electronic file system would alleviate storage issues, it does not address the sheer quantity of documentation

I urge the Board of Pharmacy to consider these exemptions as they add addition work to a hospital pharmacy while providing unclear benefit. The intent of this regulation seems to be documenting the practice of mass compounding in the event of a potential safety recall. However, in the inpatient hospital setting, a majority of IV admixtures involves small batches that are generally used within 24 hours. Any recall of product would be unlikely to be tracked in these small batches. To reiterate, **THIS PROPOSED REGULATION ADDS ADDITIONAL WORK WITH LITTLE TO NO BENEFIT IN TERMS OF PROTECTING THE PUBLIC.**

Sincerely,

William Yee, Pharm.D.
Clinical Information Coordinator
St. Joseph's Medical Center, Stockton, CA

Eduardo Morin, Pharm.D.
13145 Trent Way
Jackson, CA 95642

March 11, 2009

Board of Pharmacy
Attn: Carolyn Klein, Manager, Legislation and Regulation
1625 N. Market Blvd. N219
Sacramento, CA 95834
carolyn_klein@dca.ca.gov

Re: Proposed Regulations - Article 4.5 General Compounding

Dear Ms Klein:

I am very concerned with the sweeping changes proposed to the compounding and documentation of **sterile injectable** products. As I understand it, the California Board of Pharmacy was originally tasked to strengthening compounding practice and safety for **"traditional"** compounding. This area of pharmacy practice lacks specific regulation to adequately protect patients. Additional regulation is needed in the area of **"traditional"** compounding. Unfortunately, the proposed regulations have crept into an area that is out of scope and fully regulated. My concern is that **sterile injectable** compounding should not be lumped together with the **"traditional"** form of compounding. Current regulations regarding **sterile injectable** compounding are very specific and detailed from both the United States Pharmacopeia (USP) Convention guidelines at the federal level and current state BOP regulations.

There has been no documentation offered that shows changing compounding regulations for **sterile injectable** products will have any impact to patient care. Current regulations in California code and USP provide adequate safeguards and documentation. Adding regulations for additional documentation to **sterile injectable** products that will be administered within the next 24 hours is not only labor intensive but offers no benefits or clear value. The addition of thousands of records per day per site will have NO impact to patient safety or any recall process.

I am additionally concerned patient care may be jeopardized by the additional documentation requirements suggested for **sterile injectable** compounding if lumped together with **"traditional" non-sterile** compounding. The added workload of this documentation will reassign pharmacy staff away from other patient care functions. Unfortunately this new workload has not been shown to benefit the patient, while other clinical programs and patient care activities with clear documented patient benefit would be decreased or eliminated.

I suggest **sterile injectable** and **non-sterile** compounding remain in separate regulations. Current California regulations, Article 7 Section 1751 (Sterile Injectable Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug Products) cover the issues related to **sterile injectable** compounding. These current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) to assure patient safety. In addition, the Board requires additional

licensure or accreditation of pharmacies to perform the functions of ***sterile injectable*** compounding. Changes or additional regulations to these sections are NOT needed.

The requirements for the safe preparation of ***sterile injectable*** and "***traditional***" ***non-sterile*** products are distinctly different. The United States Pharmacopeia (USP) regulates these processes separately in 2 distinct chapters. USP 797 deals with Pharmaceutical Compounding – Sterile Preparations and USP 795 deals with Pharmaceutical Compounding – Nonsterile Preparations.

Thank you for considering these issues. I ask that the Board address the patient safety needs of "***traditional***" ***non-sterile*** compounding and move forward on those regulations. This is urgently needed. There is no need to change the current status and regulations for ***sterile injectable*** compounding.

Respectfully,

Eduardo Morin

Attachment 2

Proposed Amendment to 16 CCR §1773 and Addition of 16 CCR §1773.5 – Ethics Course

Board of Pharmacy

Modified Text

Changes made to the regulatory text noticed on September 5, 2008, are indicated. Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text, are indicated by a double underline, thus: added language.

Add Section 1773.5 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1773.5 Ethics Course Required as Condition of Probation.

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

- a. The board will consider for approval an ethics course that at minimum satisfies the following requirements:
- (1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.
 - (2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.
 - (3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.
 - (4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.
 - (5) Content. The course shall contain all of the following components:
 - (A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.
 - (B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of ~~medicine~~ pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.
 - (C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

- (D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.
- (E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.
- (F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.
- (6) Class Size. A class shall not exceed a maximum of 12 participants.
- (7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.
- (8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.
- (9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

Attachment 3

*Proposed Amendment to Title 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist
Licensure Examination/Confidentiality.*

**Board of Pharmacy
Specific Language**

Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~card~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

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

Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

Attachment 4

*Proposed Adoption of Title 16 CCR §1751.9 – Accreditation Agencies for Pharmacies that
Compound Sterile Injectable Drug Products*

Board of Pharmacy
Specific Language to Add Section 1751.9

Add Section 1751.9 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

- (a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1, shall provide evidence satisfactory to the board that:
 - (1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least every three years.
 - (2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standard-setting organizations.
 - (3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation.
 - (4) The accrediting agency is recognized by at least one California healthcare payors (e.g., HMOs, PPOs, PBGH, CalPERS).
 - (5) The accrediting agency is able to accredit California and non-resident pharmacies.
- (b) An agency seeking recognition from the board to become an approved accrediting agency must submit a comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding. The applicant agency's request will not be processed unless the comparison demonstrates the agency's standards are in compliance with California Pharmacy Law.
- (c) The board shall consider the length of time the agency has been operating as an accrediting agency.
- (d) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies.
- (e) On an annual basis, no later than July 1 of each year, an approved accrediting agency will submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.
- (f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.
- (g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an

approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.