TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on April 23, 2012.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at: Loma Linda University–Centennial Complex, Damazo Amphitheater, 24760 Stewart Street, Loma Linda, CA 92354, at 1:30 p.m. on Tuesday, May 1, 2012.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference. Pursuant to the authority vested by Sections 4005 and 4127of the Business and Professions Code, and to implement, interpret or make specific Sections 4005, 4036, 4037, 4051, 4052, 4127, 4169, and 4076 of the Business and Professions Code, the Board of Pharmacy is proposing 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.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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 and would update the revision date of the form to "Rev. 02/12."

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."

The board conducted a search of Title 21 Code of Federal Regulations (Food and Drugs), as well as the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq) and found no existing federal regulations or statutes that are comparable to the board's proposal. Further, the board conducted a search of the California Code of Regulations and found no existing state regulations that duplicate or address the scope of changes proposed by the board. Based on

this initial evaluation, the board does not believe that the proposed regulation is inconsistent or incompatible with existing state or federal regulations.

Anticipated Benefits of the Proposed Regulations: Please see "Benefits" below under "Results of the Economic Impact Analysis." In coming to this conclusion, the board considered specific benefits anticipated by the proposed amendment of the sections described, including, to the extent applicable, nonmonetary benefits such as the protection of public health and safety, worker safety, or the environment, the prevention of discrimination, the promotion of fairness or social equity, and the increase in openness and transparency in business and government, among other things.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

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

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

Cost Impact on Representative Private Person or Business: The agency is not aware of any cost impacts that a representative business would necessarily incur in reasonable compliance with the proposed action. This determination is based on the fact that the equipment used to compound a drug product must currently be documented; this proposal changes where that information is documented. Also, the board believes that to protect the public health it is important to document the expiration date of each component of a compounded drug product.

Effect on Housing Costs: None

Small Businesses: The board's proposal may affect small businesses; however, the board does not have nor does it maintain data to determine if any of its licensed pharmacies are "small businesses" as defined in Government Code Section 11342.610.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS

The Board of Pharmacy conducted an Economic Impact Analysis (EIA) and has made an initial determination that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs, businesses or the expansion of businesses in the State of California.

The Board's proposed rulemaking will impact pharmacists and pharmacies. As of October 2011, the board had approximately 37,743 pharmacists (individuals) with current licenses issued by the board. Also, as of October 2011, the board had approximately 6,900 pharmacies (sites) with current licenses issued by the board.

Benefits: Business and Professions Code section 4005 states that "the board may adopt rules and regulations….pertaining to the practice of pharmacy…." 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. The board believes the regulatory changes proposed herein will serve to protect the public health by ensuring that compounded drug products are prepared efficaciously; that records of compounded drug products contain relevant and necessary information, that compounded cytotoxic drug products are labeled appropriately; and that sterile injectable drug products compounded on a one-time basis for administration to an inpatient, as specified, are stored appropriately.

CONSIDERATION OF ALTERNATIVES

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

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION

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

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's Web site http://www.pharmacy.ca.gov.

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

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

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Board of Pharmacy's Web site (www.pharmacy.ca.gov).

CONTACT PERSON

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

Name:	Carolyn Klein
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
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E-Mail Address:	Carolyn.Klein@dca.ca.gov

The backup contact person is:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7910
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Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.