

Title 16. Board of Pharmacy

Changes made to the current regulation language are shown by strikethrough for deleted language and underline for added language. Additionally, [Brackets] indicates language that is not being amended.

Amend section 1735.2, subdivision (i) in Article 4.5 of Division 17 of Title 16 California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

[.....]

- (i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.
- (1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:
- (A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
 - (B) the chemical stability of any one ingredient in the compounded drug preparation;
 - (C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
 - (D) ~~180 days~~ for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
 - (E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
 - (F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
 - (G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:
 - (i) the nature of the drug and its degradation mechanism,
 - (ii) the dosage form and its components,
 - (iii) the potential for microbial proliferation in the preparation,
 - (iv) the container in which it is packaged,
 - (v) the expected storage conditions, and
 - (vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

- (2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:
 - (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
 - (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
 - (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
 - (D) The beyond use date assigned for sterility in section 1751.8.
- (3) For sterile compounded drug preparations, ~~E~~-extension of a beyond use date is only allowable when supported by the following:
 - (A) Method Suitability Test,
 - (B) Container Closure Integrity Test, and
 - (C) Stability Studies
- (4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.
- (5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

[.....]

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.