

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Compounding Drug Products

Sections Affected: Amend 16 Cal.Code Reg. § 1735.1, § 1735.2, § 1735.3 and § 1751.2

Specific Purpose of the Proposed Changes:

The Board of Pharmacy (“Board”) proposes to amend Sections 1735.1, 1735.2, 1735.3 and Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations (“CCR”) for the purpose of amending the board’s regulations specific to the compounding of drug products, as specified below. As specified in Business and Professions Code Section 4001.1, protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Existing regulations at 16 CCR § 1735.1 specify requirements related to the compounding of drug products, to include definitions of terms used throughout the article. The board’s proposal will add a definition of “equipment” for purposes of compounding drug products. The definition would define “equipment” as those items that must be calibrated, maintained or periodically certified.

Existing regulation at 16 CCR § 1735.2 specifies limitations and requirements for all compounded drug products. This section specifies that a drug product shall not be compounded until the pharmacy first prepares a written master formula to include specified information. A written master formula may be likened to a ‘recipe’ for compounding a drug product. The board’s proposal would require that the written master formula record specify what equipment is to be used in compounding the drug product. The board believes that indicating the equipment to be used in the written master formula record will provide for consistency in the compounding of drug products. The board’s proposal also seeks to renumber existing elements in this Section, specified in subdivision (d). This section also incorporates by reference a self-assessment form that must be completed by a pharmacy’s pharmacist-in-charge before any compounding can be done in a pharmacy (“Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. 01/11); the regulation also specifies that a pharmacist-in-charge shall complete the self-assessment form by July 1 of every odd-numbered year. The board’s proposal would update this self-assessment form to reflect the changes proposed in the Notice.

Current regulations at 16 CCR § 1735.3 require that a pharmacy record be maintained for each drug product that is compounded and specifies what information shall be included in the record, to include the master formula record, the date the drug product was compounded, and other information. Currently, this section specifies that the equipment used in compounding be included in the pharmacy record. Because the board’s proposal would require that the

master formula record specify the equipment to be used in compounding a drug product (and the master formula record is a part of the pharmacy record), this item is being removed. In addition, paragraph (a)(6) of this section requires that the pharmacy record specify the manufacturer and lot number of each component of the compounded drug product. The board's proposal would require that, in addition to these required elements, the expiration date of each component in the compounded drug product be specified. Also, paragraph (a)(6) currently provides that a hospital that compounds a sterile injectable drug product on a one-time basis for administration to an inpatient, as specified, is exempt from recording the manufacturer and lot number of each component of the compounded drug product in the pharmacy record. This proposal would also specify that the expiration date of each component of a sterile injectable drug product be exempt from recording in the pharmacy record; it would extend the period of time to seventy-two hours (from 24 hours) that the drug can be used; and specifies that the sterile injectable drug must be stored in accordance with United States Pharmacopeia Standards.

Current regulations at 16 CCR § 1751.2 specify additional labeling requirements for sterile injectable drug products that are compounded. The Board's proposal would clarify the labeling requirements for cytotoxic agents. Currently, all cytotoxic agents must bear a special label that states "Chemotherapy – Dispose of Properly." However, not all cytotoxic agents are chemotherapy agents. Thus, the board's proposal would also specify an alternate label that reads "Cytotoxic Product – Dispose of Properly."

Factual Basis/Rationale/Problem Addressed

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 4127 requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

In 2008 the board initiated a rulemaking to revise its regulations related to general compounding and to sterile injectable compounding, and the board's regulations became effective in July 2010. Following the effective date of those regulations, the board began receiving comments asking for further information or clarity of some regulations. In response, the Board established a Compounding Subcommittee of the Board's Licensing Committee. That committee first met on August 22, 2011, and again on January 4, 2012. The Subcommittee provided the Board with summaries of its meetings at the October 2011 and January 2012 Board Meetings. At the January 31-February, 2012 Board Meeting, the Compounding Subcommittee proposed changes to the Board's compounding regulations. In response and after taking additional public comment on the proposals, the Board on February 1, 2012, directed board staff to initiate a rulemaking to propose the changes herein. The rationale for the proposed changes follows.

Proposed amendments to Section 1735.1: The Board received comments that its interpretation that all equipment used for compounding each drug product, including items like scales,

syringes, and needles, must be recorded in the daily log was overly broad and burdensome for pharmacies (e.g., hospital pharmacies) that compound large volumes of drug product. It was argued that such delay caused by the recording of all equipment could interfere with the provision of critical patient drugs and affect patient safety. After review, the Board determined that the definition should be narrowed to require a log of only those equipment items that must be calibrated, maintained or periodically certified, as these items would pose the most potential risk of harm to patients if not properly accounted for by the compounding pharmacy on a daily basis. In addition, the board believes that this definition will aid pharmacies in determining what specific information needs to be recorded in its records.

Proposed amendments to Section 1735.2: Proposed amendments to Section 1735.2(d) are necessary to make clear that equipment, as proposed to be defined in Section 1735.1, used to compound a drug product must be recorded in the pharmacies' master formula to ensure that critical equipment is accounted for in the preparation of the compounded drug product. In addition, the board's proposal seeks to renumber existing elements, specified in subdivision (d); the board believes that listing requirement elements in alphabetical order will assist the reader to more easily identify important information required in the master formula. The board's proposal would update the self-assessment form cross-referenced in this Section to reflect the changes proposed in the Notice. The board believes that having a self-assessment form with current information will assist the pharmacy in its compliance with board regulations.

Proposed amendments to Section 1735.3: The addition of a recording requirement for the expiration date of a compounded drug product would help ensure that expiration dating requirements are clearly indicated for each component in a compounded drug product, aiding the proper labeling of the drug product prior to dispensing to a patient. This requirement would also add an additional check to prevent expired medication from reaching patients and would allow for traceability and accountability for the compounded drug product.

Additionally, this proposal would also specify how the expiration date, manufacturer, and lot number of each component of a sterile injectable drug product would be exempt from recording in the pharmacy's record. It would extend the period of time to seventy-two hours (from 24 hours) that the drug can be used; and would specify that the sterile injectable drug must be stored in accordance with United States Pharmacopeia Standards. After review and discussion, the board believes that extending the period of time for exemption from certain recording requirements (recording manufacturer, expiration date, and lot number) to seventy-two hours from the current 24 hours would not compromise public safety provided that the compounded drug product is stored consistent with the US Pharmacopeia standards. Extending the exemption to 72 hours could also reduce the amount of compounded drugs that are discarded, thus allowing pharmacies to more quickly meet the critical needs of their patients.

Finally, because the board's proposal would require that the master formula record specify the equipment to be used in compounding a drug product (and the master formula record is a part of the pharmacy record), this item is being removed from current subsection (a)(7). The board believes this change will benefit a pharmacy's understanding of the requirements by removing duplication.

Proposed amendments to Section 1751.2: Currently, all cytotoxic agents must bear a special label that states “Chemotherapy – Dispose of Properly.” However, not all cytotoxic agents are chemotherapy agents, and seeing such a label on a cytotoxic agent (that is not chemotherapy) could be alarming to a patient. Thus, the board’s proposal would also specify an alternate label that reads “Cytotoxic Product – Dispose of Properly.”

Underlying Data

1. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Licensing Committee, Compounding Subcommittee Meeting held August 22, 2011
2. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Board Meeting held October 19, 2011
3. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Licensing Committee, Compounding Subcommittee Meeting held January 4, 2012
4. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Board Meeting held January 31-February 1, 2012
5. Economic Impact Analysis

Business Impact

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed changes will help protect the public health based on the proposed changes described in the Notice.

Benefits

Business and Professions Code section 4005 states that “the board may adopt rules and regulations....pertaining to the practice of pharmacy...” Further, Business and Professions Code 4001.1 states that the “protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.” The board believes the regulatory changes as described in the Notice will serve to protect the public health by ensuring that compounded drug products are prepared efficaciously; that the drug products are labeled appropriately; that they are stored in a manner so as to protect the effectiveness of the drug products; and to provide safeguards so that compounded drug products dispensed to patients have appropriate expiration dates.

Specific Technologies or Equipment

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

Consideration of Alternatives

The Board of Pharmacy has made an initial determination that no reasonable alternative to adopting or amending the regulations 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 or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described the Notice.