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



To: Board Members

Subject: Agenda item VIII. Discussion and Consideration of Recommendations to Delete Previously Approved Regulation Text from Proposed Title 16 CCR sections 1737.7, subdivision (e) related to the use of Respirators and 1737.18 Related to Medical Surveillance

Background

USP Chapter 800 provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients, and the environment. Consistent with action taken by the USP Compounding Expert Committee, USP Chapter 800 shall become compendial on November 1, 2023.

In anticipation of the November 1, 2023, date, the Enforcement and Compounding committee met on several occasions to consider the new and revised USP Chapters and the Board's regulations to determine, in the interest of patient safety, where changes are appropriate. Following the work of the Committee, at its April 19-20, 2023, Board meeting the Board considered and voted to approve the text of proposed regulations, including proposed new Article 4.7, titled Hazardous Drugs. Consistent with the motion, staff was directed to prepare the rulemaking file and initiate the rulemaking process. Further, the Enforcement Committee Chair and Executive Officer were delegated authority to make any nonsubstantive changes or clarifying changes necessary and consistent with the Board's policy.

For Board Consideration

As part of the necessary review prior to initiating the rulemaking process, staff have identified two specific areas of the proposed language related to hazardous compounding that they recommend removing, in part to avoid a potential conflict with CalOSHA requirements. As such changes to the language are substantive and would exceed the authority delegated to the Enforcement Committee chair and Executive Officer, these two specific recommended changes are being brought forward to the Board for consideration and action.

During the meeting, members will have the opportunity to review these two specific (sub)sections to determine if removal of either or both is appropriate before initiating the rule making process . As agendized, discussion is limited to these two very specific issues. Discussion and consideration of the compounding regulations in their entirety will occur

during the formal rulemaking process. Members of the public and interested stakeholders will have an opportunity to provide comments on all proposed language at that time both during the public comment period and subsequent Board Meetings as necessary.

The recommended changes to the language is included as an attachment to this memo and reflected in double strikethrough deletions. Note, however, that if the Board votes to remove any of the language, when the rulemaking is noticed, that language will simply not be included. It will not be shown as struck-through.

Should members agree with the staff recommendation, the following language could be used:

Recommended Motion: Prior to initiation of the formal rulemaking process, update the previously approved regulation text for proposed Article 4.7, section 1737.7 removing subsection (e) related to the use of respirators and removing section 1737.18 related to medical surveillance.

Attachment 1

Recommended deletions to proposed language reflected with ~~double strikethrough~~.

1737.7. Personal Protective Equipment (PPE).

In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.

- (a) Two pairs of gloves that meet the ASTM D-6978 standard shall be worn for handling HD waste, cleaning HD spills, and performing routine cleaning in HD areas.
- (b) The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during HD compounding unless otherwise recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves labeled to meet the ASTM D-6978 standard shall be sterile.
- (c) Outer gloves used for HD compounding shall be changed between each different HD preparation.
- (d) PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.
- ~~(e) An appropriate full facepiece, chemical cartridge type respirator, or powered air-purifying respirator (PAPR) shall be worn when there is a risk of respiratory exposure to HDs, including when:
 - ~~(1) Attending to HD spills larger than what can be contained with a spill kit~~
 - ~~(2) Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEG~~
 - ~~(3) There is a known or suspected airborne exposure to powders or vapors.~~~~

Note: Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

1737.18. Medical Surveillance.

In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. Elements of a medical surveillance program shall be consistent with the entity's Human Resource policies, and employees handling HDs must be aware of the program.

Note: Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.