

## **Board of Pharmacy**

### **Addendum to the Final Statement of Reasons**

The following information is provided as an addendum to the Final Statement of Reasons:

Section 1735.2(j) of Title 16 of the California Code of regulations requires a pharmacist-in-charge to complete a self-assessment form developed by the board, prior to allowing any drug product to be compounded in a pharmacy. As part of the rulemaking process, proposed form 17M-39 Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment was distributed in hard copy and by electronic mail with the Initial Notice and proposed regulatory text released on August 22, 2008. In addition to being distributed with the Initial Notice and proposed text, all rule making documents – including the draft form 17M-39 – was placed on the board’s web site for ease of access. The board’s web site is a commonly known source of information for the regulated population. In addition, the form also was made available, upon request, to any person who contacted the board and requested the draft form.

The board determined that, in accordance with Title 1 section 20(c), publishing Form 17M-39 in its entirety in the California Code of Regulations would be cumbersome, unduly expensive, or otherwise impractical. Likewise, the Informative Digest published in the California Regulatory Notice Register 2008, Volume No. 34-Z, item 5., summarized the requirements of section 1735.2, including the requirement to complete the self-assessment requirement

#### **SUMMARY AND RESPONSE TO ORAL COMMENTS**

The rulemaking file contained minutes of the regulatory hearing conducted on October 29, 2008. The board herein provides responses to oral comments made at that hearing.

Comments from Maria Serpa and William Yee, California Society of Health-System Pharmacists.

Comments: On behalf of CSHP, Ms. Serpa provided general comments regarding the need to regulate the compounding of drugs and stated compounding is a large issue of patient safety and is in dire need of regulation. However, she stated that CSHP’s concern is extending regulations to the processing or compounding of sterile injectable products prepared in a hospital setting. She expressed concern over the record keeping requirements, especially in a “stat” or emergency situation when a compounded dose required immediate delivery, and she provided information with regard to the identification of batches that are tracked in a hospital setting. She

expressed her concern that the proposed regulations would require additional documentation of doses that are currently tracked and administered in a hospital setting. Mr. Yee provided a perspective from a 300-bed community hospital and the administration of “stat” medications. Mr. Yee specifically referenced proposed section 1735.3(b) and asked that the board exclude “immediate use of stat medication” in a hospital setting from the regulations as set forth. It was clarified that CSHP’s objections were to the specific provisions within 1735.3(a)(6) and (8), which are the manufacturer’s name and lot numbers and the pharmacy-specific reference.

Response: The board provided a response to Mr. Yee’s written comment (reference Comment #139 in the Final Statement of Reasons) which is reflective of his oral testimony. In addition to the board’s responses to Ms. Serpa’s written comments (see responses to comments #63 and #64 in the Final Statement of Reasons, the board – following both of the 15-day comment periods -- 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 twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The board believes the resulting language strikes a balance between the needs of pharmacy operations in an acute care setting and that of patient safety.

Comments from Ms. Jenny Partridge, representing California Pharmacists Association Academy of Compounding Pharmacists

Comments: Ms. Partridge stated it would be difficult to document all of the ingredients (including preservatives and the like) contained in a compounded product, and wanted to be sure that, as stated in proposed section 1751.2(b) and in proposed section 1735.4(a) and (c) that the board intended that the “principal active ingredients” were required to be documented.

Response: Section 1735.4(a) and (c) as adopted by the board specifies that only the principal active ingredients must be documented.

Section 1751.2(b) is current regulation. Comments on this section are outside the scope of this rulemaking.

Mr. Allan Schaad, Catholic Healthcare West and Woodland Healthcare

Comments: Mr. Schaad stated his concern on the “overreaching shadow of the umbrella” that the proposed regulations cast and stated he did not believe he will be able to incorporate the requirements of the proposed regulations into his workflow.

He stated that the proposed regulations are tremendously burdensome with recordkeeping requirements.

Response: The proposed regulations do expand on current recordkeeping requirements (Article 4.5 and Article 7) to include 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 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. Further, the documentation of the equipment used is necessary to allow for a quality assurance review to be completed 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. To strike a balance between the needs of pharmacy operations in an acute care setting and that of patient safety – and following both of the 15-day comment periods – 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 twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

#### Comments from Heidi Barsuglia, California Retailers Association

Comments: Ms. Barsuglia stated that the members of the California Retailers Association do not support the regulatory proposal as noticed because some of the requirements would hinder pharmacists from engaging in non-sterile basic compounding. She voiced their members concerns for a pharmacy engaging in only non-sterile basic compounding to have to complete a self assessment and their need to comply with other requirements for a compounding policy and procedure manual, documentation of the facilities and equipment necessary for compounding, documentation of pharmacy staff training, ongoing competency evaluation and a written quality assurance plan if the pharmacy in fact only engages in compounding on a non-routine basis.

Response: Recordkeeping requirements as they relate to compounding are not new, however, the proposed regulations do expand on current recordkeeping requirements (Article 4.5 and Article 7) to include 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 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. The board believes that the recordkeeping information required, as adopted, provides for consumer protection. Further, the documentation of the equipment used is necessary to allow for a quality assurance review to be completed 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 Ms. Jenny Partridge, representing herself.

Comments: Ms. Partridge stated that in her experience she has found the board's self-assessment forms to be very helpful. She stated that software is available from various manufacturers which may provide for the documentation of information as required by the proposed regulation.

Response: The board appreciates the comments of Ms. Partridge.

#### SUMMARY AND RESPONSE TO WRITTEN COMMENTS

The board herein expands on the responses to comments found in the Final Statement of Reasons. The numbers identified below correspond to the comment number and related response as stated in the Final Statement of Reasons.

Written comments made by Margaret C. Bradshaw, R.Ph, Mendocino Coast District Hospital

80.c.

Board's amended response: 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. In the board's opinion, a licensed pharmacist responsible for a compounded drug product would utilize his or her professional training, knowledge and experience in making a professional judgment of a compounded drug products expiration date. This would include knowledge of the nature of a compound utilized in a compounded drug product.

Written comments from Raffi Svadjian, PharmD, MBA, USC School of Pharmacy

67.

Mr. Svadjian makes general comments that 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 and that 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's Amended Response: The comments offered by Mr. Svadjian do not address any concerns with specific text within the regulatory proposal nor do they offer any proposed modifications. This rulemaking provides for essential consumer protection. To strike a balance between the needs of pharmacy operations in an acute care setting and that of patient safety – and following both of the 15-day comment periods – 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 twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

During the development of this rule making, the board considered various practice settings, and made exceptions to certain requirements where appropriate. The board determined that the end product testing, as adopted, is appropriate and necessary to ensure that a consumer receives an appropriately compounded to ensure that a patient receives the desired outcome of the medicine. Further, quality assurance is defined in pharmacy law as well as this rulemaking.

Dr. Svadjian also states that the regulation does not make any distinction between the complexity of compounding and the amount of regulation needed and provides an example, but does not offer any suggested language.

The board disagrees with the comment. To the contrary, the regulation does make a distinction. While Mr. Svadjian did not provide specifics, the proposed regulations do expand on current recordkeeping requirements (Article 4.5 and Article 7) to include 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 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. Further, the documentation of the equipment used is necessary to allow for a quality assurance

review to be completed 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. To strike a balance between the needs of pharmacy operations in an acute care setting and that of patient safety – and following both of the 15-day comment periods – 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 twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.