

BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Revision of Self-Assessment forms.

Title 16 Sections Affected: Amend 16 California Code of Regulations (“CCR”) Section 1715 and 16 CCR Section 1784 and three forms adopted by reference with in those regulations, Form 17M-13, Form 17M-14, and Form 17M-26.

Updated Information

When the Notice of Proposed Action and the text of the regulations were sent out to interested parties, a Notice of Availability of Language erroneously entitled “Notice of Proposed Modifications” was included (attached as Exhibit B). That one-page document set out, underlined for emphasis, the dates of the first comment period, from March 20, 2015 to May 4, 2015, and to whom comments should be directed. This document was mistakenly given the heading “Notice of Proposed Modification” which is the heading used for a 15-day notice, instead of the heading “Notice of Proposed Action” used for a 45-day notice. The body of the Notice was correct. After the close of the first comment period, the Board also discovered that the email which had been sent to individuals who had signed up on the Board of Pharmacy (“Board”) website for notification of regulatory actions by email had been incomplete. The PDF attached to that email contained only the Notice of the Availability of Language (mislabeled as described above) and the text of the regulation, and was missing the Notice of Proposed Action. The posting to the website, the sending out a Subscriber Alert, and mailing hard copies by U.S. mail had all been done correctly, but for the 102 people receiving emails, their notice had been deficient. During that first comment period, one set of comments was received from Dale Neuls, PharmD, of Med RX Infusion.

Because those 104 individuals had received deficient notice, the Board opened up second 45-day comment period from May 29, 2015 to July 13, 2015. The Board gave notice of this second comment period by sending out the regulation text, the Notice of Proposed Action, and a new Notice of Availability of Language explaining that the Board was opening another 45-day comment period (entitled “Notice of Proposed Action” attached as Exhibit B). These three documents were: 1) mailed via U.S. Mail to individuals who had requested mailed notice of regulatory actions, 2) emailed to the 104 individuals who had requested email notification of regulatory actions, 3) notice of the second comment period was posted on the Board website, and 4) a Subscriber Alert was emailed alerting subscribers to the second comment period. During the second comment period, one set of comments was received from Rosemarie Hicks, PharmD, of Sharp Healthcare.

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the Board of Pharmacy’s position regarding the amendment of the above sections, and is updated to include the following information. The Board of Pharmacy’s notice indicated that the Board of Pharmacy (“Board”) did not intend to hold hearing on the

matter, unless requested. No request for hearing was received by the Board during either 45-day comment period.

In the Initial Statement of Reasons, in the “Underlying Data” section, item 2 had a typographical error, so that it read “October 29-30, 2014 Meeting ...,” which should have read, “October 28-29, 2014 Meeting ...” and is corrected herein.

The non-substantive changes made are described as follows:

Form 17M-13 “Community Pharmacy Self-Assessment, Hospital Outpatient Pharmacy Self-Assessment.”

On page 1, second paragraph from the top, change: “must be competed in entirety” to “must be completed in its entirety.” This change is believed to be non-substantive because it corrects a typographical and a grammatical error.

On page 1, third paragraph from the top, the revised date is added to ensure reference to the correct edition of the form to read (17M-39 Rev. 02/12).

On page 1, last sentence “Website address (optional): _____” is added to allow community pharmacies the option of providing a website address should they wish to do so. The change is non-substantive because it is optional and pharmacies are not required to provide the information.

On page 2, at top, second sentence, after “(Please attach additional sheet if necessary)” add, as a cross-reference, a legend which reads: “APP=Advanced Practice Pharmacist, DEA = Drug Enforcement Administration.” APP is the acronym for Advanced Practice Pharmacist, referred to within the form on page 8, at Section 7. Duties of an Advanced Practice Pharmacist. The category of Advanced Practice Pharmacist was added in 2013 with the adoption of Business & Professions Code (“B&P”) section 4052.6 (SB 493, Hernandez, Chapter 469, Statutes of 2013). DEA stands for the Drug Enforcement Administration, the US federal law enforcement agency under the Department of Justice, and citations to the DEA website and CA DEA offices are set out within the form at page 33. DEA is a common acronym used in the pharmacy setting. This change is believed to be non-substantive because it revises the structure of the form to set out both the acronyms and what they stand for at the top of page 2, essentially adding a cross-reference to information found elsewhere in the document.

On page 2, within entries 6-8, below the entries “INT# _____ Exp. Date: _____” remove the proposed added designation “APP# _____ Exp. Date: _____” and below that the designation “DEA# _____ Exp. Date : _____” Pharmacy Interns will not have an APP# or a DEA#. This change is believed to be non-substantive because it revises the structure of the form by removing superfluous designations.

On page 2, within entries 9-11, below the entries “TCH# _____ Exp. Date: _____” Remove the proposed added designations “APP# _____ Exp. Date: _____” and below that the designation “DEA# _____ Exp. Date _____” Pharmacy

Technicians will not have an APP# or DEA#, This change is believed to be non-substantive because it revises the structure of the form by removing these two superfluous designations.

On page 3, Section 1.10 should read section 27 instead of section 24 and should state “Compounding” and not “Compounding-Sterile Injectable Drug.” This change is believed to be non-substantive because it correctly identifies the corresponding section within the document.

On page 7, Section 6.1 – add an “s” to correct incorrect verb tenses in several spots, add a comma, and add an “es” to correct an incorrect verb tense in the section (all double-underlined herein) to read as follows: “The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmitss a valid prescription to another pharmacist; administerss drugs and biological products ordered by the prescriber; manufacturess, measuress, fitss to the patient or sellss and repairss dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; providess consultation, trainings and education to patients about drug therapy disease management and disease prevention; provides professional information and participates in multidiscipline review of patient progress; furnishess medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement products, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; orderss and interpretss tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052).” These changes are believed to be non-substantive because they merely correct the grammar.

On page 7, Section 6.3, semi-colons were added within the paragraph for grammatical clarification.

On page 8, Section 6.6, the citation was changed from H&SC 1206(a) to B&PC 1206.6. This change is necessary to properly reference the correct statute.

On page 9, Section 6.7, the citation was changed from H&SC 1206.6 to B&PC 1206.6. This change is necessary to properly reference the correct statute.

On page 9, Section 7.2.1, the citation of B&PC 4052.6(a) was added to consistency within the document.

On page 9, Section 7.2.2, the citation of B&PC 4052.6(a) was added to consistency within the document.

On page 9, Section 7.2.5, an extra parentheses is removed from the statute reference.

On page 11, Section 12.2, direction was changed to direct for grammatical clarification.

On page 11, Section 12.6, “a” was added before prescriber’s office for grammatical clarification.

On page 11, Section 12.8, “C” was added after H&S for formatting consistency.

On page 13, Section 13.4.2, the citation was changed from CCR 1707.5[a][22] to CCR 1707.5[a][2] to properly reference the correct statute.

On page 13, Section 13.11, the citation within the existing text was changed from 25 USC 1473 section 4(b) to 15 USC 1473(b) to properly reference the correct title and statute.

On page 17, Section 19.3, 4145.5 was added for clarification to the correct Business and Professions Code reference.

On page 17, Section 19.3.3, 10 or few was removed due to a change in law.

On page 17, Section 19.3.3, “.5” was added after 4145 for clarification to the correct Business and Professions Code reference.

On page 17, Section 19.5, “B&PC 4105” was added for clarification to the correct Business and Professions Code reference.

On page 18, Section 20.8, “or electronic equivalent (CSOS)” was added to allow for electronic submission of the required data.

On page 19, Sections 20.4 and 20.5, “21” was added in front of CFR to reference the proper title number and for formatting consistency.

On page 21, Section 21.12 – change the preposition in the phrase “substances that are received by the prescriber” to read “substances that are received by from the prescriber.” This change is believed to be non-substantive because changing the preposition used merely corrects either a typographical or grammatical error.

On page 23, Section 24.7, “or” was changed to “of” for grammatical clarity.

On page 26, Section 26.3, the statute reference was changed from 4052.3(a)(2) to 4052.3(a)(1) to clarify to the correct Business and Professions Code.

On pages 26-28, Section 26.2 – 26.3.7 were improperly duplicated and have been removed.

On page 27, Section 27.1, was incorrectly identified as Section 27 in the Initial Statement of Reasons. Additionally, (Rev. 01/11.) was changed to (Rev. 02/12) to ensure reference to the correct edition of the form.

On page 29, Sections 30.1.1.1 and 30.1.1.2, the reference was changed from H&SC 150201(a)(1) to H&SC 150201(b)(1) to properly reference the correct statute.

On page 32, which lists Legal References, at the bottom of the page, remove the line for the Pharmacist In Charge to initial and remove the label underneath which reads “PIC Initials.” This change is believed to be non-substantive because it simply revises the structure of the form to remove an unnecessary spot for the PIC to initial.

On page 33, which is a continuation of the list of Legal References, at the bottom of the page, remove the line for the Pharmacist In Charge to initial and remove the label underneath which

reads "PIC Initials." This change is believed to be non-substantive because it simply revises the structure of the form to remove an unnecessary spot for the PIC to initial.

Form 17M-14 "Hospital Pharmacy Self-Assessment"

On page 1, second paragraph from the top, change: "must be completed in entirety" to "must be completed in its entirety." This change is believed to be non-substantive because it corrects a typographical and a grammatical error.

On page 1, between the first three paragraphs, remove the extra lines of space in between the paragraphs at the top of page 1 to make room for the addition of a legend. This change is believed to be non-substantive as it revises the structure of the form.

On page 1, third paragraph from the top, the revised date is added to ensure reference to the correct edition of the form to read (17M-39 Rev. 02/12).

On page 1, at the bottom of page after "Pharmacy Staff (Pharmacists, interns, technicians)" add, as a cross-reference, a legend which reads: "APP=Advanced Practice Pharmacist, DEA = Drug Enforcement Administration." APP is the acronym for Advanced Practice Pharmacist, referred to within the form on page 8, at Section 7. Duties of an Advanced Practice Pharmacist." The category of Advanced Practice Pharmacist was added in 2013 with the adoption of Business & Professions Code ("B&P") section 4052.6 (SB 493, Hernandez, Chapter 469, Statutes of 2013). DEA stands for the Drug Enforcement Administration, the US federal law enforcement agency under the Department of Justice, and citations to the DEA website and CA DEA offices are set out within the form at Page 33. DEA is a a common acronym used in the pharmacy setting. This change is believed to be non-substantive because it revises the structure of the form to place the acronyms and what they stand for at the bottom of page 1, essentially adding a cross-reference to information found elsewhere in the document.

On page 2, within entries 6-8, below the entries "INT# _____ Exp. Date: _____" remove the proposed added designation "APP# _____ Exp. Date: _____" and below that the designation "DEA# _____ Exp. Date : _____" Pharmacy Interns will not have an APP# or a DEA#. This change is believed to be non-substantive because it revises the structure of the form by removing superfluous designations.

On page 2, within entries 9-11, below the entries "TCH# _____ Exp. Date: _____" Remove the proposed added designations "APP# _____ Exp. Date: _____" and below that the designation "DEA# _____ Exp. Date _____" Pharmacy Technicians will not have an APP# or DEA#. This change is believed to be non-substantive because it revises the structure of the form by removing superfluous designations.

On page 2, renumber the items so there are four INT# entries and four TCH# entries filling the page. This change is believed to be non-substantive because it is merely renumbering items.

On page 3, since once the excess items are removed that page would be left blank, move the text from page 4 up to make a new page 3, and renumber the succeeding pages 4-23. This change is believed to be non-substantive because it simply renumbers the pages.

On page 4, Section 1.4, “30 days” was changed to “14 days” as required by statute in B&PC 4104(c).

On page 5, Section 1.12, changed from “Section 24” to “Section 27” and removed “Sterile Injectable Drugs” as the reference is no longer correct.

On page 8, Section 6.2, “CCR 1709.2(b)” was changed to “CCR 1709.1(b)” to properly reference the correct statute.

On page 8, Section 8 – add a “d” so that the Section heading reads “Duties of an Advanced Practice Pharmacist.” This change is believed to be non-substantive because it simply corrects the spelling of this word.

On page 9, Sections 8.2.2 and 8.2.3, added citation references of “B&PC 4052.6(a)” to maintain consistency within the document.

On page 9, Section 8.2.3 – combine the words “in to” to read “into” as one word. This change is believed to be non-substantive as it corrects a typographical error.

On page 9, Section 8.2.5, corrected the citation reference from “B&PC 4052.6(01)” to “(B&PC 4052.6(d))” to properly reference the correct statute.

On page 10, Section 10.8.2, after pharmacist, added “then used by the technician to fill unit dose distribution and floor and ward stock” was added to comply with 16 CCR 1793.8(b).

On page 13, Section 14.3, changed “received” to “receive” for proper grammar.

On page 13, Section 15.1, added section number “15.1” in front of the text to properly identify it.

On page 15, Section 18.2.9, added citation references of H&SC 150204(k) and B&PC 4105(c) to properly identify all statute references.

On page 17, Section 21.1, added section number “21.1” in front of the text to properly identify it.

On page 17, Section 22.1, moved the semicolon from the end of the reference to in front of the reference.

On page 20, Section 26.1.5, “30 days” was changed to “14 days” as required by statute in B&PC 4104(c).

On page 21, Section 27, was incorrectly identified as Section 27 in the Initial Statement of Reasons. Additionally, (Rev. 01/11.) was changed to (Rev. 02/12) to ensure reference to the correct edition of the form.

On page 24, in the footer, add in “17M-15 (Rev.10/14)” and “23 of 23” This change is believed to be non-substantive because it essentially is just a renumbering of the page by editing the footer on this page to make it consistent with the other pages in the document

On page 23, which lists Legal References, at the bottom of the page, remove the line for the Pharmacist In Charge to initial and remove the label underneath which reads “PIC Initials.” This change is believed to be non-substantive because it simply revises the structure of the form to remove an unnecessary spot for the PIC to initial.

On Page 24, where the Legal References continue, at the bottom of the page, add in the designation “17M-14 (Rev. 10/14) and, centered at the bottom, “24 of 24.” This change is believed to be non-substantive because it simply revises the structure of the form to remove an unnecessary spot for the PIC to initial.

Form 17M-26 “Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment”

On page 1, “(Use additional sheets if needed)” was added below “Other Permit #” to allow licensees to attach additional pages if needed. Wholesalers can be licensed in every state and the area provided may be insufficient.

On page 5, Section 3.2, reference to B&PC 4053.1(b) to provide accurate citation reference to the statutory requirement.

On page 12, Section 12.3, “Schedule III” was changed to “Schedule III, IV, and V” as required by 21 CFR 1301.72(b).

On page 12, Section 12.6 – change the capitalization of the letter **B** in business so that it is lower case. This change is believed to be non-substantive as it corrects a typographical error.

On page 13, Section 12.14, remove unnecessary dash and the underline of the dash, and the inadvertent highlight of the parenthesis following the unnecessary dash. This change is believed to be non-substantive as it corrects a typographical error.

On page 15, Section 13, remove the question marks at the end of each sentence of every subsection within section 13. This change is believed to be non-substantive as it merely changes the punctuation and syntax of the subsections.

On page 15, Section 13.1, “the following” was added at the end of the sentence to provide additional clarity and guidance.

On page 15, Section 13.1.7, “errors” was changed to “errors and inaccuracies in inventories” to conform with the language of 16 CCR 1780(f)(1).

On page 16, Section 14.1, added section number “14.1” in front of the text to properly identify it.

On page 16, Section 15.1, section “15” was changed to section “16” due to renumbering.

On page 20, Section 18.1 added section number “18.1” in front of the text to properly identify it. Additionally, added “Use additional sheets if necessary” to allow licensees to attach additional documents if needed.

On page 21, which lists Legal References, at the bottom of the page, remove the line for the Designated Representative In Charge or Pharmacist to initial and remove the label “DRIC/RPH Initials.” This change is believed to be non-substantive because it simply revises the structure of the form to remove an unnecessary spot for the DRIC/RPH to initial.

On page 22, which continues the list of Legal References, at the bottom of the page, remove the line for the Designated Representative In Charge or Pharmacist to initial and remove the label “DRIC/RPH Initials.” This change is believed to be non-substantive because it simply revises the structure of the form to remove an unnecessary spot for the DRIC/RPH to initial.

Local Mandate: None.

Business Impact: This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of substantive comments and the lack of any requests for a hearing regarding this rulemaking proposal.

Consideration of Alternatives: No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the board/bureau/commission/program would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulation or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Objections or Recommendations/Responses to Comments

The comments addressing revising the forms which were received by the Board during the 45-day comment periods from March 20, 2015 to May 6, 2015, and from May 29, 2015 to July 13, 2015 were reviewed and considered by the Board.

Summary of Comments Received During the 45-Day Comment Period:

The Board received comments from two individuals during the two 45-day public comment periods discussed above in Updated Information as follows:

Comment from Dale Neuls, PharmD, Med RX Infusion

Dr. Neuls submitted comments restricted to the self-assessment form entitled “Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment” (Form 17M-13, Rev 01/11) which is incorporated by reference in 16 CCR Section 1715. Dr. Neuls requested a legend be added for clarifying the meaning of APP# and DEA#, and inquired as to why an APP# or DEA# was

asked for from interns and pharmacy technicians. Dr. Neuls also asked about including an NPI# (which is a National Provider Number).

Dr. Neuls asked that the typographical error or grammar be corrected by changing the preposition used in Item 21.12 as follows: “21.12. Electronic prescriptions (e-scripts) for controlled substances that are received by from the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311).”

Board Response

The Board appreciates Dr. Neuls’ comments. The structural change of adding a legend explaining the acronyms used on page 2 will improve the form’s clarity. It is essentially adding a user-friendly cross-reference, because the meaning of the acronyms can be gleaned from other references to APP and DEA elsewhere in the form. This is also being done on Form 17M-14 “Hospital Pharmacy Self-Assessment” for consistency across those two forms.

The Board agrees with Dr. Neuls’ observation that it is unnecessary to ask for APP#s and DEA#s for interns and pharmacy technicians, and has removed those lines to improve the structure of the form. This is also being done on Form 17M-14 “Hospital Pharmacy Self-Assessment” to maintain consistency across those two forms. The Board does not have a need for pharmacists’ NPI # thus; the Board declines to add language asking for NPI # and rejects this comment.

The Board appreciates Dr. Neuls’ comment about item 21.12 and has made the change in order to use of the proper preposition in item 21.12, correcting the incorrect grammar (or typographical error) pointed out in his suggestion.

Comment from Rosemarie Hicks, PharmD, Sharp Healthcare

As to Form 17M-14, “Hospital Pharmacy Self-Assessment,” Dr. Hicks asked for clarification on item 8.1 in Section 8, asking what “personally registered with the federal Drug Enforcement Administration” means in that item. She asks if the item is referring to registration with CURES, or pharmacists working under a collaborative agreement, or if it was for APP pharmacists, and suggested a link be provided within the form to the location where a pharmacist needs to register.

Board Response

The Board appreciates Dr. Hicks’ comment, but does not agree that greater clarification of Item 8.1 is needed. It is the first item in Section 8, which (as corrected) is titled “Duties of an Advanced Practice Pharmacist,” and this is sufficient to make clear that the item refers to the need for Advanced Practice Pharmacists to register and obtain a DEA#. As an Advanced Practice Pharmacist will be initiating or adjusting drug therapy, they are required to be “personally” registered with the DEA. Additionally, the requirement for “personal registration” is specified in Business and Professions Code section 4052.6(d). The Board does not believe Form 17M-14 would be improved by adding a link to the DEA website, and is confident that any Advanced Practice Pharmacist seeking to register will be able to navigate their way there

without an embedded link within the form. Additionally, adding such a link would incorporate that link by reference into the regulation, requiring the Board to update the regulation whenever a change is made to the DEA website, and the Board does not wish to have to constantly revise the form or fail to do so and inadvertently create an underground regulation.

On January 19, 2016, after having considered all comments in the record, the Board itself adopted the regulation with the revisions above and authorized the Executive Officer to make any non-substantive changes necessary to complete the rulemaking file.

Incorporation by Reference

The incorporation by reference method was used because it would be impractical and cumbersome to publish the three self-assessment forms in the California Code of Regulations (CCR). The self-assessment forms are intended to help Pharmacists-in-Charge (PIC) of community or hospital pharmacies and Designated Representatives-in-Charge (DRIC) for wholesalers comply with current state and federal laws and regulations. The self-assessment forms make the pharmacy and wholesaler site inspection process more meaningful by providing the PIC or DRIC with useful information on statutory and regulatory requirements. They are printed out by the PIC or DRIC, who then walk through the pharmacy or wholesalers' site and check off the items. Once completed, they serve as an easy reference guide for the PIC or DRIC. If the self-assessments were incorporated into the CCR, it would increase the size of Division 17 and may cause confusion to the user. The revised self-assessments were made available to the public and were posted on the Board's website."