BOARD OF PHARMACY

INITIAL STATEMENT OF REASONS

No hearing is presently planned unless one is requested no later than 15 days before the close of the 45-day comment period.

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

The sections affected by these regulations are 16 California Code of Regulations ("CCR") §1715 and 16 CCR §1784 and three forms, adopted by reference with in those regulations, Form 17M-13, Form 17M-14, and Form 17M-26.

Specific Purpose of each Amendment:

Existing regulation at 16 CCR §1715 requires a pharmacist-in-charge ("PIC") of a pharmacy licensed under Business & Professions Code ("B&P") §4029 or §4037 to complete a self-assessment form 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. 16 CCR §1715 incorporates by reference both Form 17M-13: “Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (Rev. 01/11)” and Form 17M-14: “Hospital Pharmacy Self-Assessment (Rev. 01/11).” Both of these forms were last updated through the rulemaking process in 2011.

Existing regulation at 16 CCR §1784 requires the Designated Representative-in-Charge ("DRIC") of a wholesaler to complete a self-assessment form before July 1 of every odd-numbered year, or within 30 days of (1) a new wholesaler permit being issues; (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. 16 CCR §1784 incorporates by reference Form 17M-26: “Wholesaler Dangerous Drugs & Devices Self-Assessment (Rev. 01/11).” This form was last formally updated through the rulemaking process in 2011.

The problem to be addressed by these regulations is that there have been changes in pharmacy laws and regulations since January of 2011. The Board of Pharmacy ("Board") proposes to amend CCR §1715 and §1784 to update, revise, and improve three self-assessments forms: Form 17M-13, Form 17M-14, and Form 17M-26. These self-assessment forms are essentially a compilation of relevant laws that apply to community and hospital pharmacies and wholesalers licensed by the Board.

The anticipated benefits from this regulatory action are that the revised self-assessment forms will continue to help bring about compliance with the law and regulations, and will now include laws and regulations adopted since 2011, and exclude laws and regulations superseded or deleted since 2011. When a PIC or a DRIC goes through the self-assessment form biennially, it helps insure that the pharmacy’s or wholesaler’s operations conform to statutory and regulatory requirements, and makes the pharmacy and wholesaler site inspection process more meaningful by providing useful information to the PIC or DRIC about controlling statutes and regulations. Self-assessment forms also serve as an easy reference guide for a PIC or DRIC.
Specific Changes and Factual Basis/Rationale

This proposal seeks to amend 16 CCR §1715 and 16 CCR §1784. The only change in the text of those regulations will be updating the existing revision date on the referenced self-assessment forms from “(Rev. 01/11)” to read “(Rev. 10/14).” All other proposed changes are within the three self-assessment forms incorporated by reference in 16 CCR §1715 and 16 CCR §1784. Every change proposed to be made on each form is listed below by form and page number. All proposed changes are to the 2011 version of each form, the last formally amended version.

B&P Code §4001.1 mandates that the protection of the public shall be the highest priority for the Board and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public comes first. Pursuant to that mandate, the Board provided licensees with updated versions of these forms on the Board website. This formal rulemaking is undertaken to reduce possible confusion between the last formally approved versions of 2011 and the informally revised versions of 2013 on the website, by codifying all revisions needed to bring all three forms up-to-date.

B&P Code §4300 specifies that every license issued by the Board may be suspended or revoked and is subject to disciplinary action. These revisions reassure PICs and DRICs that the Board is providing them with most current information as of the new revision date, and that compliance with the laws as set out in the form will help them avoid disciplinary action.

FORM 17M-13: The Board proposes all of the changes set forth below be made within Form 17M-13 “Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment:” These proposed changes both remove out-of-date material and add new sections, items, and sub-paragraphs. The changes result in the renumbering of subsequent pages and items. To simplify locating the proposed changes, all page references refer to the page of the form revised as of 01/11 (no matter how long that page would become due to added items), and item numbers are referred to by the original item number from the 01/11 revision, followed, in parenthesis, by the new item number if the form is amended as proposed in these regulations.

On every page of Form 17M-13, the footer at the bottom left corner which reads “17M-13 (Rev. 01/11)” should be changed to read “17M-13 (Rev. 10/14).”

On p.1, in the letterhead on the upper right, 3rd line down, move the word “Governor” to be in front of the name Edmond G. Brown Jr. and delete it where it is presently located after the name Edmond G. Brown Jr.

On p.1, in the first paragraph, third sentence, after the words “within 30 days whenever” add a colon “:” before the phrase “(1) a new pharmacy permit ….”

On p.1, under “Notes:” in the first sentence, after the phrase “… dispenses prescriptions for outpatient use,” delete the word “a” and insert the word “this” Continuing in this sentence, after the words ”… use, this Hospital Outpatient” insert the word “Pharmacy” before the words “Self-Assessment.” In the second sentence, add a period after the words “Hospital Pharmacy Self-
Assessment.” Revise the citation (17M-14 Rev. 01/11) to read “(17M-14 Rev. 10/14)” with no additional punctuation after the closed parenthesis.

On p.1, 4th line up from the bottom, after the line that reads “Licensed Sterile Compounding Permit # _______ Expiration: ______,” on the next line down, delete the word “or” before the word “Accredited by:” and insert the word “(optional)” placed in parenthesis after the words “Accredited by:”.

On p.1, 2nd line up from the bottom, after the word “Hours,” and before the word “Daily,” insert the word “Weekdays.” Then delete the word “Daily.”

On p.2, for each numbered item on this page, lined up in a column underneath each entry that lists “RPH #” add the word “APP#” with a line after it. Continuing this line, below each entry that reads “Exp. Date,” add the words “Exp. Date:” with a line after it. Below that, still lined up in a column, now underneath the entry that lists “RPH#” add the word “DEA#” with a line after it. Continuing along this new line, below each entry that reads “Exp Date,” add the words “Exp. Date:” with a line after it. Add those to each of the items numbered 1-11.

On p.2, delete the lines 12-15.

On p.3, under section “1. Facility” at item 1.4, delete the period at the end of the sentence after the words “orderly condition” insert a comma and add the words “properly lighted and free from rodents and insects.” This was added at the request of our field inspectors.

On p.3, at entry 1.10, first line, remove the word “injectable” from the phrase “sterile injectable drugs.” On the second line, remove the words “section 24” and insert the phrase, “section 39 through 51,” and after the word “Compounding” add the words “Sterile Drugs.” This change harmonizes the form with the new compounding regulations (initially noticed on Sept. 5, 2014), which encompass not only sterile injectable drugs, but also sterile drugs to be placed in the eye, the nose, or inhaled.

On p.4, in entry 1.13, in the first sentence, change “within 30 days” to read “within 14 days”. This item was based on B&P §4104(c) which was amended to shorten the notice period to 14 days (Amended Stats 2011, Chapter 646).

On p.5, under the heading “2. Delivery of Drugs” at item 2.1, correct the typing error that misspelled the word “premise” add an “s” at the end so that it reads “premises.”

On p.5, for all of the numbered sub-paragraphs under Item 2.2, and a period between the second and third numbers so the numbered sub-paragraphs read: “2.2.1, 2.2.2, 2.2.3, 2.2.4, and 2.2.5.”

On p.5, under the heading “3. Drug Stock” in front of the one item there, insert the number “3.1”

On p.5, under the heading “3. Drug Stock” insert a new item 3.2 which reads:
3.2 Dangerous drugs or dangerous devices are purchased, traded sold or transferred with an entity licensed with the board as a wholesaler or pharmacy, or a manufacturer, and provided the dangerous drugs and devices: (B&PC 4169)

- 3.2.1. Are known or reasonably are known to the pharmacy as not being adulterated.
- 3.2.2. Are known or reasonably are known to the pharmacy as not being misbranded.
- 3.2.3. Are not expired.

This item and sub-paragraphs were based on B&P §4104(c) which now includes these requirements (Amended Stats 2014, Chapter 507).

On p.5, insert a new section 4, which reads:

4. Voluntary Drug Repository and Distribution Program (H&SC 150200)

Yes No N/A

- 4.1 Does the pharmacy donate to or operate a County-Approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section 29 of this Self-Assessment)

This item is based on H&S §150200 (Amended Stats. 2012, Chapter 709) and refers to H&S §150204 (Amended Stats. 2014, Chapter 155).

On p.5, and going forward, renumber section “4. Pharmacist-in-charge (PIC)” to make it section 5. Also renumber the items under former section 4 to now be items of section 5, deleting the references made to 4, making items 5.1, 5.21, 5.3, 5.4, 5.5, 5.6, and 5.7 (an item 5.8 will be inserted).

On p.5, under “Pharmacist-in-Charge” insert a new section 4.8 (in the revised version, section 5.8) which reads:

Yes No N/A

- 5.8. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration form from DCPH to conduct such tests. [H&SC 1206, 1265].

This item is based on H&S §1206 and §1265 which were amended.


On p.6, add a new item 6.1 which reads:
Yes No N/A

6.1 The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmit a valid prescription to another pharmacist; administer drugs and biological products ordered by the prescriber; manufacture, measure, fit to the patient or sell and repair dangerous devices or furnish instructions to the patient or patient representative concerning the use of the dangerous devices; provide consultation, training and education to patients about drug therapy disease management and disease prevention; provide professional information and participate in multidiscipline review of patient progress; furnish medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement product, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administer immunizations pursuant to a protocol; order and interpret tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052).

This item was based on B&P §4052 which was amended to include these requirements (Amended Stats 2013, Chapter 469).

On p.6, in item 5.2, (in the revised version, item 6.2), correct the typing error that misspelled the words “per formed” making it now read “performed.” Later in the same section, after the phrase “… facility a licensed clinic” add the phrase “and a licensed home health agency” before the phrase “in which there is physician oversight,” Still later in same section, after the phase “…biologicals by injection” add the words “initiating and” before the phrase “adjusting the drug regimen”. This item was based on several sections cited at the end of this item, including B&P §4052(a)(5), which was amended to include these requirements (Amended Stats 2013, Chapter 469).

On p.6, after item 5.2, add a new item (in the revised version, item 6.4), which reads:

Yes No N/A

6.4 Pharmacists are able to access information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through the CURES Prescription Drug Monitoring Program (PDMP). (H&SC 11165.1)

This item is based on H&S §11165.1.

On p.6, renumber item 5.3 to be item 6.5.

On p.6, in item 5.3 (in the revised version, item 6.5), after the phrase “…contraceptive pursuant to” add the word “the” before the phrase “statewide protocol found …”

On p.7, after item 5.3 (in the revised version item 6.5) add two new items 6.6 and 6.7 which read:
6.6 Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (H&SC 1206.6[a])

6.7 Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (H&SC 1206.6)
CDPH (CLIA) Registration #:_________________ Expiration: __________________

These items are based on H&S §1206.

On p.7, please check the renumbering of the items in former section 5, deleting the references made to 5, and resulting in items 6.1, 6.2, 6.3, 6.4, 6.5, 6.6 and 6.7.

On p.7, after what in the new version is all of item 6, insert a new heading “7. Duties of an Advance Practice Pharmacist” with subsequently and sequentially labeled sub-paragraphs and sub-sub-paragraphs 7.1, 7.2, 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, and 7.2.6. This entire new section reads:

7. Duties of an Advance Practice Pharmacist

7.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

7.2. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)

☐ 7.2.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers;

☐ 7.2.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers;

☐ 7.2.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient’s primary care provider or diagnosing provider; (B&PC 4052.6[b])

☐ 7.2.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient’s diagnosing prescriber or enters the appropriate
information in a patient’s record system shared with the prescriber; (B&PC 4052.6[b])

☐ 7.2.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])

☐ 7.2.6 Ordering of tests is done in coordination with the patient’s primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

These items and sub-paragraphs were based on B&P §4016.5 (Added Stats. 2010, Chapter 653), B&P §4210 (Added Stats. 2013, Chapter 469), and B&P §4052 (Added Stats 2013, Chapter 469), which, taken together, create and define an Advanced Practice Pharmacist.

On p 7, renumber the section heading “6. Duties of an Intern Pharmacist” from number 6 to number 8, and renumber the subsequent sub-paragraphs sequentially, 8.1, 8.2, 8.3, and 8.4.

On p. 7, add a new section 6.4 (in the revised version, item 8.4) which reads:

Yes No N/A

☐☐☐ 8.4. During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

This item was based on 16 CCR 1714.1(d)(Operative 1-1-2000), and was added at the request of our field inspectors asking that this part of the regulation be given greater emphasis by adding it within the form.

On p.7, renumber the section heading of “7. Duties of a Pharmacy Technician” from number 7 to number 9, and renumber the subsequent sub-paragraphs sequentially, 9.1, 9.2, 9.3, 9.4, and insert in a 9.5 (see below).

On p.7, add a new item 7.5 (in the revised version, item 9.5) which reads:

Yes No N/A

☐☐☐ A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)
This item was based on B&P §4115.5 (Amended Stats. 2005, Chapter 621) and was added due to our field inspectors asking that this section of the law be given greater emphasis by adding it within the form.

On p. 8, renumber the section heading of “8. Duties of a Non-Licensed Personnel” from number 8 to number 10, and renumber the subsequent sub-paragraphs sequentially as 10.1 and 10.2.


On p.8, in item 9.1 (in the revised version, item 11.1), move the colon presently after the parenthetical citation to sources to before the parenthetical citation to sources. In sub-paragraph 11.1.4, after the phrase “… pharmacist deems it,” add the word “is” before the phrase, “warranted in the ...”

On p.9, renumber the section heading “10. Prescription Requirements” from number 10 to number 12, and renumber the subsequent items sequentially, 12.1, 12.2, 12.3, 12.4, 12.5, 12.6, 12.7, 12.8, and 12.9.

On p.9, at item 10.8 (in the revised version, item 12.8), after the phrase “written under H&SC 11159.2” add the word and citation “and H&SC 11167.5,” before the word “all.” After that word “all” add the word “written” before the phrase “controlled substances prescriptions ...” At the end of the item, add the citation H&SC 11167.5” after the citation “H&SC 11164.(a),”


On p. 9, add an item 13.4 with three sub-paragraphs after 11.3 (in the revised version, item 13.3), that reads:

Yes No N/A

13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])

☐ 13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.

☐ 13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.3.1; (CCR 1707.5[a][22])
13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])

This item and sub-paragraphs were based on 16 CCR §1707.5 (Added effective 1-1-2011), and are added to harmonize the form with the new amendments to the regulation on patient-centered labeling (effective April 1, 2015).

On p10, in item 11.13 (in the revised version, item 13.14), delete the word “This” which starts the section, and replace it with “The”

On p.10, after item 11.15 (in the revised version, item 13.16) add new items 13.17 with sub-paragraphs and item 13.18 which read:

13.17 The pharmacy dispenses not more than a 90-day supply of a dangerous drug (other than controlled substances, or psychotropic medication or drugs): (B&PC 4064.5)

13.17.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; and where: (B&PC 4064.5[a])

13.17.1.1 The prescriber has not indicated “no change to quantity” or words of similar meaning; (B&PC 4064.5[d])

13.17.1.2 The patient has completed an initial 30-day supply; (B&PC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. B&PC 4064.5[b])

13.17.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])

13.17.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (B&PC 4064.5[a][3])

13.17.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

13.17.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

13.18. The pharmacist includes a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (B&PC 4074[b])

These items and sub-paragraphs were based on B&P §4064.5 (Added Stats 2012, Chapter 455), and B&P §4074 (Amended Stats. 2013, Chapter 304).
On p. 11, renumber the section heading “12. Refill Authorization” from number 12 to number 14, and renumber the items within the section, 14.1, 14.2, 14.3, 14.4 and 14.5.

On p. 11, renumber the section heading “13. Quality Assurance and Medication Errors” from number 13 to number 15, and renumber the subsequent items and sub-paragraphs sequentially, 15.1, 15.2, 15.3, 15.4, 15.5, 15.6, 15.6.1, 15.6.2, 15.6.3, 15.6.4, 15.7, and 15.8.

On p. 11, in item 13.3 (in revised version, Item 15.3), within the citation add the letters “CCR” before the numbers “1711(c)(2)(A).”

On p. 12, renumber the section heading “14. Erroneous or Uncertain Prescriptions/Corresponding Responsibility for Filing Controlled Substance Prescriptions” from number 14 to number 16, and renumber the subsequent items sequentially, 16.1, 16.2, 16.3, and 16.4, 16.5, and 16.6.

On p. 12, after item 14.3, add in new items 14.4, 14.5, and 14.6 (in revised version items 16.4, 16.5 and 16.6) which read:

Yes No N/A

16.4 Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])

Yes No N/A

16.5. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

Yes No N/A

16.6. All pharmacists have obtained approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice (HSC 11165.1[a][1][A][i])

These items were based on B&P §4067 (Added Stats 2003, Chapter 250), and 21 United States Code §820, 21 United States Code §802 and H&S §11165.

On p. 12, renumber the section heading “15. Prescription Transfer” from number 15 to number 17, and renumber the subsequent items sequentially, 17.1, 17.2, 17.3, and 17.4.

On p. 13, renumber the section heading “16. Confidentiality of Prescriptions” from number 16 to number 18, and renumber the subsequent items sequentially, 18.1, 18.2, 18.3, 18.4, 18.5, and 18.6.

On p. 13, renumber the section heading of “17. Record Keeping Requirements” from number 17 to number 19, and renumber the subsequent items and sub-paragraphs sequentially, 19.1,

On p. 14, after sub-paragraph 13.3.3, insert a new item 17.4 with sub-paragraphs (in revised version, item 19.4 with sub-paragraphs), which reads:

Yes No N/A

19.4. When hypodermic needles and syringes are furnished by a pharmacy or hypodermic needle and exchange program without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e][f])

☐ 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.

☐ 19.4.2. Furnish or make available mail-back sharps containers.

☐ 19.4.3. Furnish or make available sharps containers.

This item and sub-paragraphs were based on B&P §4145.5 which was amended (Amended Stats 2014, Chapter 331).

On p.14, after item 17.4, insert a new item (in revised version, item 19.6), which reads:

Yes No N/A

19.6. The pharmacy dispenses epinephrine auto-injector to a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care in accordance with H&SC 1797.197a (B&PC 4119.3)

☐ 19.6.1. A physician/surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed (B&PC 4119[a][1])

☐ 19.6.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation “Section 1797.197a responder” and “First Aid Purposes Only”, the dosage, use and expiration date. (B&PC 4119.3[a][1])

☐ 19.6.3. Each dispensed prescription includes the manufacturer’s product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2])

This item and sub-paragraphs were based on B&P §4119 (Amended Stats. 2010, Chapter 653) and B&P §4119.3 (Added Stats. 2013, Chapter 725).
On p. 14, renumber the section heading “18. DEA Controlled Substances Inventory” from number 18 to number 20.

On p. 14, after item 18.3, add a new item 18.4 (in revised version item 20.4) which reads:

Yes No N/A

20.4. Indicates on the inventory record whether the inventory was taken at the “open of business” or at the “close of business.” (CFR 1304.11[a])

This item was based on the Code of Federal Regulations §1304.11 (79 FR 53562, amended Sept 6, 2014).

On p. 15, after item 18.16, add item 18.18 (in revised version, item 20.18) which reads:

Yes No N/A

20.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner’s general dispensing to patients. (21 CFR 1306.04[b])”

This item was based on 21 Code of Federal Regulations §1306.04(b) (70 FR 36343, amended June 23, 2005), and requested by our field inspectors.


On p. 16, renumber the section heading “19. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substances Prescriptions” from number 19 to number 21.

On p. 16, in item 19.2 (in revised version, item 21.2), after the phrase “An oral” add the phrase “Or electronically transmitted” before the phrase “prescription for a.” In the same item, delete the last sentence, but not the citations in parenthesis. At the end of the second to last sentence, delete the period and add “and:” before the parenthetical citations. Below item 19.2 (draft 21.2) add in the following sub-paragraphs which read:

- “21.2.1. The licensed facility provides the pharmacy with a copy of the prescriber’s signed order, when available.
- 21.2.2. The prescription is endorsed by the pharmacist with the pharmacy’s name, license, and address.
- 21.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.
- 21.2.4. The signature of the person who received the controlled substance for the
These sub-paragraphs were based on the Code of Federal Regulations §1306.11 (75 FR 16307, Mar. 31, 2010) and H&S §11167.5.

On p.16, delete all of item 19.3.

On p.17, within item 19.10 (in revised version, item 21.9), add “CCR” in front of the citation “1717.4(d).”

On p.17, add three new items after item 19.10 (in revised version, items 21.10, 21.11, 21.12) which read:

Yes No N/A

21.10. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

Yes No N/A

21.11. Controlled substances written with the “11159.2 exemption” for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

Yes No N/A

21.12. Electronic prescriptions (e-scripts) for controlled substances that are received by the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

These items were based on 21 Code of Federal Regulations §1306.08 (75 FR 16307, Mar. 31, 2010), 21 Code of Federal Regulations §1306.05 (75 FR 16307, Mar. 31, 2010), 21 Code of Federal Regulations §1306.11 (75 FR 16307, Mar. 31, 2010), H&S §11159.21, and 16 CCR 1745 (Amended effective 4-1-2014).


On p. 17, renumber the section heading “20. Automatic Dispensing/Delivery Devices” from number 20 to number 22, and the subsequent items and sub-paragraphs sequentially, 22.1, 22.2, 22.3, 22.3.1, 22.3.2, 22.3.3, 22.4, 22.4.1, and 22.4.2.

On p.18 and beyond, renumber the section heading “21. Repackaging by the Pharmacy” from number 21 to number 23, and renumber the subsequent items sequentially, 23.1, 23.2, and 23.3.

On p.18, item 21.1 (in revised version, item 21.2, within the parenthesis, after the citation, “CCR 17.51” insert a comma and “, 21 CFR Parts 210, 211)"
On p.18 and beyond, renumber the section heading of “Refill Pharmacy” from number 22 to number 24, and renumber the subsequent items and sub-paragraphs sequentially, 24.1, 24.2, 24.3, 24.4, 24.5, 24.6, 24.7, 24.8, and 24.9.

On p.19, insert a new section (in revised version section 25) which reads:

“25. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A
☐ 25.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)
☐ 25.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])
☐ 25.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])
☐ 25.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])
☐ 25.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

25.2. The pharmacy meets the following requirements:

☐ 25.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])

☐ 25.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])

☐ 25.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])

☐ 25.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])
25.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])

25.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product’s approved package insert. (HSC 125286.25[f])

25.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])

25.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])

25.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])

25.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls. (HSC 125286.25[j])

25.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])

25.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[l])

These items and sub-paragraphs are based on H&S §125286.20 and H&S §125286.25.

On p.19 and beyond, renumber the section heading of “Policies and Procedures” from number 22 to number 26, and renumber the subsequent items and sub-paragraphs sequentially, 26.1,

On p.19, in item 23.1, sub-paragraph 23.1.2 (in revised version item 26.1, sub-paragraph 25.1.2) delete the word “effects” and insert in it’s stead, the word “affects.” After the phrase, “authorized by his or her license,” insert the phrase “including the reporting to the board within 14 days of receipt or development.”

This item is based on B&P §4104 (a) and (c) (Amended Stats. 2011, Chapter 646).

On p.19, in item 23.1, 23.1.3 after the phrase “drugs belonging to the pharmacy” add the phrase, “including the reporting to the board within 14 days of receipt or development.”

This item is based on B&P §4104 (a) and (c) (Amended Stats. 2011, Chapter 646).

On p.20 add items 23.3 and 23.4 (in revised version, items 26.3 and 26.4) which read:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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26.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][2]? (B&PC 4052, CCR 1746) If yes, does the pharmacy:

- 26.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)

- 26.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

- 26.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)

- 26.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)

- 26.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

- 26.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist’s refusal to dispense a prescription or order? (B&PC 733[b])

- 26.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (B&PC 733[b], B&PC 4052.3)
26.3.8. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

26.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.01[a])

26.4.1. Procedures to ensure education of the person to whom the drug is furnished, not limited to opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient.

26.4.2. Procedures for the notification of the patient’s primary care provider with patient consent of any drug or device furnished to the patient or entry of appropriate information in a patient record system."

These items and sub-paragraphs are based on B&P §§733, 4052 (Amended Stats. 2013, Chapter 469), 4052.01 (Added Stats. 2014, Chapter 325), 4052.3 (Amended Stats. 2013, Chapter 469) and 16 CCR §1746 (Amended Effective 7-1-2013).

On p.20, delete the all capitals flush left section heading “COMPOUNDING” Insert a section heading “27. Compounding” and renumber item 24 as Item 27. After “Form 17M-39,” change the Rev. 01/11 to reach *(Rev. 02/12),” before (CCR 1735.2[j])*


On p.20, add item 26 (in revised version, item 29) which reads:

“29. Pharmacies that Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

29.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202.5, 150204, B&PC 4169.5)

29.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (H&SC 150202.5)

29.1.2. The pharmacy’s primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)
29.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (B&PC 4169.5)

29.3. No controlled substances shall be donated. (H&SC 150204[c][1])

29.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

- 29.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- 29.4.2. Were received directly from a manufacturer or wholesaler. (H&SC '150202.5[a])
- 29.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H&C 150202.5[b], 150204[c][3])
- 29.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])
- 29.4.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

These items and sub-paragraphs were based on B&P §4169.5 (Added Stats. 2014, Chapter 10) and H&S §§150202.5, 150204, 150204.5.

On p.20, add two new sections after section 25 Nuclear Pharmacy (draft section 29), including sections 29 and 30 which read:

“30. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

30.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

- 30.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (H&SC 150201[a][1])

- Is county owned (H&SC 150201[a][1]) or
Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[a][1], 150200)

30.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (H&SC 150201[a][2])

30.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (H&SC 150204[a][5])

Issued By: ____________________________________ Date: __________________

30.3. Date that the county health department confirmed receipt of the pharmacy’s “notice of intent” to participate in the program: ___________________ (H&SC 150204[a][3])

30.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (H&SC 150204[a][4][A])

Date last quarterly report was submitted: __________________

30.5. The pharmacy complies with the county’s established written procedures. (H&SC 150204[b])

Drugs and Maintenance of Drug Stock

30.6. Donated medications are segregated from the participating entity’s other drug stock by physical means, for purposes that include inventory, accounting and inspection. (H&SC 150204[j])

30.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity’s other drug acquisition and disposition records. (H&SC 150204[k])

30.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

30.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 150204[c])
30.9.1. Are received from authorized sources. (H&SC 150202, 150203)

30.9.2. No controlled substances are received. (H&SC 150204[c][1])

30.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])

30.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (H&SC 150204[c][3])

30.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])

30.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])

30.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

30.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (H&SC 150204[d], 150204[h])

**Transferring Donated Drugs From One Participating Entity to Another**

30.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H&SC 150204[g][4])

30.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (H&SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

30.13. Donated medication is not transferred by any participating entity more than once. (H&SC 150204[g][4][B])
30.14. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (H&SC 150204[g][4][C])

30.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (H&SC 150204[g][4][C])

Dispensing to Eligible Patients

30.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H&SC 150204[i])

30.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H&SC 150204[f])

These items and sub-paragraphs were based on H&S §§150200 (Amended Stats. 2012, Chapter 709), 150201 (Amended Stats. 2014, Chapter 10), 150202 (Amended Stats. 2014, Chapter 10), 150202.5. (Added Stats. 2012, Chapter 709), 150203, 150204 (Amended Stats. 2014, Chapter 155).

FORM 17M-14: The Board proposes all of the changes set out below be made within Form 17M-14 “Hospital Pharmacy Self-Assessment.” The proposed changes below both remove out-of-date material and add new sections, items, and subparagraphs. The changes result in re-numbering subsequent pages and items. To simplify locating the proposed changes, all page references refer to the page of the form revised as of 01/11 (no matter how long that page would become due to added items), and item numbers are referred to by the original item number from the 01/11 revision, followed in parenthesis by the new item number as proposed in these amendments.

On every page of Form 17M-14, the footer at the bottom left corner which reads “17M-14 (Rev. 01/11)” should be changed to read “17M-14 (Rev. 10/14).”

On p.1, under “Notes:” change the revision reference at the end of “Hospital Outpatient Pharmacy Self-Assessment” to read “(17M-13 Rev.10/14).”

On p.1 in the fourth line up from the bottom, below the line that reads “Licensed Sterile compounding Permit #__________ Expiration: _______________” delete the word “or” before the phrase “Accredited by:” and immediately after that, insert the word in parenthesis “(optional)”

Insert on the next line down, Centralized Hospital Packaging Permit #:_________________ Exp. Date: _______________ ”

On p.1, 2nd line up from the bottom, after the word “Hours,” and before the word “Daily,” insert the word “Weekdays.” Then delete the word “Daily.”
On p.2, for each numbered item on this page, lined up in a column underneath each entry that lists “RPH #” insert the word “APP#” with a line after it. Continuing across on this line, below each entry that reads “Exp. Date,” insert the words “Exp. Date:” with a line after it. Below that, still lined up in a column, now underneath the entry that lists “APP#” add the word “DEA#” with a line after it. Continuing across on this new line, below each entry that reads “Exp Date:” add the words “Exp. Date:” with a line after it. Add those to each of the items numbered 1-12.

On p.2, in adding the additional lines as referred to above, the lines for listing pharmacy personnel spills over to the next page. Please delete the items 13-18 so the lines for listing pharmacy personnel only fills up one page.

On p.4, in item 2.2, after the phrase “The pharmacist” insert a comma, a space and the words “intern, or pharmacy technician.” This was added based on B&P §4114(a) (Amended Stats.2005, Chapter 621) and B&P §4115.5 (Amended Stats. 2005, Chapter 621). At the end of item 2.2, in the citation within parenthesis, before the citation 22 CCR 7026[q][10], insert “B&PC 4119.7[c], 4115[j],”

On p.5, insert in section “4. Drug Stock” new items 4.4 and 4.5, which read:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tbody>
<tr>
<td>4.4</td>
<td>All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient’s bedside. (B&amp;PC 4128.4, 4128.5)</td>
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<tr>
<td>4.5</td>
<td>All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer’s guidelines. (B&amp;PC 4119.7[b]</td>
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</tr>
</tbody>
</table>

This item and sub-paragraphs were based on B&P §§4119 (Amended Stats 2010, Chapter 653), 4128.4 (Added Stats. 2012, Chapter 687) and 4128.5 (Added Stats. 2012, Chapter 687).

On p.5, insert a new section “5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program” which reads:

5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&amp;SC 150202, 150202.5, 150204)</td>
<td></td>
</tr>
<tr>
<td>5.1.1</td>
<td>The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (H&amp;SC 150202.5)</td>
<td></td>
</tr>
</tbody>
</table>
5.1.2. The hospital pharmacy’s primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, board and care, or mail order. (H&SC 150202.5)

5.2. No controlled substances shall be donated. (H&SC 150204[c][1])

5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (H&SC 150202.5[b], 150204[c][3])

5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

These items and sub-paragraphs were based on H&S §§150202 (Amended Stats. 2014, Chapter 10), 150202.5 (Added Stats. 2012, Chapter 709), and 150204 (Amended Stats 2014, Chapter 155).

On p.6, renumber the section heading “5. Pharmacist-in-Charge (PIC)” from number 5 to number 6, and renumber the subsequent items sequentially, 6.1, 6.2, 6.3, 6.4, and 6.5.

On p.6, renumber the section heading “6. Duties of a Pharmacist” from number 6 to number 7, and renumber the subsequent items sequentially, 7.1 and 7.2.

On p.7, insert a new section “8. Duties of an Advance Practice Pharmacist” which reads:

8. Duties of an Advance Practice Pharmacist
8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

8.2. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)

- 8.2.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers;
- 8.2.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers;
- 8.2.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient’s primary care provider or diagnosing provider; (B&PC 4052.6[b])
- 8.2.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient’s diagnosing prescriber or enters the appropriate information in a patient’s record system shared with the prescriber; (B&PC 4052.6[b])
- 8.2.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[01])
- 8.2.6 Ordering of tests is done in coordination with the patient’s primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

These items and sub-paragraphs were based on B&P §4210 (Added Stats. 2013, Chapter 469), and B&P §4052 (Added Stats 2013, Chapter 469), which created and define an Advanced Practice Pharmacist.

On p.7 and beyond, renumber the section heading “7. Duties of an Intern Pharmacist” from number 7 to number 9, and renumber the subsequent items and sub –paragraphs sequentially as in 9.1, 9.1.1, 9.1.2, 9.2, 9.3, and 9.4.

On p.7, under item 7.1 (in revised version, item 9.1) insert sub-paragraphs 9.1.1 and 9.1.2 which read:

- 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (B&PC 4119.6)
- 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (B&PC 4119.7[c])

These sub-paragraphs were based on B&P §4119.7 (Added Stats. 2014, Chapter 319).
On p.7, insert after item 7.2 (in revised version, item 9.2), a new item 9.3 which reads:

9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist.  
(CCR 1714.1[d])

This item was based on 16 CCR 1714.1(d) (Operative 1-1-2000), and was added due to our field inspectors asking that this part of the regulation be given greater emphasis by adding it within the form.

On p.7, renumber the section heading “8. Duties of a Pharmacy Technician” from number 8 to number 10, and renumber the subsequent items and sub–paragraphs sequentially as in 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7, 10.8, 10.8.1, 10.8.2, 10.8.3, 10.8.4, 10.8.5, 10.9, 10.9.1, 10.9.2, and 10.9.3. As this spans several pages, please take out any “Yes No N/A” that are not labeling the uppermost boxes on the page, or after a new section, or after lines or a PIC to fill in information, and add in a “Yes No N/A” over the uppermost boxes at the top of each page.

On p.7, after item 8.6, insert a new item 8.7 (in revised version, item 10.7) which reads:

10.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist’s temporary absence is reviewed by the pharmacist.  
(B&PC 4115[g], CCR 1714.1[c])

This item was based on B&P §4115 (Added Stats. 214, Chapter 319) and 16 CCR 1714.1(d) (Operative 1-1-2000).

On p.8, in sub-paragraph 8.7.4 (the revised version, sub-paragraph 10.8.4), after the words “The pharmacy technician” delete the word “check” and insert the word “checking” in its stead.

On p.8, in sub-paragraph 8.7.5 (the revised version, sub-paragraph 10.8.5), after the words “of the program that uses” delete the word “specially” and insert the words “specialized and advanced “ before “trained pharmacy technicians …”

On p.8, insert a new item 10.9 which reads:

10.9. Pharmacy technician duties include the following:

- 10.9.1. Package emergency supplies for use in the health care facility and the hospital’s emergency medical system.  
(B&PC 4119, 4115[i])
- 10.9.2. Seal emergency containers for use in the health care facility.  
(B&PC 4115[i])
- 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer.  
(B&PC 4115[i])
This item was based on B&P §4115 (Added Stats. 2014, Chapter 319) and B&P §4119 (Amended Stats. 2010, Chapter 653).

On p.8, renumber the section heading “9. Duties of Non-Licensed Pharmacist” from number 9 to number 11, and renumber the subsequent items and sub-paragraphs sequentially as 11.1, and 11.2.

On p.8, under centered heading “PHARMACY PRACTICE,” renumber the section heading “10. Pharmaceutical Service Requirements” from number 10 to number 12, and renumber the subsequent items and sub-paragraphs sequentially as 12.1, 12.1.1, 12.1.2, 12.1.3, 12.1.4, 12.1.5, 12.1.6, 12.1.7, 12.1.8, 12.1.9, 12.1.10, 12.1.11, 12.1.12, 12.1.13, 12.2, 12.2.1, and 12.2.2. As this spans several pages, please take out any “Yes No N/A” that are not labeling the uppermost boxes on the page, or after a new section, or after lines or a PIC to fill in information, and add in a “Yes No N/A” over the uppermost boxes at the top of each page.

On p.9, renumber the section heading of “11. Medication/Chart Order” from number 11 to number 13, and renumber the subsequent items sequentially as 13.1, 13.2, 13.3, and 13.4.

On p.9, insert new item 13.4 which reads:

13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (B&PC 4119.7)

This item was based on B&P §4119.7 (Added Stats. 2014, Chapter 319).

On p.9, renumber the section heading “12. Labeling and Distribution” from number 12 to number 14, and renumber the subsequent items sequentially as 14.1, 14.2, and 14.3.

On p.10, renumber the section heading “13. Duration of Drug Therapy” from number 13 to number 15.

On p.10, renumber the section heading “14. Confidentiality of Charge Orders, Prescriptions and Patient Medical Information” from number 14 to number 16, and renumber the subsequent items sequentially as 16.1, 16.2, 16.3 and 16.4.

On p.10, renumber the section heading of “15. Quality Assurance and Medication Forms” from number 15 to number 17, and renumber the subsequent items and sub-paragraphs sequentially as 17.1, 17.2, 17.3, 17.4, 17.5, 17.6, 17.6.1, 17.6.2, 17.6.3, 17.6.4, 17.7, and 17.8.

On p.11, renumber the section heading “16. Record Keeping Requirements” from number 16 to number 18, and renumber the subsequent items sequentially as 18.1, 18.2, 18.2.1, 18.2.2, 18.2.3, 18.2.4, 18.2.5, 18.2.6, 18.2.7, 18.2.8, 18.2.9, 18.3, 18.4, 18.5, 18.6, 18.7, 18.8, 18.9, 18.10, 18.11, 18.12, and 18.13.
On p.11, after sub-paragraph 16.2.8 (in revised version sub-paragraph 18.2.8), insert sub-paragraph 18.2.9, which reads:

☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H&SC 150200, 150202[a][1])

This item was based on H&S §150200 (Amended Stats. 2012, Chapter 709), and H&S §150202 (Amended Stats. 2014, Chapter 10).

On p.12 in item 16.8 (in revised version, item 18.8) delete the citation within the parenthesis “1305.09” and insert “1305.12.”

On p.12 in item 16.9 (in revised version, item 18.9), delete the citation within the parenthesis “1305.09” and insert “1305.13.”

On p.12, renumber the section heading “17. After-Hours Supply of Medication” from number 17 to number 19.

On p.13, renumber the section heading “18. Drug Supplies for Use in Medical Emergencies” from number 18 to number 20, and renumber the subsequent items sequentially as 20.1, 20.2, 20.3, and 20.4.

On p.13, renumber the section heading “19. Schedule II-V Controlled Substances Floor Stock Distribution Records” from number 19 to number 21.

On p.13, renumber the section heading “20. Emergency Room Dispensing” from number 20 to number 22, and renumber the subsequent items and sub-paragraphs sequentially as 22.1, 22.1.1, 22.1.2, 22.1.3, 22.1.4, 22.1.5, 22.1.6, 22.2, 22.3, 22.4, 22.5, 22.6, and 22.7.

On p.14, renumber the section heading “21. Discharge Medications/Consultation Services” from number 21 to number 23, and renumber the subsequent items sequentially as 23.1, 23.2, 23.3, 23.4, 23.5, 23.6, 23.7, 23.8, 23.9, 23.10, 23.11, and 23.12.

On p.15, delete the section heading “22. Central Fill” and replace that with the heading “24. Central Filling of Patient Cassettes For Other Hospital Pharmacies.” Renumber the section from number 22 to number 24, and renumber the subsequent items sequentially as 24.1, 24.2, 24.3, 24.4, 24.5, 24.6, and 24.7.

On p.16, insert a new section 25 which reads:

25. Centralized Hospital Packaging Pharmacy

Yes No N/A
☐ ☐ ☐ 25.1. The pharmacy packages unit dose medication for inpatients of one or more hospitals under common ownership within a 75-mile radius: (B&PC 4128)
Hospitals to which central packaged unit dose medications are provided:

25.1.1. ______________________________________ Distance (miles): ________
25.1.2. ______________________________________ Distance (miles): ________
25.1.3. ______________________________________ Distance (miles): ________
25.1.4. ______________________________________ Distance (miles): ________

25.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)

25.3. All unit dose medications produced by a centralized hospital packaging pharmacy are barcoded and readable at the inpatient’s bedside. The barcode information contains: (B&PC 4128.4)

☐ 25.3.1. The date the medication was prepared.
☐ 25.3.2. The components used in the drug product.
☐ 25.3.3. The lot number or control number.
☐ 25.3.4. The expiration date.
☐ 25.3.5. The National Drug Code Directory number.
☐ 25.3.6. The name of the centralized hospital packaging pharmacy.

25.4. The label for each unit dose medication produced by a centralized hospital packaging pharmacy contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements. (B&PC 4128.5)

25.5. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (B&PC 4128.7)

These items and sub-paragraphs were based on B&P §4128, 4128.3, 4128.4, 4128.5, 4128.7, all of which were (Added Stats. 2012, Chapter 687),

On p.16, renumber the section heading “23. Policies and Procedures” from number 23 to number 26, and renumber the subsequent items sequentially as 26.1, 26.1.1, 26.1.2, 26.1.3, 26.1.4, 26.1.5, 26.1.6, 26.1.7, 26.1.8, and 26.1.9. Should this end up taking up more than one page, please take out any “Yes No N/A” that is not labeling the uppermost boxes on the page, and add in a “Yes No N/A” over the uppermost boxes at the top of each new page.
On p.16, renumber the section heading “24. Compounding” from number “24” to number “27.”

**Form 17M-26** The Board proposes the following changes be made in Form 17M-26 “Wholesalers of Dangerous Drugs and Devices Self-Assessment.” The proposed changes below both remove out of date material and add new sections, items, and subparagraphs. The changes result in renumbering subsequent pages and items. To simplify locating the proposed changes, all page references refer to the page of the form revised as of 01/11 (no matter how long that page would become due to added items), and item numbers are referred to by the original item number from the 01/11 revision, followed in parenthesis by the new item number as proposed in these amendments.

On every page of Form 17M-26, the footer at the bottom left corner which reads “17M-26 (Rev. 01/11)” should be changed to read “17M-26 (Rev. 10/14).”

On p.1 in the first sentence, delete “18” after the phrase “explained on page” and insert “21.”

On p.1 four lines into the form, where the line reads “Wholesaler E-mail address (optional)” delete the word in the parenthesis: “(optional).”

On p.1 underneath the line which reads “DEA Registration #” and “Expiration Date: __________” insert a line that reads: “VAWD Accreditation # __________ Expiration Date __________.” Two lines below that, where the line begins with “Hours:” strike the word “Daily” and replace it with the word “Weekdays.” After the line which begins “DRIC License #” insert a line that reads: “Website Address (optional): _______________”

On p.3 in item 1.2, where there is a citation to regulations in parenthesis, move “CCR” from the end of the line to directly in front of “1780(f)(3)” so the citation is all together on one line and easier to read.

On p.4, at item 2.6, move the number “2.6” over to the right so it is not lined up with the boxes, and the number and the words are separated only by two spaces. Thus, delete “2.6” over boxes and insert “2.6” in front of the words of that item.

On p.4 in sub-paragraph 2.6.3, where there is a citation to regulations in parenthesis, move “CCR” from the end of the line to be directly in front of “1780(c)(2)” so the citation is together on one line and easier to read. Also correct the indentation for the last line so it aligns with the line above it.

On p.5, below item 2.9, in the “Note:” just above Section 3, after the phrase “these additional requirements are in Section “ change the section number “11” to “12.”

On p.5, in item 3.2, after the phrase “… designated representative-in-charge” add the words “at least 18 years of age and is” before the phrase “responsible for the wholesaler’s …”

*This item was based on B&P 4160 (Amended Stats. 2014, Chapter 507).*
On p.6, at item 5.2, delete the “Yes No N/A” above the boxes. Add a section 5.3, with response boxes without “Yes No N/A” on top which reads:

5.3. For license verification, the wholesaler may use the licensing information displayed on the board’s Internet web site (B&PC 4106).

This item was based on B&P 4106 (Amended Stats.2005, Chapter 621), and was added at the request of our field inspectors.

On p.6, in the “Note:” after section 5, in the phrase “these additional requirements are in Section 11” change the section number from “11” to “12.”

On p.7, in the “Note:” after section 6, in the phrase “these additional requirements are in Section 11” change the section number “11” to “12.”

On p.8 in the “Note:” after section 7, in the phrase “these additional requirements are in Section 11” change the section number “11” to “12.”

On p.8, at 8.6, insert three boxes to the left of the numbered item, and insert “Yes No N/A” above the boxes.

On p.9, in item 8.10, delete the entire sentence “Commencing on July 1, 2017, an electronic pedigree must accompany all drugs (B&PC 4163), even those for which your business is an authorized distributor.”

This item was based on B&P §4163 (Repealed and Added Stats. 2014, Chapter 492).

On p.10, at item 8.12, delete the “Yes No N/A” above the boxes. Throughout the document, the “Yes No N/A” above the 3 boxes is to be only above the first set of boxes on a page, over the first set of boxes under a new section, and over the first set of boxes underneath lines for the DRIC to fill in information.

On p.10, at item 8.14, delete the “Yes No N/A” above the boxes.

On p.10, in the “Note:” after section 8, in the phrase “these additional requirements are in Section 11” change the section number “11” to “12.”

On p.10, insert a new section “9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)” which reads,

9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)

Yes No N/A

9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)
9.2. No controlled substances shall be donated. (H&SC 150204[c][1])

Yes No N/A

9.3. Drugs that are donated are unused, unexpired and meet the following requirements:
(H&SC 150204[c])

☐ 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

☐ 9.3.2. Have never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])

☐ 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

These items and sub-paragraphs were based on H&S §150200 (Amended Stats. 2012, Chapter 709), H&S §150203, and H&S §150204 (Amended Stats. 2014, Chapter 155).

On p.10, renumber the section “9. Outgoing Shipments of Drugs” from “9” to “10” and renumber the subsequent items sequentially as 10.1, 10.2, and 10.3.

On p.11, in the “Note:” after item 9, in the phrase “… these additional requirements are in Section 11” change the section number “11” to “12.”

On p.11, renumber the section “10. Delivery of Drugs” from “10” to “11” and renumber the subsequent items sequentially as 11.1, 11.2, 11.3 and 11.4.

On p. 11, at the end of item 10.2 (the revised version, item 11.2), where the citation is in parenthesis, correct the citation to read “B&PC 4059.5[d]”

On p.11, renumber the section “11. Controlled Substances” from “11” to “12” and renumber the subsequent items sequentially as 12.1, 12.2, and 12.3, and remove “Yes No N/A” above the boxes for item 11.4 (the revised version, item 12.4) from above the boxes for consistency.

On p.12, after 11.5 (the revised version, item 12.5) insert a new item 12.6 which reads:

☐ ☐ 12.6 Does the biennial inventory record document that the inventory was taken at the “close of business” or “opening of Business. (CFR 1304.11)

This item was based on 21 Code of Federal Regulations §1304.11 (79 FR 53562, Sept. 9, 2014).
On pps.12, 13, 14 and 15 renumber the subsequent items of the old section 11 as items 12.5, 12.6, 12.7, 12.8, 12.9, 12.10, 12.11, 12.12, 12.13, 12.14, 12.15, 12.16, 12.17, 12.18, 12.19, 12.20, 12.21, 12.22, 12.23, 12.24, 12.25, 12.26, 12.27, 12.28, and 12.29. As this spans several pages, please take out any “Yes No N/A” that is not labeling the uppermost boxes on the page, and add in a “Yes No N/A” over the uppermost boxes at the top of each page.

On p.13, in item 11.14 (the revised version, item 12.14) delete the underline between “diversion of controlled substances.” and the citation in parenthesis.

On p.13, item 11.19 (the revised version, item 12.19), after the phrase “close of that month?” Delete “(CFR 1309.13(b))” and insert “(CFR 1305.13(b))”

On p.13, item 11.21 (the revised version 12.21) insert a citation in parenthesis “(CFR 1305.21, 1305.22)”.

On p.13, item 11.23 (the revised version, item 12.23), delete the citation to “CFR 1305.09[d]” and insert the citation CFR 1305.17 [c]. Delete “H & S” and insert “H&SC”.

On p.14, item 11.27 (the revised version, item 12.27) delete the citation “(CFR 1305.16)” and insert the citation “(CFR 1305.17[d])”.

On p.14, renumber the section heading “12. Policies and Procedures” from “12” to “13” and renumber the subsequent items and sub-paragraphs sequentially as 13.1, 13.1.1, 13.1.2, 13.1.3, 13.1.4, 13.1.5, 13.1.6, 13.1.7, 13.1.8, 13.1.9, 13.1.10, 13.1.11, and 13.1.12. Should this end up taking up more than one page, please take out any “Yes No N/A” that is not labeling the uppermost boxes on the page, and add in a “Yes No N/A” over the uppermost boxes at the top of each new page.

On p. 14, in item 12.1 (the revised version, item 13.1) after “policies and procedures for:” insert the citation in parenthesis “(CCR 1780[f])”

On p. 14, sub-paragraph 12.1.7 (the revised version, sub-paragraph 13.1.7) take out the question mark “?” after the phrase “correcting errors?” and insert “and inaccuracies in inventories?” This was added at the request of our field inspectors.

On p.15, renumber the section heading “13. Training” from “13” to “14” and delete the first word “Is” and insert the word “Are”.

On p.15, renumber the section heading “14. Dialysis Drugs” from “14” to “15” and renumber subsequent items sequentially as 15.1, 15.2, 15.3, 15.4. and 15.5.

On p.16, renumber the section heading “15. Record Keeping Requirements” from “15” to “16”
and renumber the subsequent items sequentially as 16.1, 16.2, 16.3, 16.4, 16.5, 16.6, 16.7, 16.8, 16.9, 16.10, 16.11, 16.12, 16.13, 16.14, and 16.15,

On p.16, delete “Yes No N/A” over the boxes at 15.8 (the revised version, item 16.8).

On p.17, delete “Yes No N/A” over the boxes at 15.13 (the revised version, item 16.13).

On p.17, at the “Note:” in the phrase “these additional requirements are in Section 11” change the section number from “11” to “12.”

On p.17, renumber the section heading “16. Reporting Requirements to the Board” from “16” to “17” and renumber subsequent items sequentially as 17.1, 17.2, 17.3, 17.4, 17.5, 17.6, 17.7, 17.8, 17.9, 17.10, and 17.11.

On p.19, renumber the section heading “17. Additional Licenses/Permits Required” from “17” to “18.” At section 17, insert item numbers “17.1” in front of the item there.

Underlying Data:

1. January 27-28, 2015, Meeting of the Board of Pharmacy, see Meeting Materials, Legislation and Regulation Committee Report, within attachments at page 34 and page 37.
2. October 29-30, 2014, Meeting of the Board of Pharmacy, see Minutes, pages 9-10, and attachments to the Legislation and Regulation Committee Report, at pages 163 to 264.
3. July 30-31, 2013, Meeting of the Board of Pharmacy, see Meeting Materials, Legislation and Regulation Committee, Regulations Report, attachment 2, pages 13 to 87.
5. 21 United States Code 829,
6. 21 United States Code 802
7. 21 Code of Federal Regulations §1304.11 et seq.,
8. 21 Code of Federal Regulations 1306.04(b)
9. 21 Code of Federal Regulations 1306.05
10. 21 Code of Federal Regulations 1306.08
11. 21 Code of Federal Regulations 1306.11 et seq.
12. 21 Code of Federal Regulations 1311
14. 4052.6 (Added Stats. 2013, Chapter 469) SB 493 (2013-2014)
15. 4064.5 (Amended Stats. 2012, Chapter 455) SB 1301 (2011-2012)
17. 4074 (Amended Stats. 2013, Chapter 304) AB 1136 (2013-2014)
18. 4081 (Amended Stats. 2014, Chapter 507) AB 2605 (2013-2014)
19. 4104 (Amended Stats. 2011, Chapter 646) SB 431 (2011-2012)
The Board did not rely upon any technical, theoretical or empirical studies in revising the self-assessment forms. The Board’s field inspectors have reported to the Board about issues that have arisen during field inspections, and requested certain additions. Additionally, seven members of the Board are pharmacists with a high degree of familiarity with the everyday practice of pharmacy. While not a formal study, the Board’s field inspectors consistently tell the Board that completing the self-assessment forms helps PICs and DRICs stay in compliance with relevant laws and regulations.

**Business Impact:** This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the fact that Board already requires pharmacists and wholesalers to complete certain self-assessment forms every two years, and when triggered by certain circumstances. The Board finds that correcting and updating the laws and regulations cited in the self-assessment forms will have no negative impact on businesses, and may possibly have a positive impact, by helping PICs and DRICs comply with laws and regulations enacted since the last amendment of the forms in 2011.

**Economic Impact Assessment:**

This regulatory proposal will have the following effects:
- It will not create or eliminate jobs in the State of CA because PICs and DRICs are already required to complete self-assessment forms biennially as of July 1 of every odd-numbered year and upon triggering conditions. The proposed amendments allow the Board to remove superseded or deleted laws and regulations, and add in citations to new laws and regulations.

- It will not create new business or eliminate existing businesses within California because the proposed amendments merely update self-assessment forms PICs and DRICs are already required to complete.

- It would not affect the expansion of businesses currently doing business in California because all PICs and DRICs are required to follow all applicable laws and regulations regardless, but these updated self-assessments will help keep them apprised of what are the laws and regulations adopted since the last amendment of the forms in 2011.

- This regulatory proposal benefits the health and welfare of California residents because having pharmacies and wholesalers follow all applicable laws and regulations helps insure the safety, quality and proper tracking of controlled substances.

- This regulatory proposal benefits worker safety because having pharmacies and wholesalers follow all applicable laws and regulations makes the pharmacies and wholesale sites safer places to work.

- This regulatory proposal does not affect the state’s environment because it simply brings up to date mandatory forms the PICs and DRICs already must complete biennially.

**Specific Technologies or Equipment:** This regulation would not mandate the use of specific technologies or equipment.

**Consideration of Alternatives:** The Board of Pharmacy has determined that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board’s attention, would either be more effective in carrying out the purpose for which the actions are proposed, or would be as effective and less burdensome to affected private persons than the proposals described herein, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policies and other provisions of law.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected by the Board.

Alternative number 1: Draft a new, separate supplementary self-assessment that PICs and DRICs would complete alongside the existing self-assessment. Issuing separate “update” self-assessments is not the most effective means of informing PICs and DRICs of changes in the laws and regulations. While PICs and DRICs would be instructed to strike out any now invalid sections of the last formally revised self-assessment forms, this might not get done, and then the older form would be rendered inaccurate and misleading. Regardless, having two or three part self-assessment forms would be very cumbersome for PICs and DRICs to complete for minimal additional benefit. Issuing updates as separate documents defeats the purpose of having the self-assessment act as an easy reference guide for PICs and DRICs. Adding
additional separate documents increases the record-keeping burden placed on PICs and DRICs.

Alternative number 2: Continue to post updated versions of the self-assessment forms on the Board’s website, without going through the formal rulemaking process. Having both the original revision, which was adopted through the rulemaking process, along with the most up-to-date revision of the self-assessment forms, available on the Board’s website, can cause confusion. While the most recent form may appear to be the obvious choice, the self-assessment forms are incorporated by reference in 16 CCR §1715 and 16 CCR §1784, a reference which includes the latest revision date (Rev. 01/11). This makes it unclear to PICs and DRICs whether they must use the self-assessment with the revision date cited in the statute, or the updated version. PICs and DRICs who fill out the older formally-adopted form will not be informed of recent changes to the law and regulations, and may fall out of compliance. A part of how the Board meets its mandate to serve the public and increase public safety is by providing PICs and DRICs with updated self-assessments that serve as a summary of all relevant laws and regulations, including those adopted, superseded or deleted, since the last amendment of the forms in 2011.