Comments on Proposed CA Nonsterile Compounding Regulations

Rick Rhoads, Pharm.D.

February 14th, 2023

1735.1. Introduction and Scope-Nonsterile Compounding

In addition to the standards in the USP Chapter 795, the preparation of CNSP shall meet the following requirements of this article.

(a) For the purposes of this article, nonsterile compounding occurs, by or under the supervision of a licensed pharmacist, pursuant to a patient specific prescription.

(b) Repackaging of a conventionally manufactured drug product shall be not considered compounding but must be compliant with USP General Chapter 1178 titled Good Repackaging Practices.

(c) Reconstitution of a conventionally manufactured drug product in accordance with directions that have not been Food and Drug Administration (FDA) approved in accordance with 21 U.S.C.A Section 3S5 is considered compounding and this article applies.

(d) Unless otherwise provided in this article, no CNSP shall be compounded unless the CNSP is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescriber and the CNSP otherwise meets the requirements of section 503A of the Federal Food. Drug and Cosmetic Act (21 U.S.C. section 353a), as applicable.

If the compounded preparation is essentially a copy of a commercial medication, a notation must be made on the prescription that the compound is necessary for the identified patient.

> ***Reason:*** *Unless the prescribed medication is an essential copy, prescribers rarely notate that the compound is necessary for the patient. This is implied by the submission of the prescription. Calling the prescriber for every prescription would significantly delay care.*

In addition to prohibitions and requirements for compounding established in federal law pursuant to 21 U.S.C. section 353a, no CNSP shall be prepared that:

[l} Is essentially a copy of one or more commercially available drug products. unless:

(A) the drug product appears on an ASHP (American Society of Health-System Pharmacists} or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispense, or

(B) the compounding of that CNSP is justified by a specific, documented medical need made known to the pharmacist prior to compounding. A copy of the documentation of the shortage or the specific medical need shall be maintained

in accordance with Business and Profession Code section 4081 for three years from the date of receipt of the documentation.

(2) Is made with any component not suitable for use in a CNSP for the intended patient population.

Reason: *The word "intended" could potentially become problematic for several ingredients used appropriately in nonsterile compounding. Manufacturers of components may not intend for their products to be used specifically in nonsterile compounding, but they still may be appropriate for use in compounding. For example, Cetaphil cream is often used as a topical cream base, but the manufacturer does not intend for it to be used in compounding. This could also apply to components made for pharmaceutical manufacturing, but not compounding. Changing the word from "intended" to "suitable" would clarify this.*

1735.2. Personnel Training and Evaluation

(d) Compounding personnel or personnel with direct oversight over personnel performing compounding. verifying and/or handling a CNSP who fails any aspect of training or demonstrated competency shall not be involved in the compounding process related to the sections failed until after successfully passing reevaluations in the deficient area(s) detailed in the facility's standard operating procedures (SOPs) for nonsterile compounding as described in section 1735.11.

Reason: *If an employee fails a section of training for a new and completely separate competency (eg. they are currently trained on compounding creams and then later begin to learn compounding capsules), they would be barred from compounding creams. I think this could have a negative unintended consequence of pharmacies choosing less stringent training with fewer domains for fear of employees becoming disqualified from doing any compounding at all.*

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1735.7. Master Formulation and Compounding Records

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) A CNSP shall not be compounded until the pharmacy has first prepared a written master formulation record in compliance with Section 7.1 of USP Chapter 795 and identified in that document the following additional elements:

(ll) The referenced source material (e.g., peer reviewed article, published scientific book) used to support the assigned beyond-use date (BUD), if it exists: each source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CNSP is dispensed.

Reason: *Compounders are required to consider stability data for all BUDs assigned and it is appropriate to cite this data to support the BUD. However, some preparations don't have any stability data. If so, a conservative BUD must be assigned within the limits of Table 4 in USP <795>. The current language may be interpreted to mean that compounders must have stability studies for all preparations (instead of just for the preparations with extended BUDs).*

(b) Where a pharmacy does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 795 standards and this section.

(c) A compounding record shall be a single document. The document shall satisfy the compounding record requirements in Section 7.2 of USP Chapter 795. as well as the following:

(1) The date or date and time of preparation, if the BUD is listed in hours. The time of preparation is when compounding the CNSP started, which also determines when the assigned BUD starts if the BUD is listed in hours.

(2) The manufacturer, lot number, and expiration date for each component.

(3) The assigned internal identification number shall be unique for each CNSP.

(4) The total quantity compounded shall include the number of units made and the volume or weight of each unit.

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(5) The identity of each person performing the compounding, have direct oversight of compounding, and pharmacist verifying the final drug preparation.

> ***Reason:*** *This language is helpful to clarify that the date and/or time of compounding refers to when the compounding process started. However, this language may be confused to mean that the BUD must specify a day and time (eg. Discard after 06/15/2023 at 1PM). However, most BUDs are assigned in days only, which would make the time started irrelevant. The time compounded would only be applicable when the BUD is listed in hours.*

(4) The total quantity compounded shall include the number of units made and the volume or weight of each unit, if immediately packaged into the final dispensing container after compounding.

> ***Reason:*** *Anticipatory compounding often includes storing the preparation in a bulk container and later packaging in the final dispensing device when the prescription is received. It is difficult to anticipate the exact quantity of medication that will be prescribed.*