State of California
Office of Administrative Law

In re:
Board of Pharmacy

Regulatory Action:

Title 16, California Code of Regulations

Amend section: 1735.2

NOTICE OF APPROVAL OF EMERGENCY REGULATORY ACTION

Government Code Sections 11346.1 and 11349.6

OAL Matter Number: 2018-0907-01

OAL Matter Type: Emergency Readopt (EE)

This action readopts the prior emergency action that established procedures allowing pharmacists to extend the beyond-use date (BUD) for non-sterile compounded drug preparations and clarified BUD procedures for sterile compounded drug preparations. (See OAL file nos. 2017-1211-01E, 2018-0607-01EE.)

OAL approves this emergency regulatory action pursuant to sections 11346.1 and 11349.6 of the Government Code.

This emergency regulatory action is effective on 9/17/2018 and will expire on 12/18/2018. The Certificate of Compliance for this action is due no later than 12/17/2018.

Date: September 17, 2018

Nicole C. Carrillo
Attorney

For: Debra M. Cornez
Director

Original: Virginia Herold, Executive Officer
Copy: Lori Martinez

STATE OF CALIFORNIA–OFFICE OF ADMINISTRATIVE LAW

NOTICE PUBLICATION/REGULATIONS SUBMISSION

EMERGENCY

(See instructions on reverse)

STD. 400 (REV. 01-2013)

For use by Secretary of State only

ENDORSED - FILED
in the office of the Secretary of State
of the State of California
SEP 17 2018
1:54 PM

OAL FILE NUMBERS	NOTICE FILE NUMBER	REGULATORY ACTION NUMBER	EMERGENCY NUMBER
	Z-		2018-0907-01EE

For use by Office of Administrative Law (OAL) only

2018 SEP -7 A 10:07

OFFICE OF ADMINISTRATIVE LAW

NOTICE | REGULATIONS

AGENCY WITH RULEMAKING AUTHORITY
Board of Pharmacy

AGENCY FILE NUMBER (If any)

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE

3. NOTICE TYPE	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
☐ Notice re Proposed Regulatory Action ☐ Other			

OAL USE ONLY	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER	PUBLICATION DATE
	☐ Approved as Submitted ☐ Approved as Modified ☐ Disapproved/ Withdrawn		

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S)
Compounded Drug Preparations

1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
2017-1211-01E, 2018-0607-01EE per agency request NC 9/14/18

2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) **(Including title 26, if toxics related)**

SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)

TITLE(S)
16

ADOPT

AMEND
1735.2

REPEAL

3. TYPE OF FILING

- ☐ Regular Rulemaking (Gov. Code §11346)
- ☐ Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)
- ☐ Emergency (Gov. Code, §11346.1(b))
- ☐ Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.
- ☐ Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)
- ☒ Emergency Readopt (Gov. Code, §11346.1(h))
- ☐ File & Print
- ☐ Other (Specify) _____
- ☐ Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
- ☐ Print Only

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

- ☐ Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))
- ☒ Effective on filing with Secretary of State
- ☐ §100 Changes Without Regulatory Effect
- ☐ Effective other (Specify) _____

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

- ☐ Department of Finance (Form STD. 399) (SAM §6660)
- ☐ Fair Political Practices Commission
- ☐ State Fire Marshal
- ☒ Other (Specify) Dean R. Grafilo, Director, Department of Consumer Affairs E Shutt for N.G.

7. CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional)
Lori Martinez	916-574-7917	916-574-8617	Lori.Martinez@dca.ca.gov

8. **I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.**

SIGNATURE OF AGENCY HEAD OR DESIGNEE

DATE
9/7/2018

TYPED NAME AND TITLE OF SIGNATORY
Virginia Herold, Executive Officer

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

SEP 17 2018

Office of Administrative Law

Title 16. Board of Pharmacy

The use of [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) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) 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, 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.