

## Board of Pharmacy

### Initial Statement of Reasons

Subject Matter of

Proposed Regulation: Self-Assessments for Pharmacies and Wholesalers

Sections Affected:

Amend 16 Cal.Code Reg. § 1715, § 1735.2, § 1751 and § 1784

#### Specific Purpose of the Proposed Changes:

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, makes the pharmacy inspection process more meaningful, and also 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. . Proposed changes to the self-assessment forms are as follows:

Proposed Changes to 17M-13 "Community Pharmacy Self-Assessment" "Hospital Outpatient Pharmacy Self-Assessment"

- The opening paragraphs were modified to reflect the proposed requirement that a self-assessment be completed whenever there is a change in the licensed location of the pharmacy.
- The "Notes" were modified to reflect the proposed change to the name of Form 17M-13 and to reference the self-assessment that is required (17M-39) if the pharmacy compounds drug products. This reference was added because the board's regulations related to compounded drug products went into effect on July 6, 2010. (See 16 CCR Sections 1735.-1735.8. [Article 4.5 specific to compounding, added July 6, 2010] and 16 CCR Sections 1751, 1751.01.-1751.02., and 1751.1.-1751.12. [Article 7, specific to sterile injectable compounding, amended July 6, 2010].)
- The letterhead was modified to reflect the current Governor's name (Brown), and the page footers were modified to reflect a new revision date of the form (Rev. 01/11) and to also include a total page count within the page numbering.
- Throughout the document, as needed, "nonbreaking spaces" were placed between a number (i.e., "5") and the word that preceded or followed so that a word group would be read together on one line. This reflects the preferred practice to keep together word groups that should be read together. Thus, "30 days" or "page 5" would print on the same line.
- Throughout the document, "nonbreaking spaces" were placed between legal reference citations (i.e., "B&PC", "CCR", "H&SC", "US") and section numbers, so that the citation did not break between two lines. For example, "CCR 1717" would print together on one line, instead of being broken between two lines. This reflects the preferred practice to keep together word groups that should be read together.
- Throughout the document, as needed, acronyms were corrected to reflect various statutes, such as the Business and Professions Code (B&PC), the California Code of Regulations (CCR), and the Health and Safety Code (H&SC).
- Throughout the document, "bullets" were added to items that were indented below an opening sentence or paragraph to provide for easy separation and reading.
- Throughout the document, a set of three check boxes appears next to each item so that the pharmacist-in-charge can mark the pharmacy's level of compliance with that item. The heading "Yes No N/A" is to appear above each set of check boxes whenever there is (1) a new section of items or (2) the first time a set of check boxes appears on a new page. Where extra sets of these headings appear, or where pagination changed, these headings were omitted or added to provide conformity throughout the document.

- In item “1. Facility” a “period” was moved from outside a quotation mark to inside the quotation mark at the end of a sentence to reflect the preferred American style of writing where periods and commas always go inside a closing quotation mark.
- In item “1. Facility” a reference to a pharmacy’s requirement to subscribe to the board’s e-mail notifications was added. This is found in Business and Professions Code section 4013, which became operative on July 1, 2010, and requires any facility licensed by the board to join the board’s e-mail notification list, as specified (See SB 795, Yee, Chapter 307, Statutes 2009.) Also, this section was amended in the 2009-2010 Legislative Session to allow an owner of two or more facilities licensed by the board to comply with the e-mail notification requirement by subscribing a single e-mail address to the board’s e-mail notification list, where the owner maintains an electronic notification system with all of its licensed facilities and immediately transmits to those board-licensed facilities any e-mail notice that is issued by the board, as specified. Thus, a reference to this latter statutory change was also added to item “1. Facility.” (See SB 1479, Senate Committee on Business Professions and Economic Development, Chapter 653, Statutes 2010.)
- In item “11. Prescription Labeling, Furnishing and Dispensing” references to prescription labeling requirements found in 16 CCR 1707.5 were added. On January 1, 2011, as a result of a separate formal rulemaking, regulations went into effect related to patient-centered prescription labels. References to the formatting of a prescription label, as well as the requirement to provide a prescription label printed in 12-point font, if requested by the consumer, was added to the self-assessment as the pharmacy is required to comply with 16 CCR 1707.5.
- In item “11. Prescription Labeling, Furnishing and Dispensing” a reference was added to a pharmacy’s exemption from the prescription labeling requirements of 16 CCR 1707.5. This was added because as of January 1, 2011, the board had the statutory authority to exempt from the patient-centered prescription label requirements (16 CCR 1707.5) prescriptions, as specified. (See SB 1489, Senate Committee on Business Professions and Economic Development, Chapter 653, Statutes of 2010, Amendment to B&PC 4076.5.)
- Also in item “11. Prescription Labeling, Furnishing and Dispensing” the words “and progesterone” were stricken from a reference to patient package inserts, because the federal regulation (21 CFR 310.516) was removed effective November 16, 2000 (see Federal Register, Vol. 64, November 16, 1999). Finally, an extra space was removed between “H&SC 11200” and the closing parentheses.
- In item “13. Quality Assurance and Medication Errors” – in the third item therein - a space was added between “CCR” and “1711[c][2][A]” and a closing parentheses was added to the end of the line.
- In item “14. Erroneous or Uncertain Prescription / Corresponding Responsibility for Filling Controlled Substance Prescriptions” – in the second item therein – a set of ‘check boxes’ was added so the pharmacist could indicate the level of compliance with this item.
- In item “14. Erroneous or Uncertain Prescription / Corresponding Responsibility for Filling Controlled Substance Prescriptions” – in the third item therein, first line – a typographical error was corrected to reflect the proper spelling of “dispense.”

- In item “15. Prescription Transfer” – in the first item therein – the regulation reference at the end of the line was corrected to reflect the subdivision [e] (not “[f]”) of CCR 1717. This corrects a typographical error contained in the previous version in the form.
- In item “15. Prescription Transfer” – in the fourth item therein, closing reference – the reference was corrected to reflect subdivision [e] (not “[f]”) of CCR 1717, which corrects a typographical error contained in the previous version of the form.
- In item “17. Record Keeping Requirements” – in the second item therein - one reference was corrected to read “B&PC” (not “CCR”), as the reference is to the Business and Professions Code, not the California Code of Regulations. Also, “B&PC” was added to the reference for the second indented line, to correct information that was omitted in the previous version of the form.
- In item “17. Record Keeping Requirements” – in the third item therein – a set of ‘check boxes’ was added so the pharmacist could indicate the level of compliance with this item.
- In item “17. Record Keeping Requirements” – in the fourth item therein – a closing ‘period’ was added to the end of the last sentence. This corrects an omission of a punctuation mark in the previous version of the form.
- In item “18. DEA Controlled Substances Inventory” – in the second indented bullet – a reference to “Schedule 111” was changed to “Schedule III” so that the schedule numbers were printed in Roman Numerals and are consistent with the type in the Health and Safety Code and in the Code of Federal Regulations.
- In item “19. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescription” – in the third item – a closing parentheses mark was added to the closing reference to correct an omission from the previous version.
- In item “19. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescription” – in the eighth and ninth items – reference “CCR” was added to the closing citations, as they were omitted in the previous version.
- In item “21. Repackaging by the Pharmacy” – in the first item, closing reference – reference to CCR 1707.5 was added, as drugs that are repackaged in the pharmacy for dispensing to patients pursuant to a prescription must have a patient-specific label that is formatted in accordance with 16 CCR 1707.5.
- In item “21. Repackaging by the Pharmacy” – in the second item – the closing reference was updated. In 2009/2010 the board promulgated regulations related to compounding drug products. The new compounding regulations went into effect on July 7, 2010. Through that rulemaking, the record keeping requirements for records that must be made and kept were moved to 16 CCR 1751.1.
- In item “22. Refill Pharmacy” – in the third item, closing sentence – the section number is corrected so that – if the answer to the questions, as stated, is “no” or “not applicable” – they would go to the next section (“23” – not “22”).
- In item “22. Refill Pharmacy” – in the fifth item – reference to “CCR 1707.5” was added, because through regulations promulgated in 2010, the pharmacy must format the refill prescription label in accordance with 16 CCR 1707.5.
- In item “22. Refill Pharmacy” – in the second through ninth item – reference to “CCR” was added before the section numbers to correct omissions from the previous version.

- In item “23. Policies and Procedures” – in the first item – “bullets” were added for ease of reading. Also, in the first indented bullet, the B&PC section number was corrected to “4052.1[a][3].” This correction is necessary because in 2006, Business and Professions Code was recodified into several sections. This resulted in the reference being moved from B&PC 4052[a][5][A][iii] to B&PC 4052.1[a][3]. (See Chapter 777, Statutes of 2006, AB 2408 [Negrete McLeod]).
- In item “23. Policies and Procedures” – in the eighth indented item – the reference to the Combat Methamphetamine Epidemic Act of 2007 was corrected to provide the entire federal reference of “Title VII of Public Law 109-177.”
- In item “23. Policies and Procedures” – a twelfth indented bullet was added to reference the pharmacy’s requirement to have policies and procedures for assisting patients with limited or no English proficiency understand the information on the prescription container label. (See 16 CCR 1707.5., effective January 1, 2011.)
- Item 24. related to Compounding was stricken from the form. Since the last revision of Form 17M-13, the board promulgated regulations related to compounding (see Article 4.5. and Article 7. of Division 17 of Title 16 of the California Code of Regulations, which became effective on July 6, 2010). Any pharmacy that compounds drug products is required to comply with Article 4.5. of Division 17 of Title 16 of the California Code of Regulations, and any pharmacy that compounds sterile injectable drug products must also comply with the requirements of Article 7. of Division 17 of Title 16 of the California Code of Regulations. Section 1735.2 incorporates by reference a separate self-assessment form for compounding; thus, the references in Form 17M-13 are duplicative of more current requirements.
- Item 26. was renumbered to Item 25, because item 24. was removed from the self-assessment form. Also, in the third item in “25. Nuclear Pharmacy” a reference was added because any pharmacy that compounds medication must complete the self-assessment that is required by Article 4.5 of Division 17 of Title 16 of the California Code of Regulations.
- The signature block on 17M-13 was modified to add an acknowledgement by 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 therein could result in the revocation of the license issued by the board.
- The closing pages where legal references and various phone numbers and addresses were modified to reflect consistent formatting and make corrections to phone numbers, addresses and web site references.

#### Proposed Changes to 17M-14 “Hospital Pharmacy Self-Assessment”

- The letterhead was modified to reflect the current Governor’s name (Brown), and the page footers were modified to reflect a new revision date of the form (Rev. 01/11) and to also include a total page count within the page numbering.

- The opening paragraphs were modified to reflect the proposed requirement that a self-assessment be completed whenever there is a change in the licensed location of the pharmacy.
- The “Note” was modified to cross reference the self-assessment form (17M-13) that is required to be completed if a hospital dispenses prescriptions for outpatient use, and to also cross-reference the self-assessment form (17M-39) that must be completed if the hospital compounds drug products.
- Throughout the document, as needed, “nonbreaking spaces” were placed between a number (i.e., “5”) and the word that preceded or followed so that a word group would be read together on one line. This reflects the preferred practice to keep together word groups that should be read together. Thus, “30 days” or “page 5” would print on the same line.
- Throughout the document, “nonbreaking spaces” were placed between legal reference citations (i.e., “B&PC”, “CCR”, “H&SC”, “US”) and section numbers, so that the citation did not break between two lines. For example, “CCR 1717” would print together on one line, instead of being broken between two lines. This reflects the preferred practice to keep together word groups that should be read together.
- Throughout the document, as needed, acronyms were corrected to reflect various statutes, such as the Business and Professions Code (B&PC), the California Code of Regulations (CCR), and the Health and Safety Code (H&SC).
- Throughout the document, “bullets” were added to items that were indented below an opening sentence or paragraph to provide for easy separation and reading.
- Throughout the document, a set of three check boxes appears next to each item so that the pharmacist-in-charge can mark the pharmacy’s level of compliance with that item. The heading “Yes No N/A” is to appear above each set of check boxes whenever there is (1) a new section of items or (2) the first time a set of check boxes appears on a new page. Where extra sets of these headings appear, or where pagination changed, these headings were omitted or added to provide conformity throughout the document.
- On the first page, where the pharmacy identifies its Licensed Sterile Compounding Permit number, an area was added to insert the expiration date of the permit; also, reference to the accreditation agency (previously referenced on page 24) was moved to the cover page, and lines were added so the pharmacist could indicate the dates the accreditation is granted. These changes were necessary to organize on one page the pharmacy’s information as it relates to various permit and license numbers.
- In item “1. Pharmacy” – in the first item – reference to B&PC 4116 was added, because that section specifies that the pharmacist is responsible for any individual who enters the pharmacy. Also, a reference to a pharmacy’s requirement to subscribe to the board’s e-mail notifications was added. This is found in Business and Professions Code section 4013, which became operative on July 1, 2010, and requires any facility licensed by the board to join the board’s e-mail notification list, as specified (See SB 795, Yee, Chapter 307, Statutes 2009.) Also, this section was amended in the 2009-2010 Legislative Session to allow an owner of two or more facilities licensed by the board to comply with the e-mail notification requirement by subscribing a single e-mail address to the board’s e-mail notification list, where the owner maintains an electronic notification system with

all of its licensed facilities and immediately transmits to those board-licensed facilities any e-mail notice that is issued by the board, as specified. Thus, a reference to this latter statutory change was also added to item "1. Pharmacy." (See SB 1479, Senate Committee on Business Professions and Economic Development, Chapter 653, Statutes 2010.)

- In item "7. Duties of an Intern Pharmacist" – a third item was added to indicate that intern hours affidavits are to be signed by the pharmacist under whom the experience was earned. This requirement has been specified in statute since 2004 and was omitted from previous versions of the form (see SB 1913, Chapter 695, Statutes 2004).
- In item "21. Discharge Medication/Consultation Services" – in the third item – language was added to reflect the requirement that the prescription label is formatted in accordance with 16 CCR 1707.5. 16 CCR 1707.5 became effective on January 1, 2011. A fourth item was added to reference the requirement that the prescription label be printed in 12-point typeface if requested by the patient. A fifth item was added to reference a pharmacy's exemption from the prescription labeling requirements of 16 CCR 1707.5. This was added because as of January 1, 2011, the board had the statutory authority to exempt from the patient-centered prescription label requirements (16 CCR 1707.5) prescriptions, as specified. (See SB 1489, Senate Committee on Business Professions and Economic Development, Chapter 653, Statutes of 2010, Amendment to B&PC 4076.5.)
- In item "23. Policies and Procedures" – a ninth indented bullet was added to reference the pharmacy's requirement to have policies and procedures for assisting patients with limited or no English proficiency understand the information on the prescription container label. (See 16 CCR 1707.5., effective January 1, 2011.)
- The information in item "24. Compounding" was stricken, and a sentence was added to cross reference the self-assessment form that is required by Article 4.5 of Division 17 of Title 16 of the California Code of Regulations related to compounding. This was done to eliminate duplication between 17M-14 and the self-assessment that is required by CCR 1735.2(j).
- The signature block on 17M-14 was modified to add an acknowledgement by 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 therein could result in the revocation of the license issued by the board.
- The closing pages where legal references and various phone numbers and addresses were modified to reflect consistent formatting and make corrections to phone numbers, addresses and web site references.

Existing regulation at Section 1735.2 of Article 4.5 of Division 17 of 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. Proposed changes to the self-assessment form are as follows:

#### Proposed Changes to 17M-39, "Compounding Self-Assessment"

- The letterhead was modified to reflect the current Governor's name (Brown), and the page footers were modified to reflect a new revision date of the form (Rev. 01/11).
- Throughout the document, as needed, "nonbreaking spaces" were placed between a number (i.e., "5") and the word that preceded or followed so that a word group would be read together on one line. This reflects the preferred practice to keep together word groups that should be read together. Thus, "30 days" or "page 5" would print on the same line.
- Throughout the document, "nonbreaking spaces" were placed between legal reference citations (i.e., "B&PC", "CCR", "H&SC", "US") and section numbers, so that the citation did not break between two lines. For example, "CCR 1717" would print together on one line, instead of being broken between two lines. This reflects the preferred practice to keep together word groups that should be read together.
- Throughout the document, as needed, acronyms were corrected to reflect various statutes, such as the Business and Professions Code (B&PC), the California Code of Regulations (CCR), and the Health and Safety Code (H&SC).
- Throughout the document, "bullets" were added to items that were indented below an opening sentence or paragraph to provide for easy separation and reading.
- Throughout the document, a set of three check boxes appears next to each item so that the pharmacist-in-charge can mark the pharmacy's level of compliance with that item. The heading "Yes No N/A" is to appear above each set of check boxes whenever there is

(1) a new section of items or (2) the first time a set of check boxes appears on a new page. Where extra sets of these headings appear, or where pagination changed, these headings were omitted or added to provide conformity throughout the document.

- Prior to item “1. Definitions” the word “ALL” was added before “COMPOUNDING,” and the text “Complete Sections 1 through 8” was added so that a pharmacist in charge would be directed to complete the identified sections if their pharmacy compounded drug products.
- In item “4. Labeling of Compounded Drug Products” – in the second item related to information on the label – reference was made to the requirement to format the prescription label in accordance with CCR 1707.5, which became effective on January 1, 2011.
- In item “4. Labeling of Compounded Drug Products” – a new third item was added to reference the pharmacy’s requirement to provide a prescription label in 12-point typeface, if requested by the patient. This new requirement went into effect on January 1, 2011 (See 16 CCR 1707.5(a).)
- In item “4. Labeling of Compounded Drug Products” – a new fourth item was added so that the pharmacist-in-charge could indicate if the pharmacy is exempt from the prescription label requirements of 16 CCR 1707.5, and also to indicate the date on which the board granted such an exemption. This reflects new statutory language found in B&PC 4075.4(d) which became effective on January 1, 2011. (See SB 1489, Senate Committee on Business Professions and Economic Development, Chapter 653, Statutes of 2010, Amendment to B&PC 4076.5.)
- Prior to item “9. For Pharmacies that Compound Sterile Injectable Drugs” – and before the un-numbered item where the pharmacist-in-charge would indicate if the pharmacy has a board issued Licensed Sterile Compounding Permit – a statement was added so that the pharmacist-in-charge could indicate whether or not the pharmacy compounded sterile injectable drugs, and – if “yes” – to complete sections 9. through 19.
- The first, un-numbered item related to whether or not the pharmacy has a board-issued Licensed Sterile Compounding Permit was re-numbered to item 10. In that item, the article “The” was added in front of the word “pharmacy” to correct the grammatical structure of the sentence. This also renumbered each successive item.
- In item “13. Sterile Injectable Labeling Requirements” – in the opening sentence, the number “16” was removed in front of “CCR 1735.4 because it is unnecessary. On page 3 of the document, below the heading, the statement is made that all references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.
- The signature block on 17M-39 was modified to add an acknowledgement by 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 therein 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 of Title 16 of the California Code of Regulations specifies limitations and requirements for compounding sterile injectable

drug products. These limitations and requirements are in addition to the requirements found in Article 4.5 of Division 17 of 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. Proposed changes to the self-assessment form itself are as follows:

Proposed changes to Form 17M-26 “WHOLESALE Dangerous Drugs & Dangerous Devices Self Assessment”

- The letterhead was modified to reflect the current Governor’s name (Brown), and the page footers were modified to reflect a new revision date of the form (Rev. 01/11).
- The second opening sentence was modified to provide that “B&PC” is the acronym used throughout the document for the Business and Professions Code. Throughout the document, where “B & P” appears in relation to the Business and Professions Code, the acronym was change to “B&PC.” This provides conformity throughout the various self-assessment forms used by the board.

- Throughout the document, as needed, “nonbreaking spaces” were placed between a number (i.e., “5”) and the word that preceded or followed so that a word group would be read together on one line. This reflects the preferred practice to keep together word groups that should be read together. Thus, “30 days” or “page 5” would print on the same line.
- Throughout the document, “nonbreaking spaces” were placed between legal reference citations (i.e., “B&PC”, “CCR”, “H&SC”, “US”) and section numbers, so that the citation did not break between two lines. For example, “CCR 1717” would print together on one line, instead of being broken between two lines. This reflects the preferred practice to keep together word groups that should be read together.
- In item “2. Facility” – two items were added to the end of the section to restate the requirements found in Business and Professions Code § 4013. First, to provide a reference where the designated-representative-in-charge (DRIC) could indicate if the facility is registered to the board’s e-mail notifications, and to indicate the date the facility last received a notification, and also to indicate what e-mail address is registered with the board. Second, an item was added so that the DRIC could indicate if the facility receives the board’s e-mail notifications through the facility owner’s electronic notice system (in lieu of the board’s e-mail notification system) and also indicate the date the last notification was received, and what e-mail address is registered with the board. Finally, a space was added to indicate any “Corrective Action or Action Plan” the DRIC might note for this item.
- In item “8. Sale or Transfer of Drugs by this Business” – on page 9, second item from the bottom – dates were corrected to reflect the date by which an electronic pedigree must accompany all drugs. (See SB 1307, Ridley-Thomas, Chapter 713, Statutes of 2008.)
- Throughout the document, a set of three check boxes appears next to each item so that the pharmacist-in-charge can mark the pharmacy’s level of compliance with that item. The heading “Yes No N/A” is to appear above each set of check boxes whenever there is (1) a new section of items or (2) the first time a set of check boxes appears on a new page. Where extra sets of these headings appear within a section, or where pagination changed, these headings were deleted or included so that the PIC could easily reference what box to check in relation to the pharmacy’s level of compliance with any given item.
- The signature block on 17M-26 was modified to add an acknowledgement by 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 therein could result in the revocation of the license issued by the board.

### Factual Basis/Rationale

Business and Professions Code section 4001.1 mandates that protection of the public shall be the highest priority for the Board of Pharmacy and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

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 4300 specifies that every license issued by the board may be suspended or revoked and is subject to disciplinary action.

Board of Pharmacy regulations, as described herein, incorporate by reference various self-assessment forms. Self-assessment forms serve as an easy reference guide for a Pharmacist-in-Charge or a Designated Representative-in-Charge. As pharmacy statutes and regulations are added, amended, or repealed, and if they are applicable to a licensee that utilizes any of the self-assessment forms incorporated by reference, as specified in this proposal, it is necessary to update those citations and references.

### Underlying Data

1. February 2-3, 2011 Board Meeting. Relevant pages of the Agenda, Meeting Materials, and Minutes
2. October 20-21, 2010 Board Meeting. Relevant pages of the Agenda, Meeting Materials and Minutes
3. July 28-29, 2010 Board Meeting. Relevant pages of the Agenda, Meeting Materials and Minutes
4. Senate Bill 1489, Chapter 653, Statutes of 2010
5. Senate Bill 795, Chapter 307, Statutes of 2009
6. Senate Bill 1307, Chapter 713, Statutes of 2008
7. Assembly Bill 2408, Chapter 777, Statutes of 2006
8. Senate Bill 1913, Chapter 695, Statutes of 2004
9. Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations Related to Patient-Centered Prescription Labels (Effective Date of Regulation January 1, 2011)
10. Articles 4.5 and 7. of Division 17 of Title 16 of the California Code of Regulations Related to Compounding of Drug Products (Effective Date of Regulation July 6, 2011)
11. Federal Register, Vol. 64, November 16, 1999, 62110-62112
12. Search Result for U.S. Drug Enforcement Administration, Office of Diversion Control, "Combat Methamphetamine Epidemic Act of 2005"
13. The Gregg Reference Manual, 10<sup>th</sup> Edition. ISBN 0-07-293653-3

### 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 following facts or evidence/ documents/testimony:

The Board discussed this regulatory proposal at its Board Meeting held February 2-3, 2011, and the proposed addition to each form's signature block indicating an acknowledgement of the

holder of the board-issued license. Completing a self-assessment is a current requirement for a Pharmacist-in-Charge (PIC) or a Designated Representative-in-Charge (DRIC). If a PIC or a DRIC identifies deficiencies as a result of completing the self-assessment, the holder of the board-issued license needs to be aware of any such deficiencies, because the holder of the license is ultimately responsible for the pharmacy's or wholesaler's compliance with laws and regulations. The board does not believe it is burdensome for the holder of a board-issued license to acknowledge a review of a self-assessment completed by its PIC or DRIC.

#### Specific Technologies or Equipment

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

#### Consideration of Alternatives

The only alternative to this proposal is to not amend sections 1715, 1735.2, 1751, and/or 1784 of Title 16 of the California Code of Regulations or the self-assessment forms that incorporated by reference in these sections.

No reasonable alternative to amending the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons than the proposed regulation.