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. 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 25, 2011.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 15 days prior to the close of the written comment period.

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 Section 4005 of the Business and Professions Code, and to implement, interpret or make specific Sections 4005, 4127 and 4300 of said code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulation.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Existing regulation at Section 1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations requires a pharmacist-in-charge (PIC) of a pharmacy licensed under sections 4029 or 4037 of the Business and Professions Code to complete a self-assessment before July 1 of every odd-numbered year; and within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the PIC, and he or she becomes the new PIC of a pharmacy. The regulation incorporates by reference Form 17M-13 “Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment” (Rev. 10/08) and Form 17M-14 “Hospital Pharmacy Self-Assessment” (Rev. 10/08). A self-assessment assists the pharmacy to increase compliance with federal and state requirements; and also makes the pharmacy inspection process more meaningful and provides relevant information to PICs.

The Board of Pharmacy proposes to amend Section 1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations for the purposes of requiring a pharmacist-in-charge of a pharmacy licensed pursuant to sections 4029 or 4037 of the Business and Professions Code to complete a self-assessment within 30 days whenever there is a change in the licensed location of the pharmacy. This proposed requirement is consistent with the requirements of wholesalers licensed by the board and would assist the pharmacist-in-charge to ensure that pharmacy operations at the new location are compliant with statutory and regulatory requirements. The proposal also would modify the name of Form 17M-13 to “Community Pharmacy Self-Assessment” “Hospital
Outpatient Pharmacy Self-Assessment” – this change would clearly state that the self-assessment applies to both a “Community Pharmacy” and also to a “Hospital Outpatient Pharmacy.” This proposal would provide for a revision date of “Rev. 01/11” for both Form 17M-13 and Form 17M-14. These changes would indicate to the pharmacist-in-charge that the information and references contained in the forms were current as of January 2011. The board also proposes changes to each self-assessment form that is incorporated by reference to (1) update citations/references since the last revisions (10/08); (2) correct previously misstated references and typographical errors; (3) make formatting changes; and (4) incorporate references to new regulatory or statutory requirements. These changes would assure the pharmacist-in-charge that the information and references contained in the forms were current as of the new revision date. Also, because Section 1735.2 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations requires any pharmacy that compounds drug products to complete a self-assessment incorporated by reference in that section (17M-39), items related to compounding have been removed from 17M-13 and 17M-14 for the purpose of eliminating duplication. Finally, the signature block for each self-assessment form was modified to add for an acknowledgement for the holder of the license issued by the board. This will ensure that the holder of the license has read and reviewed the completed self-assessment form, and would acknowledge that failure to correct any deficiency identified in the self-assessment(s) could result in the revocation of the license issued by the board.

Existing regulation at Section 1735.2 of Article 4.5 of Division 17 Title 16 of the California Code of Regulations specifies limitations and requirements for compounding drug products. Compounding regulations became effective July 6, 2010. Subdivision (j) of § 1735.2 requires a pharmacist-in-charge to complete a self-assessment (1) before July 1 of each odd-numbered year; (2) within 30 days of the start of a new pharmacist-in-charge; and (3) within 30 days of the issuance of a new pharmacy license. The regulation incorporates by reference “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” (Form 17M-39 Rev. 01/10). Any pharmacy that compounds drug products is required to complete this self-assessment, which includes a section applicable to general compounding, and a section applicable to sterile injectable compounding.

The Board of Pharmacy proposes to amend Section 1735.2 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to modify the title of the regulation section to also reference the self-assessment requirement. This change would indicate to the reader that a self-assessment is required by the section. The board also proposes a new revision date of the self-assessment form incorporated by reference (Form 17M-39) to be “Rev. 01/11” – this new revision date would indicate to the reader that the information and references contained in the form were current as of the revision date. Finally the proposal would make changes to the self-assessment form that is incorporated by reference. Those changes would (1) modify the name of the self-assessment form to be “Compounding Self-Assessment” (2) update citations/references since the last revision (01/10); (3) correct previously misstated references and typographical errors; (4) make formatting changes; and (5) incorporate references to new regulatory requirements. These changes would assure the pharmacist-in-charge that the information and references contained therein reflected current statutory and regulatory requirements. Finally, the proposed regulation would modify the signature block on the self-assessment form to add an acknowledgement for the holder of the license. This would ensure that the holder of the license has read and reviewed the completed self-assessment, and would acknowledge that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board.
Existing regulation at Section 1751 et al. of Article 7 of Division 17 Title 16 of the California Code of Regulations specifies limitations and requirements for compounding sterile injectable drug products. For a pharmacy that compounds drug products, these limitations and requirements are in addition to the requirements found in Article 4.5 of Division 17 Title 16 of the California Code of Regulations (Sections 1735 et al.).

The Board of Pharmacy proposes to amend Section 1751 of Article 7 of Division 17 of Title 16 of the California Code of Regulations for the purpose of rephrasing the text of subdivision (b) to make the phrase “compounding sterile injectable drug products” consistent throughout the Article; and to update Authority and Reference citations.

Existing regulation at Section 1784 of Article 10 of Division 17 of Title 16 of the California Code of Regulations requires the Designated Representative-in-Charge (DRIC) of a wholesaler to complete a self-assessment before July 1 of every odd-numbered year, or within 30 days of (1) a new wholesaler permit being issued; (2) when there is a change in the DRIC; and (3) when there is a change in the licensed location of a wholesaler to a new address. The regulation incorporates by reference “Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment” (Form 17M-26, Rev. 10/08). This self-assessment form assists wholesalers in increasing their compliance with legal requirements. The self-assessment form also makes the pharmacy inspection process more meaningful and provides relevant information to wholesalers and the DRIC.

The Board of Pharmacy proposes to amend Section 1784 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to reflect a new revision date of the self-assessment form incorporated by reference to be “Rev. 01/11.” This change would indicate to the reader that the information and references contained in the form were current as of the revision date. The proposal also corrects a punctuation mark by adding a closing quotation mark after the name of the self-assessment form. The board also proposes changes to the self-assessment form (17M-26) to (1) update citations/references since the last revision (10/08); to (2) correct previously misstated references and typographical errors; and (3) to make formatting changes. These changes would assure the designated representative-in-charge that the information and references contained therein reflected current statutory and regulatory requirements. Finally, the board proposes to modify the signature block on the form to add an acknowledgement for the holder of the license issued by the board that they have read and reviewed the completed self-assessment form. This would ensure that the holder of the license has read and reviewed the completed self-assessment, and would acknowledge that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board.
FISCAL IMPACT

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 not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. A pharmacy licensed under Sections 4029 and 4037 of the Business and Professions Code, and a wholesaler licensed under Section 4201 of the Business and Professions Code is currently required to complete a self-assessment before July 1 of every odd-numbered year. Additionally, any pharmacy licensed by the board that compounds drug products must comply with Articles 4.5 and 7. of Division 17 of Title 16 of the California Code of Regulations and must complete a self-assessment before July 1 of every odd numbered year. This proposal does not eliminate existing requirements, but it would require a pharmacy to also conduct a self-assessment when there is a change in the licensed location of the pharmacy to a new address. This is necessary to ensure that the pharmacy is compliant with statutory and regulatory requirements at the new location, and would protect the health and safety of the public.

Effect on Housing Costs: None
EFFECT ON SMALL BUSINESS

The Board has determined that this proposal would not have a significant impact on small businesses. In addition to existing requirements, the proposal would require a pharmacy licensed by the board to conduct a self-assessment when there is a change in the licensed location of the pharmacy to a new address. This is necessary to ensure that the pharmacy is in compliance with applicable statutory and regulatory requirements at the new location. This is reflective of the Board’s public protection mandate that whenever the protection of the public is inconsistent with other interest sought to be promoted, the protection of the public shall be paramount.

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 than the proposal described in this Notice.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

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 (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: California State Board of Pharmacy  
1625 N. Market Blvd., N219  
Sacramento, CA  95834  
Telephone No.: (916) 574-7913  
Fax No.: (916) 574-8618  
E-Mail Address: Carolyn.Klein@dca.ca.gov

The backup contact person is:

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