



California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Sections 1715 and 1784 Related to Community Pharmacy/Hospital Outpatient Pharmacy Self-Assessment Form 17M-13, Hospital Pharmacy Self-Assessment Form 17M-14, and Wholesaler/Third-Party Logistics Provider Self-Assessment Form 17M-26, Including Review of Comments Received During the 45-Day Comment Period

Background:

At the April 24, 2024, Board meeting, the Board approved the proposed regulation text to amend Sections 1715 and 1784 and the associated self-assessment forms specific to Community Pharmacy/Hospital Outpatient Pharmacy Self-Assessment Form 17M-13, Hospital Pharmacy Self-Assessment Form 17M-14, and Wholesaler/Third-Party Logistics Provider Self-Assessment Form 17M-26.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on January 10, 2025, which ended on February 24, 2025. Several comments were received during the comment period. Attached to this memo are the comments received and staff recommendations.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed on January 10, 2025.
2. Amend the regulation as recommended by Board staff and notice the modified text for a second 15-day comment period.

Possible Motion:

Accept the Board staff's recommended comment responses and recommended changes to the self-assessment forms in response to the comments. Additionally, delegate to the executive officer the authority to make technical or non-substantive changes as necessary. Further, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Sections 1715 and 1784 and, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Section, Subdivision	Proposed Language	Recommendation / Comment
<p>CCR 1715.(c)(5)</p>	<p>(5) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials on the self-assessment.</p> <p>(6) The pharmacist-in-charge shall certify on the final page of the self-assessment that they have completed the self-assessment of the pharmacy of which they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature on the self-assessment.</p> <p>(7) The pharmacy owner or hospital administrator shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature on the self-assessment.</p>	<p>Rationale: Currently, the board also have a pending rule making process regarding Digital Signatures CCR 1700. 1715(c) requires the PIC to initial each page with original handwritten initials and original handwritten signatures. We recommend that the form be available for electronic signature to allow for digital signatures which will help with paper reduction and a positive impact on the environment.</p> <p>Recommendation: (5) The pharmacist-in-charge shall initial each page of the self-assessment with a digital signature or an original handwritten initials on the self-assessment. (6) The pharmacist-in-charge shall certify on the final page of the self-assessment that they have completed the self-assessment of the pharmacy of which they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with a digital signature or an original handwritten signature on the self-assessment. (7) The pharmacy owner or hospital administrator shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with a digital signature or an original handwritten signature on the self-assessment.</p>

From: Tina Goodman <tina@wenoexchange.com>
Sent: Friday, January 10, 2025 4:58 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Self assessment comment

Dear Lori Martinez

I applaud the new proposed rule for the pharmacist in charge self-assessment.

CA is head in the USA and not the tail for this insight to protect CA residents rights to receive their legal prescriptions.

I suggest to add to the self assessment BPC 688(b)(3) to more clarify BPC 688[b][2] which only provides for solely denying based on the pharmacy's "proprietary" software.

Why? CA pharmacies today continue to violate BPC 688(b)(1) when it is not submitted via or compatible with a pharmacy's non-proprietary software AND they have not denied it according to the rules BPC 688[b](3) provides for. These pharmacists in charge are often without the knowledge of this rule for denying based on software. It would be wise to remind them.

1.20.1. The pharmacy's staff shall not refuse to dispense or furnish an electronic data transmission prescription solely because the prescription was not submitted via, or is not compatible with, the proprietary software of the pharmacy. (BPC 688[b][2]);

BPC 688[b][3] should be also added to the self assessment:

The pharmacy, pharmacist, or other practitioner authorized under California law to dispense or furnish a prescription pursuant to Section 4040 may decline to dispense or furnish an electronic data transmission prescription submitted via a software that fails to meet any of the following:

(3) A pharmacy, pharmacist, or other practitioner authorized under California law to dispense or furnish a prescription pursuant to Section 4040 may decline to dispense or furnish an electronic data transmission prescription submitted via a software that fails to meet any of the following:

(A) Adheres to the National Council for Prescription Drug Programs SCRIPT standard, as modified from time to time.

(B) Complies with the prescription content requirements set forth in Section 4040.

(C) For a controlled substance prescription, complies with Parts 1300, 1304, 1306, and 1311 of Title 21 of the Code of Federal Regulations, as amended from time to time.

(D) Complies with the federal Health Insurance Portability and Accountability Act of 1996, the California Confidentiality of Medical Information Act, or the security and confidentiality requirements prescribed to by the pharmacy, pharmacist, or other practitioner authorized pursuant to Section 4040.

Thanks and you are doing it right!

[Click here to book a call or online meeting with Tina Goodman](#)

Tina Goodman

CEO

Weno Exchange LLC

Cell 210-912-8143

Office 877-890-3726

email: tina@wenoexchange.com

wenoexchange.com

Board of Pharmacy Proposed Text to amend section 1715/1784 of Title 16, Division 17, Article 2 of 16
 CCR: **Hospital Pharmacy Self-Assessment**

Institution:	Valley Children’s Hospital 9300 Valley Children’s Place Madera, CA 93636	
State Board Section	Proposed Language	Comments/Recommendations
6. Pharmacist-in-Charge (PIC)	6.7. The PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the board is timely notified. (BPC 4113[d][1])	Comments: Hospital pharmacies do not have “store management”. Please consider removing 6.7.
10. Duties of a Pharmacy Technician	10.3. When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing packaging, manipulative, repetitive, or other nondiscretionary tasks. If a pharmacy technician, under the direct supervision and control of the pharmacist, prepares and administers influenza and COVID-19 vaccines via injection or intranasally, prepares and administers epinephrine, performs specimen collection for tests that are classified as waived under CLIA, receives prescription transfers, and accepts clarification on prescriptions, a second pharmacy technician shall be assisting a pharmacist with performing the tasks as defined in BPC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (BPC 4038, 4115[gf][1], CCR 1793.7[f]) 10.12. A pharmacy technician may, under the direct supervision and	To my knowledge, inpatient pharmacy technicians do not administer vaccines or epinephrine or perform specimen collection. This section is not applicable to hospitals. Please consider removing the bold section of 10.3. and 10.12. including 10.12.1., 10.12.2., 10.12.3., and 10.12.4. from the Hospital Pharmacy Self-Assessment.

Board of Pharmacy Proposed Text to amend section 1715/1784 of Title 16, Division 17, Article 2 of 16
 CCR: **Hospital Pharmacy Self-Assessment**

	<p>control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions: (BPC 4115[b][1])</p>	
<p>18. Record Keeping Requirements</p>	<p>18.2.10. Records documenting, to the extent possible, the kind and amounts of COVID-19 oral therapeutics furnished following a positive test for SARS-CoV-2, as well as information regarding any testing services provided, in the patient's record in the record system maintained by the pharmacy. (BPC 4052.04[d])</p>	<p>Inpatient pharmacists do not furnish COVID-19 oral therapies. The inpatient pharmacists dispense medications according to a provider's medication order only. Please consider removing from the Hospital Pharmacy Self-Assessment.</p>
<p>19. Inventory Reconciliation Report of Controlled Substances</p>	<p>19.3.6. In addition to Schedule II controlled substance, the pharmacy is performing an inventory reconciliation of alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine per 5ml of product at least every 12 months. (CCR 1715.65[a][2])</p>	<p>The 12-month time frame is not applicable to hospital pharmacies as stated in 19.3.10. The inpatient hospital pharmacy must perform a reconciliation of the listed medications on a quarterly basis. Please consider removing 19.3.6.</p>



February 21, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: ***Proposal to modify the Hospital Pharmacy Self-Assessment Form (17M-14)***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed modifications to its Hospital Pharmacy Self-Assessment form (17M-14). Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates.

Question number 1.15 of the Hospital Pharmacy Self-Assessment would require the Pharmacist-in-Charge (PIC) to assess the health facility's compliance with certain elements of Ryan's Law (Health and Safety Code §§ 1649). Kaiser Permanente has concerns about requiring the PIC to attest under the penalty of perjury that the health facility complies with Ryan's Law. After Ryan's law was enacted in 2021, the law was amended in 2022 to "clarify that [the law] does not require medicinal cannabis to be subject to all requirements applicable to controlled substances, nor to require that a pharmacy or pharmacist be involved in the use, storage, management, or dispensing of medicinal cannabis at a health facility."¹ The law now requires, "the patient or a primary caregiver to be responsible for acquiring, retrieving, administering, and removing medicinal cannabis."² Because of these changes to the law, at some health facilities, the PIC and the pharmacy department have no role in the implementation and ongoing oversight of Ryan's Law and as a result, do not have the direct knowledge necessary to answer proposed question number 1.15 of the Hospital Pharmacy Self-Assessment. Therefore, we encourage the Board to delete question number 1.15 in its entirety from the Hospital Pharmacy Self-Assessment as shown below. If the question remains on the self-assessment, we believe it would be appropriate for a PIC to answer the question "not applicable" if they do not have direct knowledge of how the health facility has implemented the requirements of Ryan's Law.

~~1.15. All medicinal cannabis is stored in a locked container in the patient's room, other designated areas, or with the patient's primary caregiver and is retrieved, administered, handled, removed and disposed in accordance with HSC 1649.1, 1649.2, 1649.3, 1649.4.~~

¹ California State Senate, *SB 988 Senate Floor Analysis*, https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=202120220SB988# (last visited Feb. 21, 2025).

² Cal. Health & Safety Code § 1649.2.



As question 2.2.2 is written, it could be interpreted to mean that it must be the pharmacy technician who reports any irregularities discovered while performing “unit inspections” to the director or chief executive officer of the health care facility. In contrast, the statute provides that “irregularities shall be reported to the pharmacist-in-charge and the director or chief executive officer of the health care facility in accordance with the health care facility’s policies and procedures,” but does not require that the pharmacy technician be the one to make the report to health care facility leadership.³ Therefore, to ensure consistency with the statute, we recommend that question number 2.2.2 of the Hospital Pharmacy Self-Assessment be modified as shown below:

~~A pharmacy technician shall report a~~ any irregularities **discovered by a pharmacy technician shall be reported** to the pharmacist-in-charge and to the director or chief executive officer of the health care facility within 24 hours. (BPC 4115[j][3])

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed modifications to the Board’s Hospital Pharmacy Self-Assessment form. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully,

A handwritten signature in black ink, appearing to read "J. Gray", with a long, sweeping horizontal line extending to the right.

John P. Gray, PharmD, MSL
Director, National Pharmacy Legislative and Regulatory Affairs
Kaiser Permanente

³ Cal. Bus. & Prof. Code § 4115(j)(3).

From: Lili Cui <Lili.Cui@QuVaPharma.com>

Sent: Tuesday, January 28, 2025 2:52 PM

To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>

Subject: Question regarding Proposed Regulatory Action Self-Assessments Forms

To whom it may concern,

I noticed that the Board of Pharmacy has proposed updated Self-Assessment Forms for Pharmacy/Hospital/ Wholesaler/3PL. I would like to confirm whether the updated form for 3PL applies to non-resident 3PL facilities. Thank you very much.

Sincerely,

Lili Cui



Lili Cui, RPh, PhD

Corporate Customer License Pharmacist

Pharmacy Services

3 Sugar Creek Center Blvd, Suite 250 | Sugar Land, TX
77478

Main: 888.339.0874

[QuVaPharma.com](https://www.QuVaPharma.com) | [Follow us on LinkedIn](#)

CONFIDENTIALITY NOTICE: This document (and/or the attachments accompanying it) may contain confidential information belonging to QuVa Pharma, Inc.. This information is intended only for the use of the intended recipient. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this information is strictly prohibited and should be deleted immediately. Any unauthorized interception of this document is illegal.



Proposed Amendment to California Code of Regulations, Title 16, Sections 1715 and 1784 Related to Self-Assessment Forms (Pharmacy, Hospital, Wholesaler)

Summarized 45-day Comments with Board Staff Recommendations:

Section 1715

Written Comments from L. De Martini, CA Society of Health-System Pharmacists (CSHP)

Comment 1: The commenter recommends that subsection 1715(c)(5), (6), and (7) be amended to include the ability for the use of digital signatures, which will help with paper reduction and a positive impact on the environment, which would be consistent with the Board's pending rulemaking specific to Digital Signatures, 16 CCR section 1700.

Response to Comment 1: Board staff have reviewed this comment and recommend amending the proposed text to allow for the use of digital signatures.

17M – 13 – Community Pharmacy

Written Comments from T. Goodman, Weno Exchange LLC

Comment 2: The commenter suggests adding BPC 688(b)(3) to 1.20.1 to clarify BPC 688[b][2], which only provides for solely denying based on the pharmacy's "proprietary" software. CA pharmacies today continue to violate BPC 688(b)(1) when it is not submitted via or compatible with a pharmacy's non-proprietary software, AND they have not denied it according to the rules BPC 688[b](3) provides for. These pharmacists in charge are often unaware of this rule for denying based on software. It would be wise to remind them.

Response to Comment 2: Board staff have reviewed this comment and recommend adding BPC 688(b)(3)(A through D) to 1.20.1. Below is the recommended addition.

1.20.1. The pharmacy's staff shall not refuse to dispense or furnish an electronic data transmission prescription solely because the prescription was not submitted via, or is not compatible with, the proprietary software of the pharmacy. (BPC 688[b][2]))

1.20.1.1. A pharmacy, pharmacist, or other practitioner authorized under California law to dispense or furnish a prescription pursuant to BPC 4040

may decline to dispense or furnish an electronic data transmission prescription submitted via a software that fails to meet any of the following: (688[b][3])

1.20.1.1.1. Adheres to the National Council for Prescription Drug Programs SCRIPT standard, as modified from time to time. (688[b][3][A])

1.20.1.1.2. Complies with the prescription content requirements set forth in BPC 4040. (688[b][3][B])

1.20.1.1.3. For a controlled substance prescription, complies with Parts 1300, 1304, 1306, and 1311 of Title 21 of the Code of Federal Regulations, as amended from time to time. (688[b][3][C])

1.20.1.1.4. Complies with the federal Health Insurance Portability and Accountability Act of 1996, the California Confidentiality of Medical Information Act, or the security and confidentiality requirements prescribed to by the pharmacy, pharmacist, or other practitioner authorized pursuant to BPC 4040. (688[b][3][D])

17M – 14 – Outpatient Hospital

Written Comments from A. Thomas, Valley Children's Healthcare

Comment 3: The commenter recommends removing subsection 6.7 as Hospital pharmacies do not have “store management” to report conditions to.

Response to Comment 3: Board staff have reviewed this comment and do not recommend changing the proposed text based on the comment. Board staff notes that while the commenter facility does not have “store management”, BPC 4113 does not exempt the pharmacist-in-charge or the pharmacist on duty of a hospital pharmacy from immediately notifying management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

Comment 4: The commenter indicates that inpatient pharmacy technicians do not collect specimens or administer vaccines or epinephrine. Please consider removing sections 10.3 and 10.12, including 10.12.1, 10.12.2, 10.12.3, and 10.12.4, from the Hospital Pharmacy Self-Assessment, as these sections do not apply to hospitals.

Response to Comment 4: Board staff have reviewed this comment and do not recommend changing the proposed text based on the comment. Board staff notes that while pharmacy technicians may not perform these tasks at the commenter's facilities, BPC 4115(b) authorizes them to do so under a pharmacist's direct supervision and control.

Comment 5: The commenter recommends removing subsection 18.2.10 as Inpatient pharmacists do not furnish COVID-19 oral therapies. The inpatient pharmacists dispense medications according to a provider's medication order only.

Response to Comment 5: Board staff have reviewed this comment and do not recommend changing the proposed text based on the comment. Board staff notes that while a pharmacist may not perform this task at the commenter's facilities, BPC 4052.04(a) authorizes them to do so. Should the pharmacist do so, they must document the specified items, consistent with BPC 4052.04(d).

Comment 6: The commenter recommends removing subsection 19.3.6. As stated in 19.3.10, the 12-month time frame is not applicable to hospital pharmacies. The inpatient hospital pharmacy must perform a quarterly reconciliation of the listed medications.

Response to Comment 6: Board staff have reviewed this comment and agree with the recommendation to remove subsection 19.3.6.

Written Comments from J. Gray, Kaiser Permanente

Comment 7: The commenter indicates that subsection 1.15 requires the Pharmacist-in-Charge (PIC) to assess the health facility's compliance with specified elements of Ryan's Law (Health and Safety Code §§ 1649). The commenter stated that the law was amended in 2022 to "clarify that [the law] does not require medicinal cannabis to be subject to all requirements applicable to controlled substances, nor to require that a pharmacy or pharmacist be involved in the use, storage, management, or dispensing of medicinal cannabis at a health facility." The law now requires, "the patient or a primary caregiver to be responsible for acquiring, retrieving, administering, and removing medicinal cannabis." The commenter is concerned about requiring the PIC to attest under the penalty of perjury that the health facility complies with Ryan's Law when the PIC and the pharmacy may have no role in implementing and ongoing oversight of Ryan's Law. Therefore, the commenter encourages the Board to delete subsection 1.15 in its entirety. If the question remains on the self-assessment, we believe it would be appropriate for a PIC to answer the question "not applicable" if they do not have direct knowledge of how the health facility has implemented the requirements.

Response to Comment 7: Board staff have reviewed this comment and agree with the recommendation to remove subsection 1.15.

Comment 8: The commenter indicates that subsection 2.2.2 could be interpreted to mean that it must be the pharmacy technician who reports any irregularities discovered while performing “unit inspections” to the director or chief executive officer of the health care facility. Therefore, the commenter recommends that the subsection be modified as show below:

2.2.2 A ~~pharmacy technician shall report a~~ any irregularities discovered by a pharmacy technician shall be reported to the pharmacist-in-charge and to the director or chief executive officer of the health care facility within 24 hours. (BPC 4115[j][3])

Response to Comment 8: Board staff have reviewed this comment and agree with the recommendation to amend the proposed text for clarity. Board staff recommend the following amendment to align with the language of the statute:

2.2.2 In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician performing monthly checks of the drug supplies stored throughout the health care facility, shall report any irregularities, within 24 hours, to the pharmacist-in-charge and to the director or chief executive officer of the health care facility in accordance with the health care facility’s policies and procedures.

17M – 26 – Wholesaler / 3PL

Written Comments from L. Cui, QuVa Pharma

Comment 9: The commenter would like to confirm whether the updated form for 3PL applies to non-resident 3PL facilities.

Response to Comment 9: Board staff have reviewed this comment and do not recommend changing the proposed text based on the comment. Board staff note that as the self-assessment form is a compilation of State and Federal law; while not mandated for non-resident 3PLs, non-resident 3PL facilities shipping into California may complete the assessment to ensure compliance with State and Federal Law.