Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Compounding Limitations and Requirements: Self-Assessment

Section Affected: California Code of Regulations (CCR), Title 16, Division 17, Amend Section 1735.2

Hearing Date: None unless requested, see Notice of Proposed Action

Background

The Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, hospital pharmacies, clinics, wholesalers, third-party logistics providers, and outsourcing facilities. The board's mandate and its mission is to protect the public. Business and Professions Code (BPC) section 4001.1.

Problems Addressed

Existing regulation at 16 CCR section 1735.2, specifies the limitations and requirements for compounded drug preparations. Subdivision (k) of section 1735.2 requires the pharmacist-in-charge (PIC) to complete a self-assessment form prior to allowing any drug product preparation, before July 1 of every odd-numbered year; and within 30 days whenever (1) a new pharmacy permit has been issued, (2) there is a change in the PIC, and he or she becomes the new PIC of a pharmacy, or (3) there is a change in the licensed location of a pharmacy to a new address. The self-assessment form assists the pharmacy to evaluate and improve its compliance with federal and state requirements, makes the pharmacy inspection process more meaningful and provides relevant information to PICs. This self-assessment form was last updated in February 2012.

On January 1, 2017, the board updated its compounding regulations due to changes to the federal United States Pharmacopeia, which is the national practice standard for compounding. This proposal will repeal and replace the self-assessment form that is incorporated by reference to (1) update citations/references since the last revisions (2/12); (2) correct previously misstated references and typographical errors; (3) make formatting changes; and (4) incorporate references to new regulatory or statutory requirements. These changes would assure the PIC that the information and references contained therein reflect current statutory and regulatory requirements. Due to the extensive changes that occurred to the compounding regulations (16 CCR §§ 1735 and 1751 et seq.) effective January 1, 2017, as well as statutory changes in 2020 and 2021; for clarity the board has repealed the existing compounding self-assessment form dated 2/12 and has replaced the compounding self-assessment with a completely new version of the document dated 1/22.

Benefits

This regulatory proposal benefits the health and welfare of California residents and benefits employee safety. The proposed regulation will update the self-assessment form with current law and regulations. The self-assessment form aids licensees in assessing their compliance with federal and state requirements. The proposal updates the form to include law and regulations adopted since 2012 and exclude law and regulations that have been superseded or repealed since 2012. As the PIC must complete the self-assessment form, biennially, they will identify any areas where the compounding facility may be out of compliance. This awareness can increase self-correction and makes facility site inspection process more meaningful by providing useful information to the PIC about controlling statutes and regulations. This periodic review and accountability will result in increased consumer safety, specific to compounded medication, and will improve facility operations with respect to employee safety and the state's environment.

Specific Purpose of Proposed Changes and Rationale

Due to the extensive regulatory changes that occurred effective January 1, 2017, the Board's proposal repeals the existing self-assessment form as identified in regulation (revision date of 2/12) and replaces the document with the new version of the self-assessment form with a revision date of 1/22. The repeal and replace is being completed for clarity as the updates were extensive and the self-assessment form became hard to read with the strikeout and underline format.

Form 17M-26 Incorporated by Reference

Page 1

Page 1 identifies the title of the self-assessment form and the legal requirements for the form to be completed. The title is updated from "Compounding Self-Assessment" to "Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment" for clarity as to the form's intended audience. This information is provided for clarity to ensure that the PIC is aware of the legal requirement to complete the self-assessment every odd-numbered year. Further, the form provides a space for the PIC to record the identifying information of the pharmacy. This information is necessary to list the particular location for which the form is being completed and list any associated accreditation or additional license numbers. As a hospital may have multiple compounding facilities, clearly and appropriately identifying the specific location will ensure that the form can be reviewed at a later date by the PIC and Board Inspector during the annual inspection, and that it will be easy to identify the license number and location for which the self-assessment form was completed. Changes from the current regulatory obligation include the addition of a request for a FAX number and an optional website address to provide the board with fast contact information. Additionally, the DEA Registration number on the current form's page 1 is being moved to page 2, since different staff members may have their own DEA numbers. The date of DEA inventory would be included on the Community Pharmacy (17M-13) or Hospital Pharmacy (17M-14) self-assessment forms and is therefore not needed on the compounding self-

assessment form. A new requirement to list the “Centralized Hospital Packaging License #” is added as this is a new licensing category that did not exist in 2012.

Page 2

As with the form in current regulation, Page 2 provides space for the PIC to identify all pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties. As the PIC is responsible for the staff working in the pharmacy, this space ensures that the PIC is aware of the licenses held by the staff and their expiration dates. Staff are not permitted to work with an expired license. While the information will only be current as of the date the form is completed, the PIC will still be aware of any staff with approaching license expiration dates, and the PIC will be better able to monitor and ensure that the licensee has renewed their license. This form adds a place to record the license number for an advanced practice pharmacist license. This is a new licensing category that did not exist during the last revision in 2012.

Page 3

The beginning of page 3 identifies the title of the self-assessment form again and identifies that all the law references are specific to the California Code of Regulations (CCR).

The next paragraph provides instruction for the completion of the form should a “No” answer be identified. For each “no” response, the PIC shall provide a corrective action or action plan to come into compliance with the law. This requirement provides clarity to the PIC that the board requires a written corrective action or action plan to address all areas of noncompliance identified by the PIC. This addition ensures that the PIC has created a plan for the licensed premises to remediate areas of noncompliance and makes if more likely that the licensed premises will become fully compliant. Board inspectors regularly inspect compounding facilities for compliance with laws and regulations. The development of the correction action or action plan allows for a streamlined, efficient, and effective inspection process as inspectors can check for the corrected action or monitor the implementation of the action plan. The corrective action or action plan is simply a written statement detailing how the PIC will address areas of noncompliance or what they have already done to address it and is written on the self-assessment form or can be attached to it.

Citations on this form have been altered and updated for consistency with the board’s other forms, that is, a subdivision is marked off by brackets instead of parenthesis. This avoids confusion in the parenthetical statements. Grammar and terminology are also non-substantively updated for clarity and consistency.

In Question 1.2, the prior form referenced all definitions in 1735.1. The new version of the form deletes the specific definitions of equipment, integrity, potency, quality, and strength from that greater definition list because all staff involved in compounding must know all the definitions, not just the five previously mentioned.

Pages 3-30

Pages 3 through 30, contain Sections 1 through 27 of the self-assessment form, for completion by the PIC. These sections, described separately below, identify the legal requirements within the CCR and BPC and are intended to provide easy valuation of the facilities practice and ensure compliance. Notably, the form is not adding new regulation. These are existing laws and the PIC and facilities should already be in compliance.

Each section provides the legal requirement and the statute or regulation where the requirement can be found so the PIC can cross-reference the appropriate legal authority should they wish to do so. Additionally, the at the end of each section on the form, an area is provided for the PIC to record their corrective action or action plan to address any areas of noncompliance identified in the section by the PIC. As mentioned above, this addition ensures that the PIC has created a plan for the licensed premises to remediate areas of noncompliance and makes it more likely that the licensed premises will become fully compliant, if not already.

Section 1. Definitions

This section is added to identify the regulation specific to how compounding must be completed (CCR §1735) and that the PIC understands the definitions related to compounding identified in section 1735.1 of the CCR. Having a thorough understanding of compounding and terms within the industry is necessary to ensure compliance and that products are being compounded consistent with regulatory requirements.

Section 2. Compounding Limitations and Requirements

This section identifies the legal requirements of CCR section 1735.2. This section allows the PIC to perform a step-by-step analysis of the facility's compounding practice and ensure all requirements are being met and that the facility is compounding within the limitations identified in regulation. Changes from the prior form are not imposing any additional regulatory obligations but are spelling out the current obligations from section 1735.2 (which has been amended since the form was adopted) more clearly. Additionally, section 2.13 and 2.14 were added to include the requirements for compounding human drug products as specified in BPC 4126.10. These requirements became effective January 1, 2022.

Section 3. Recordkeeping for Compounded Drug Preparation

This section identifies the legal requirements of CCR section 1735.3, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the facility's compounding recordkeeping and ensures that records are being maintained consistent with the requirements identified in regulation.

Section 4. Labeling of Compounded Drug Preparation

This section identifies the legal requirements of CCR section 1735.4, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the facility's compounding labeling process and ensures that compounded drug preparations are being labeled consistent with the requirements identified in regulation.

Section 5. Compounding Policies and Procedures

This section identifies the legal requirements of CCR section 1735.5, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the facility's compounding policies and procedures. It ensures that the facility has complete policies and procedures in place and that they are consistent with the requirements identified in regulation.

Section 6. Compounding Facilities and Equipment

This section identifies the legal requirements of CCR section 1735.6, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the overall compounding facility and the equipment used for compounding. It ensures that the facility is using certified equipment that is maintained consistent with the manufacturers' specifications, and that any hazardous compounding is being performed in compliance with the requirements identified in regulation.

Section 7. Training and Compounding Staff

This section identifies the legal requirements of CCR section 1735.7, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the training completed by the compounding staff and that they demonstrate sufficient knowledge prior to compounding, which is consistent with the requirements identified in regulation.

Section 8. Compounding Quality Assurance

This section identifies the legal requirements of CCR section 1735.8, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the facility's quality assurance process for compounded drug preparations to ensure it is consistent with the requirements identified in regulation.

Section 9. Compounding Consistent with United States Pharmacopeia – National Formulary

This section identifies the legal requirements of BPC 4126.8, which was added effective January 1, 2020, after the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the facility's compounding, including relevant testing and quality assurance to ensure they are consistent with the requirements identified in the United States Pharmacopeia – National Formulary, as required by BPC 4126.8.

Section 10. Duties of Pharmacy Issuing a Compounded Drug Recall

This section identifies the legal requirements of BPC 4126.9, which was added effective January 1, 2017, after the current form's adoption. This section ensures that the PIC is aware of the process for issuing a drug recall should it be necessary. This reminder is necessary given the nature and importance of recalls by compounding pharmacies.

Page 12

The previous ten sections were specific to facilities that compound non-sterile drug preparations. On page 12, the requirements for compounding sterile drug preparations begin. Previously, sterile drug preparations were identified in pharmacy law as sterile-injectable drugs; however, this was amended out of law in 2017 during the overhaul of the board's compounding regulations.

The PIC would indicate whether that facility compounds sterile drug preparations or not. The legal section that explains sterile compounding is identified as BPC 4127. If the facility does, the PIC continues to complete sections 11 through 27. If the facility does not, the PIC proceeds to the certification on page 30.

Section 11. Compounding Drug for Other Pharmacy for Parenteral Therapy

This section identifies the legal requirements of BPC 4123. This section ensures that the PIC is aware of the reporting requirements for contracting to deliver compounded parenteral therapy drugs to another pharmacy. The obligations of BPC 4123 and the reporting requirements remain unchanged; this section is similar to the current form section 10 with updated formatting.

Section 12. Sterile Compounding: Compounding Area

This section identifies the legal requirements of CCR section 1751, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the facility's sterile compounding area and equipment to ensure it is consistent with the requirements identified in regulation.

Section 13. Sterile Compounding; Compounding Area

This section identifies the legal requirements of 24 CCR 1250.4[1] (Building Code), and 505.12[2] and 505.12.1[3] (Mechanical Code). These sections are building standards to which compounding facilities must adhere. This section allows the PIC to perform a step-by-step analysis of the facility's sterile compounding area and equipment to ensure it is consistent with the requirements identified in these sections of law. As they are outside the Title 16 of the Board of Pharmacy, reminding the PIC of these section is necessary to help ensure compliance.

Section 14. Sterile Compounding Recordkeeping Requirements

This section identifies the legal requirements of section 1751.1, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the facility's sterile compounding recordkeeping and ensures that sterile preparation records are maintained in compliance with the requirements identified in regulation.

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[1] **California Building Code section 1250.4 Compounding area for parenteral solutions.** The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment as approved by the Commission, Federal Supply Service, General Service Administration meet standards for Class 100 HEPA (high efficiency particulate air) filtered air such as laminar airflow hood or clean room.
2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.
3. The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions.
   There shall be sufficient space, well separated from the laminar-flow hood area for the storage of bulk materials, equipment and waste materials.
4. A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.
5. Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:
   5.1. An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative adjacent areas.
   5.2. An ISO class 5 cleanroom.
   5.3. A barrier isolator that provides an ISO class 5 environment for compounding.
   Note: For additional pharmacy mechanical standard requirements, see Chapter 5, California Mechanical Code.

[2] 505.12 Pharmacies - Compounding Area of Parenteral Solutions. [CA - Board of Pharmacy] The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall be ventilated in a manner not interfering with laminar air flow.

[3] 505.12.1 Pharmacies - Laminar Flow Biological Safety Cabinet. [CA - Board of Pharmacy] In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class JI Type B vertical laminar airflow hood with bag in - bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight. Note: For additional pharmacy building standard requirements, see Chapter 12, California Building Code.

Section 15. Sterile Labeling Requirements

This section identifies the legal requirements of CCR section 1751.2, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the facility's compounding labeling process and ensures that compounded drug preparations are labeled consistent with the requirements identified in regulation.

Section 16. Sterile Policies and Procedures

This section identifies the legal requirements of CCR section 1751.3. This section allows the PIC to perform a step-by-step analysis of the facility's sterile compounding policies and procedures. It ensures that the facility has complete sterile compounding policies and procedures in place and that they are consistent with the requirements identified in regulation.

Section 17. Facility & Equipment Standards for Sterile Compounding

This section identifies the legal requirements of section 1751.4, which has also been amended since the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the overall sterile compounding facility and the equipment used for sterile compounding and ensures that the facility is using certified equipment that is maintained consistent with the manufacturers' specifications, and that any sterile hazardous compounding is being performed consistent with the requirements identified in regulation.

Section 18. Sterile Compounding Attire

This section identifies the legal requirements of section 1751.8. This section allows the PIC to perform a step-by-step analysis of the facility's compounding garment attire specific to sterile compounding to ensure it is consistent with the requirements identified in regulation.

Section 19. Sterile Compounding Consultation; Training of Sterile Compounding Staff

This section identifies the legal requirements of section 1751.6. This section allows the PIC to perform a step-by-step analysis of the sterile compounding training completed by the compounding staff and that they demonstrate sufficient knowledge prior to performing any sterile compounding, consistent with the requirements identified in regulation.

Section 20. Sterile Compounding Quality Assurance and Process Validation

This section identifies the legal requirements of section 1751.7. This section allows the PIC to perform a step-by-step analysis of the facility's sterile compounding quality assurance process and validation process for compounded drug preparations to ensure it is consistent with the requirements identified in regulation.

Section 21. Beyond Use Dating for Sterile Compounded Drug Preparations

This section identifies the legal requirements of section 1751.8. This section allows the PIC to perform a step-by-step analysis of the facility's beyond use dating processes for sterile compounded drug preparations to ensure it is consistent with the requirements identified in regulation.

Section 22. Single-Dose and Multi-Does Containers; Limitations on Use

This section identifies the legal requirements of section 1751.9, which became operative January 1, 2017, after the current form's adoption. This section allows the PIC to perform a step-by-step analysis of the facility's use of single-dose and multi-dose containers for sterile compounded drug preparations to ensure it is consistent with the requirements identified in regulation.

Section 23. Sterile Compounding Reference Materials

This section identifies the legal requirements of section 1751.10. This section allows the PIC to review the facility's sterile compounding reference material to ensure it is consistent with the requirements identified in regulation.

Section 24. Sterile Compounding License Renewal

This section identifies the legal requirements of BPC 4127.1, 4127.15 (added January 1, 2018), and 4127.2. This section allows the PIC to prepare for the annual renewal of the facility's sterile compounding license. By preparing early, the PIC will be able to submit the required documents timely to ensure the license is renewed prior to the license expiration date.

Section 25. Hospital Satellite Compounding Pharmacy

This section identifies additional legal requirements of BPC 4127.15. This section allows the PIC to review the facility's sterile compounding processes specific to a hospital satellite compounding pharmacy. If the facility is not a hospital satellite compounding facility, the PIC would simply mark N/A for not applicable and move to the next question.

Section 26. Nonresident Pharmacy

This section identifies additional legal requirements of BPC 4127.2. This section allows the PIC of a Nonresident Pharmacy to review the requirements specific to only a non-resident sterile compounding facility. If the facility is not a nonresident pharmacy, the PIC would simply mark N/A for not applicable and move to the next question.

Section 27. Duties of a Pharmacy Issuing a Sterile Compounded Drug Recall

This section identifies the legal requirements of BPC 4127.8. This section ensures that the PIC is aware of the process for issuing a drug recall on a sterile compounded drug product should it be necessary. This reminder is necessary given the nature and importance of recalls by sterile compounding pharmacies.

Page 30

Pharmacist-in-Charge Certification

As with the current form, the certification by the PIC is necessary to ensure that the PIC completed the self-assessment as required. Additionally, space is now provided for the PIC to provide an expected timeline for resolution of the noncompliance issues. As Board Inspectors regularly inspect compounding facilities for compliance with laws and regulations; the development of the correction action or action plan allows for a streamlined, efficient, and effective inspection process as inspectors can check for the corrected action or monitor the implementation of the action plan. The inspector and PIC can quickly identify possible noncompliance areas based on the resolution timeline.

Acknowledgement by Owner or Hospital Administrator

Again, a certification is provided in the current form. The certification by the owner or hospital administrator ensures that they are aware of any non-compliance issues that the PIC may have identified. The addition of the timeline notation to this new version of the form ensures that they are aware of the timeline to correct any issues identified.

Underlying Data

1. Relevant Meeting Materials and Minutes from the Board Meeting held January 27-28, 2022
2. Relevant Meeting Materials and Minutes from the Board Enforcement and Compounding Committee Meeting held January 18, 2022
3. Relevant Meeting Materials and Minutes from the Board Meeting held January 27-28, 2021
4. Relevant Meeting Materials and Minutes from the Board Enforcement and Compounding Committee Meeting held January 20, 2021
5. Relevant Building Code (24 CCR 1250.4 [Part 2, Volume 1]) and Mechanical Code (24 CCR 505.12 and 505.12.1 [Part 4, Chapter 5]) - https://www.dgs.ca.gov/BSC/Codes.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination was based on the fact that the board, per statute, already requires pharmacists to complete the appropriate compounding self-assessment form every two years, and when triggered by specific circumstances. The board finds that correcting and updating the laws and regulations cited in the self-assessment form will have no negative impact on businesses by helping PICs comply with laws and regulations enacted since the last amendment of the forms in 2012.

Economic Impact Assessment:

The board has determined that:

(1) this proposal will not create jobs within California;
(2) this proposal will not eliminate jobs within California;
(3) this proposal will not create new businesses within California;
(4) this proposal will not eliminate existing businesses within California;
(5) this proposal will not expand businesses currently doing business in the State of California.

The board determined that this proposal will not create or eliminate jobs or businesses. The self-assessment form is being updated to add and/or remove law and regulations. and does not impose new requirements. Compounding pharmacies and their PICs must continually comply with statutory and regulatory requirements and ensure their compliance is up to date. The self-assessment form is simply a tool provided by the board to aid them in doing so.

This regulatory proposal benefits the health and welfare of California residents. As the PIC is required to complete the self-assessment form, it helps educate and ensure that the PIC knows all applicable laws and regulations, which will ensure that the compounding pharmacies follow practice standards, which protects the safety and quality of compounded drug preparations.

This regulatory proposal benefits workers' safety because having pharmacies follow all applicable laws and regulations makes the pharmacies a safer place to work.

Finally, this regulatory proposal may benefit the state's environment because it helps to ensure that pharmacies are compounding consistent with pharmacy law, which will ensure that hazardous compounding is being done appropriately and that waste is disposed of properly.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment. PICs can choose to fill-out and store the forms electronically or hardcopy.

Consideration of Alternatives

The board has initially determined that no reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons. The only alternative would be to continue to use the self-assessment form last revised in 2012 and not provide updated forms. This alternative was rejected as PICs who fill out the 2012 version of the forms will not be using an up-to-date assessment tool that helps them measure compliance with the significant changes to the laws and regulations. This could jeopardize the health and welfare of California residents.