California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING MINUTES

DATE: February 15, 2023

LOCATION: Department of Consumer Affairs
1625 N Market Blvd, 1st Floor Hearing Room
Sacramento, CA 95834

Participation was also through WebEx.

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chair
Jig Patel, Licensee Member, Vice Chair
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member
Ricardo Sanchez, Public Member (remote participation via WebEx)

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Manager Specialist

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Maria Serpa called the meeting to order at 9:02 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency. Dr. Serpa advised the meeting was being conducted with participation through WebEx and being webcast. The meeting moderator provided updated WebEx instructions.

Chairperson Serpa took roll call. Members present included: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comments for

items not on the agenda; however, there were no comments made.

Member Patel arrived at 9:09 a.m.

III. Approval of January 23,2023, Enforcement and Compounding Committee Meeting Minutes

Chairperson Serpa referenced the draft minutes for the January 23, 2023, Enforcement and Compounding Committee Meeting.

Members were provided an opportunity to provide comments on the draft minutes; however, no comments were made.

Motion: Approve the January 23, 2022, Committee Meeting Minutes as presented in the meeting materials

M/S: Oh/Patel

Members of the public were provided with an opportunity to provide public comment; however, no comment was provided in Sacramento or via WebEx.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Sanchez	Not Present
Serpa	Support

IV. Presentation on US Pharmacopeia (USP) General Chapter 795, Pharmaceutical Compounding – Nonsterile Preparations

Chairperson Serpa introduced Supervising Inspector (SI) Peg Panella-Spangler who provided a presentation on US Pharmacopeia (USP) General Chapter 795, Pharmaceutical Compounding – Nonsterile Preparations.

Member Sanchez joined the meeting via WebEx at approximately 9:19 a.m.

SI Panella-Spangler provided a review on USP 795 including the following sections: Introduction and Scope; Personnel Training and Evaluation; Personal Hygiene and Garbing; Building and Facilities; Cleaning and Sanitizing; Equipment, Supplies and Components; Master Formulation and Compounding Records; Release Inspection and Testing; Labeling; Establishing Beyond-Use Dates; Standard Operating Procedures; Quality Assurance and Quality Control; CNSP Packaging and Transporting; and Documentation.

Members were provided the opportunity to comment.

President Oh thanked SI Panella-Spangler for the presentation.

Member Patel inquired if there was a document that highlights changes. Dr. Panella-Spangler indicated there wasn't one but could check. Dr. Serpa commented Member Patel may be interested in a California regulation before and after versus USP.

Members of the public were provided the opportunity to comment. Members of the public at the physical location did not have any comments.

The Committee heard a comment via WebEx about the availability of meeting materials. The commenter was advised the slides, materials and presentation would be available on the Board's website.

The Committee took a break from 10:00 a.m. to 10:10 a.m. Roll call was taken. Members present included Jignesh Patel, Licensee Member; Renee Barker, Licensee Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; and Maria Serpa, Licensee Member. A quorum was established.

V. Discussion, Consideration and Possible Action on Proposed Changes to Regulations Related to Pharmaceutical Compounding of Nonsterile Preparations (Amend Title of Article 4.5 and Repeal Sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, and 1735.8 of Article 4.5, and Adopt New Titles and Sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8, 1735.9, 1735.10, 1735.11, 1735.12, 1735.13, and 1735.14 of Division 17 of Title 16 of the California Code of Regulations)

Chairperson Serpa advised as the Committee continued the work on reviewing the various USP chapters and reviewing current and proposed regulations that may be necessary to implement, clarify, or make more specific requirements related to those respective chapters, it was appropriate that any such regulations mirror the structure of the respective USP chapters. Dr. Serpa noted this meant the numbering format and section title for proposed regulations would mirror the USP chapter. Dr. Serpa advised the goal was to clarify or make more specific the requirements. Dr. Serpa added if no clarification was needed or additional requirements was necessary for public safety, there was no additional language being proposed. Dr. Serpa advised significant parts of existing regulation were proposed to be repealed and replaced with new shorter regulations because the Board was no longer repeating USP language or the new USP chapter now incorporated the higher standards the Board previously required.

Chairperson Serpa reminded all the Board is a consumer protection agency and as development of regulations were considered, it would be through the lens of the Board's consumer protection mandate as the law makes clear whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Serpa noted this was a dynamic process and there would be opportunities to participate throughout the development and rulemaking process.

Chairperson Serpa advised licensees of the Board generally must comply with a myriad of state and federal laws and at times, a licensee may be so focused on a specific section of the law, that they may forget the larger picture and other provisions of law that may be relevant. Dr. Serpa noted this was seen in several areas of pharmacy practice, but it was quite pronounced in compounding.

Chairperson Serpa reminded participants of the excellent overview Counsel Smiley provided during the last meeting covering the requirements for authorized individuals to qualify for some exemptions to federal law under provisions of section 503A. Dr. Serpa added the livestream of the meeting and the slide presentation were available on the Board's website and encouraged those interested in this area to watch the livestream. Dr. Serpa noted it was important to emphasize again:

- The Committee would not be looking to add to regulations requirements already laid out in the USP chapters or federal law. The Committee would be concerned solely with detailing additional California state requirements related to the changes to the USP chapters.
- The discussions would be dealing with the standard for compounding pharmacies and compounding pharmacists operating in compliance with the exemption in Section 503A of the federal Food Drug and Cosmetic Act and not with 503B or outsourcing facilities.

Chairperson Serpa advised Section 503A was quite extensive, but it was appropriate to highlight that one of the specific conditions a licensee must meet to be eligible for the exemptions provided under 503A was that the drug product was compounded in compliance with USP chapters on pharmacy compounding. Dr. Serpa reminded participants it was important that members and stakeholders understand for the discussion. Dr. Serpa advised while the Board has the opportunity and authority to add additional regulations to go beyond USP requirements, it cannot promulgate a lesser standard in its regulation. Dr. Serpa noted this was further emphasized in BPC section 4126.8. Dr. Serpa added based on the written comments received in advance of the meeting, there may be some misunderstanding and thought it was appropriate to do some level setting at the front end of the discussion.

Chairperson Serpa noted the first proposed change was the repeal of current Section 1735 and replacement with the proposed Section 1735 that included definitions beyond those established in the USP Chapter including the Board's definition of "essentially a copy of a commercially available drug product" incorporating a requirement for the deviation to produce a clinically significant difference in the patient. Dr. Serpa highlighted the proposed definition of designated person didn't limit the types of individuals that may serve in such a capacity; however, it did make specific that where clinical judgement was necessary and the designated person was not a pharmacist, the PIC would review the practices that require professional judgement.

Chairperson Serpa highlighted compounding was not defined in this section and was an example where, it was recommended that additional regulation was not necessary, rather, the Board would rely solely on the definitions in federal law and USP. Dr. Serpa reminded participants federal law states that the definition of "compounding does not include mixing, reconstituting, or other such actions that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer's directions consistent with that labeling." Referencing the meeting materials, Dr. Serpa added USP defined nonsterile compounding as combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.

Chairperson Serpa addressed some of the comments received noting appreciation for comments. Dr. Serpa provided the regulation of compounding had changed dramatically over time and there were additional regulations implemented to ensure patient safety. Dr. Serpa advised comments were received late in the day prior to the meeting. Those comments were posted on the website and were in the back of the room at the physical DCA location. Dr. Serpa provided apparent with

both federal requirements as well as changes in several of the USP Chapters, the focus must remain on patient safety.

Chairperson Serpa recalled the Board is a consumer protection agency and its licensees must comply with state and federal law. In preparation for the meeting today, Dr. Serpa reviewed some of the supplemental information and FAQs provided by USP that addressed many of the comments received requesting the Board consider lower the USP requirements. Dr. Serpa specifically noted the issue of adding flavoring to medications where it was clear that the USP expert committee thoroughly considered the issue. Dr. Serpa didn't believe the Board had the authority to carve out an exemption for flavoring agents nor would Dr. Serpa support such an approach. Dr. Serpa recommended commentors provide information to help the Board strike a balance of public safety and with patient access and assurance that the Board does have the authority to consider such changes. Dr. Serpa added during public comment it would be helpful to the Board for stakeholders to highlight such information as opposed to asking the Board to take action that it lacks the authority.

Article 4.5 Nonsterile Compounding ~~in Pharmacies~~

~~1735. Compounding in Licensed Pharmacies~~

~~(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:~~

~~(1) Altering the dosage form or delivery system of a drug~~

~~(2) Altering the strength of a drug~~

~~(3) Combining components or active ingredients~~

~~(4) Preparing a compounded drug preparation from chemicals or bulk drug substances~~

~~(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s), nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.~~

~~(c) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).~~

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

1735. Compounding Definitions.

In addition to the definitions contained in United States Pharmacopeia (USP) General Chapter 795 titled *Pharmaceutical Compounding – Nonsterile Preparations* "USP Chapter 795" for the purposes of this article, the following definitions apply to this article and supplement the definitions provided in USP Chapter 795.

(a) "Approved labeling" means the Food and Drug Administration's (FDA) approved labeling in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations that contains FDA approved information for the diluent, the resultant strength, the container closure system, and storage time.

(b) "Essentially a copy of a commercially available drug product" means all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(c) Designated person(s) means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded nonsterile preparations ("CNSP" for the purposes of this article). Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not the pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as purified water or sterile water for injection.

(d) "Integrity" means retention of strength until the beyond use date provided on the label when the preparation is stored and handled according to the label directions.

(e) "Product" means a commercially or conventionally manufactured product evaluated for safety and efficacy by the FDA in accordance with the Federal Food Drug and Cosmetic Act.

(f) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, or the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 795.

(g) "Repackaging" means the act of removing a product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation, when the act is not done pursuant to a prescription.

(i) "Strength" means amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the proposed language in section 1735 provided was appropriate both legally and for consumer protection. Members were provided the opportunity to comment.

President Oh asked if each section would have definitions. Supervising Inspector Christine Acosta provided each USP Chapter was a standalone Chapter. Dr. Oh recommended this be clarified.

Member Barker inquired about (c) requesting clarification be added in front of "water." Dr. Acosta provided the intent was to leave it broad. Dr. Barker was concerned with someone reading it and thinking tap water could be used.

Members of the public were provided the opportunity to comment.

At the Sacramento location a representative of Flavor Rx and through WebEx a pharmacy owner commented in support of allowing flavoring agents to be added to medicine to help children take liquid medicine without being considered non-sterile compounding. The Flavor Rx representative was not aware of any negative impacts on patients as a result of flavoring being added. The pharmacy owner commented that she would now have to complete the compounding self-assessment now for the flavoring she adds to children's medicine.

Dr. Serpa clarified the Board wasn't proposing that flavoring was not appropriate and was clinically relevant but now falls under the auspices of compounding per USP.

Dr. Acosta recommended adding the word "purified" before water to address Dr. Barker's concern.

Chairperson Serpa referenced Section 1735.1 Introduction and Scope where the current section would be repealed and a new section proposed would be added.

~~**1735.1. Compounding Definitions**~~

~~(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.~~

~~(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).~~

~~(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building exhausting. This external exhaust should be dedicated to one BSC or CACI.~~

d) “Bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

e) “Cleanroom or clean area or buffer area” means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

1) For nonhazardous compounding a positive pressure differential of 0.02-to-0.05-inch water column relative to all adjacent spaces is required.
2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

(f) “Compounding Aseptic Containment Isolator (CACI)” means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building exhaust. This external exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) “Compounding Aseptic Isolator (CAI)” means a form of isolator specifically designed for nonhazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

h) “Controlled cold temperature” means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) “Controlled freezer temperature” means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(j) “Controlled room temperature” means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

m) "Displacement airflow method" means a concept which utilizes a low pressure differential high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

(n) "Dosage unit" means a quantity sufficient for one administration to one patient.

(o) "Equipment" means items that must be calibrated, maintained or periodically certified.

p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

(s) "Integrity" means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.

(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).

(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based

~~media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.~~

~~(v) "Non-sterile-to-sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.~~

~~(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. It does not (x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.~~

~~y) "Potency" means active ingredient strength within +/-10% (or the range specified in USP37NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.~~

~~(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.~~

~~aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.~~

~~ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.~~

~~ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.~~

~~(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.~~

~~(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label,~~

~~and the absence of inactive ingredients other than those listed on the master formula document.~~

~~(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations. include topical, sublingual, rectal or buccal routes of administration.~~

~~(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).~~
~~(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).~~

~~(ag) "Strength" means amount of active ingredient per unit of a compounded drug preparation~~
~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.~~

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 355 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, on the prescription that a compounded preparation is necessary for the identified patient and the CSNP otherwise meets the

requirements of section 503A of the Federal Food, Drug and Cosmetic Act (21 U.S.C. section 353a), as applicable.

(e) Notwithstanding subdivision (e), a limited quantity of CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care for individual patients of the pharmacy based on a documented history of prescriptions for those individual patients.

(f) 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:

(1) 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 intended for use in a CNSP for the intended patient population.

(g) Prior to allowing any CNSP to be compounded, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.

(h) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning safe handling and disposal of the CNSP and related supplies furnished to the patient and/or patient's agent.

(i) CNSPs with human whole blood or human whole blood derivatives shall be prepared in compliance with Health and Safety Code section 1602.5.

(j) CNSPs considered to be hazardous drugs as defined in USP Chapter 800 *titled Hazardous Drugs – Handling in Healthcare Settings* shall be handled in compliance with that Chapter and relevant provisions of Pharmacy Law.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4105, 4126.8 and 4169, 4301, 4306.5 and 4332 of the Business and Profession Code.

Chairperson Serpa was comfortable with the language and appreciated the clarity being provided specifically to the requirements for the repackaging of conventionally manufactured drug products and provisions for reconstitution. Dr. Serpa believed the cross references provided for hazardous compounding to be a helpful reminder. Members were provided the opportunity to comment.

President Oh asked regarding (e) if USP was silent on that section; for clarification on (f)(2); and if new (i) was necessary. Dr. Acosta advised the (e) subdivision was wrong and it would need to be edited. Dr. Acosta provided (f)(2) was for patient populations where a type of CSNP should never be done (e.g., pediatric patient

should never be made a CSNP with tetracycline, etc.). Dr. Acosta noted new subsection (i) was reminding the reader.

Members of the public were provided an opportunity to comment.

A Sutter Health representative in Sacramento commented (b) referenced USP 1178 and if it should reference something that doesn't apply as USP 1178 doesn't apply to pharmacists engaged in dispensing prescription drugs in accordance with state practice of pharmacy. Dr. Serpa advised it was considered in a different way. Dr. Acosta provided it was not relevant to immediate dispensing practice but was related to taking a 1,000-count bottle and making a number of different bottles with different numbers of capsules in it. Dr. Acosta stated it was still relevant because it was not a dispensing feature.

A representative of CSHP commented from WebEx with concern about the prior comment on how this affected the process of packaging unit dose dosage forms where the doses aren't immediately dispenses and inquired if that would be considered compounding.

Chairperson Serpa referenced Section 1735.2 Compounding Limitations and Requirements; Self-Assessment where the current section was being proposed to be amended.

~~**1735.2. Compounding Limitations and Requirements; Self-Assessment**~~

~~(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.~~

~~(b) A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.~~

(c) A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

~~(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and~~

~~(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and~~
(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; ~~and~~
~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and~~
~~(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and~~
~~(6) Does not exceed an amount the pharmacy can reasonably and safely compound.~~

~~(d) No pharmacy or pharmacist shall compound a drug preparation that:~~

~~(1) Is classified by the FDA as demonstrably difficult to compound;~~
~~(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or~~
~~(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.~~

~~(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:~~

~~(1) Active ingredients to be used.~~
~~(2) Equipment to be used.~~
~~(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.~~
~~(4) Inactive ingredients to be used.~~
~~(5) Specific and essential compounding steps used to prepare the drug.~~
~~(6) Quality reviews required at each step in preparation of the drug.~~
~~(7) Post-compounding process or procedures required, if any.~~
~~(8) Instructions for storage and handling of the compounded drug preparation.~~
~~(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.~~

~~(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.~~

~~(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.~~

~~(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.

(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than (1) year after the date of receipt by the pharmacy.

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

1735.2. Personnel Training and Evaluation

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

(a) In addition to USP Chapter 795's requirements, training, evaluation, and requalification procedures for personnel who compound or who have direct oversight of personnel performing compounding, verifying, and/or handling a CNSP shall also address the following topics:
(1) Quality assurance and quality control procedures,
(2) Container closure and equipment selection, and
(3) Component selection and handling.

(b) A pharmacist responsible for, or directly supervising, the compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, strength, quality, and labeled strength of a CNSP as described in the facilities SOPs as referenced in section 1735.11.

(c) A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is sufficient for administration or application to patients solely in the prescriber's office, ~~-~~or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing.

(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 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.

(e) Any person assigned to provide the training specified in this section shall obtain training and demonstrated competency in any subject in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1735.11.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301, 4306.5 and 4332 of the Business and Profession Code.

Dr. Serpa believed language was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa added sharing appropriate training was vital to patient safety and the cross reference to the facility's SOPs assures that the issue was fully considered in the compounding operations. Dr. Serpa noted

provisions specific to compounding for veterinary office use were not being proposed to change. Dr. Serpa ensured all members received public comment on the issue and noted there were no suggested changes to current language. Dr. Serpa advised the comment received was specifically related to the provisions of anticipatory compounding for veterinary office dispensing. Dr. Serpa believed the current language was appropriate and was not in favor of changing it. Dr. Serpa appreciated the comments and stated as a pet owner who has needed compounding veterinary medications did not believe changes were necessary. Dr. Serpa noted pharmacy compounding was generally intended for patient specific use and not volume compounding; however, the Board recognized the need to start treatment in a timely fashion and currently allows for limited office supply to strike a balance to allow a patient to receive sufficient medications to start treatment while the patient specific medication was being compounded. Dr. Serpa noted should the veterinary practice choose to do so, they can purchase sufficient supplies from an outsourcing facility or for non-patient specific use if the practice wishes to dispense the full treatment regimen beyond the five days that was allowed. Dr. Serpa reminded outsourcing facilities have extensive FDA requirements and regulations as a 503B facility and were regulated under the requirements by both the Board and the FDA. Dr. Serpa continued the patient specific was typically done by a 503A facility.

Members were provided the opportunity to comment.

President Oh inquired if the remaining section was being left where it was. Ms. Sodergren advised the language was being left where it currently resided. Ms. Sodergren noted it was not contemplated in USP and the current structure was retained for the provision in the existing law.

Members of the public were provided the opportunity to comment.

A veterinarian representative from the California Veterinary Medical Association commented in Sacramento regarding submitted comments and respectfully disagreed with Dr. Serpa. The representative added a list of drugs were provided that they are not able to get because of excessive compounding regulations. The representative said four days was not enough time to obtain patient specific prescriptions as most pharmacies are located in the east coast and were asking to extend for a seven-day period. The representative added there were only two 503B facilities in California that provide any kind of appreciative product for animals and then have to rely on 503A facilities. The representative pointed out 120-hour average wasn't telling him what he could or couldn't do with his patients and was within his ability to provide more medication to a patient. He noted this was what a pharmacist could do in anticipation of his needs. The representative didn't want to see pharmacists controlling veterinarians.

A pharmacist representative of CPhA commented in Sacramento regarding (d) re-emphasizing the potential concern regarding the interpretation and opportunity for clarification noting USP states there must be immediate corrective action in the deficient area and not all of the compounding.

A pharmacist representative of Sutter Health commented on (a) regarding the additional competency requirements in addition to USP 795 identifies additional individuals who will be required to have compounding training with only these additional components. The representative noted it was unclear who the personnel was and frequency wasn't included. The representative requested if the intent was those would be annual competencies that should be related.

The Moderator read a comment left through WebEx, "Following up on the question being discussed what the policy for compounding the office supply where we do not have patient specific data (e.g., veterinary, etc.) also what about non-veterinary offices (e.g., topical compounds, etc.) for during and post laser treatments."

Members were provided an opportunity to comment.

President Oh asked regarding training confirming it was every 12 months. Dr. Serpa provided it was referenced in another section.

Chairperson Serpa referenced Section 1735.3 Personnel Hygiene and Garbing where proposed the current section would be repealed and a new section added.

~~**1735.3. Recordkeeping of Compounded Drug Preparations**~~
~~(a) For each compounded drug preparation, pharmacy records shall include:~~

~~(1) The master formula document.~~
~~(2) A compounding log consisting of a single document containing all of the following:~~
~~(A) Name and Strength of the compounded drug preparation.~~
~~(B) The date the drug preparation was compounded.~~
~~(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.~~
~~(D) The identity of the pharmacist reviewing the final drug preparation.~~
~~(E) The quantity of each ingredient used in compounding the drug preparation.~~
~~F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.~~
~~(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile in a single lot for administration within seventy-two (72) hours to~~

~~a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.~~

~~(G) A pharmacy-assigned unique reference or lot number for the compounded drug product preparation.~~

~~H) The beyond-use date or beyond-use date and time of the final compounded drug, expressed in the compounding document in a standard date and time format.~~

~~I) The final quantity or amount of drug preparation compounded for dispensing.~~

~~(J) Documentation of quality reviews and required post-compounding process and procedures.~~

~~(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.~~

~~(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.~~

~~(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).~~

~~Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.~~

1735.3. Personnel Hygiene and Garbing

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

(a) Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other medical conditions to determine if such condition could contaminate a CNSP or the environment ("contaminating

conditions"). After such evaluation and determination the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.

(b) A gown and face mask shall be used whenever a closed system processing device is required.

(c) Disposable garb shall not be shared by staff and shall be discarded after each shift and when soiled. Garb removed during a shift must be maintained in the compounding area.

(d) Gloves shall be wiped or replaced before beginning a CNSP that has different components.

(e) Non-disposable garb shall be cleaned with a germicidal detergent and sanitized with 70% isopropyl alcohol before re-use.

(f) Any garbing accommodations provided by the designated person shall be documented and the record shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation. The record shall be retained in accordance with Business and Professions Code section 4081.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted personnel hygiene and garbing were core components to avoid contamination of a compounded preparation. Dr. Serpa believed the flexibilities provided in the language struck a balance and were appropriate for nonsterile preparations where the risk to patients was not as great.

Members were provided the opportunity to comment.

Member Barker inquired about (d) if the Board needed to clarify "wiped" in the verbiage. Dr. Acosta provided the only change was "should" to "shall" and any change would be outside what the Chapter provided. Dr. Serpa clarified it was current USP language and the Board changed it to make it a requirement. Dr. Acosta referenced USP FAQ 23 that might help to clarify.

Member Barker commented on (e) on the term germicidal detergent where most products say cleaner and detergent is a component of a cleaner. Dr. Acosta added the verbiage was from current law. The proposed subsection (e) was updated to read: (e) Non-disposable garb shall be cleaned with a germicidal detergent cleaner and sanitized with 70% isopropyl alcohol before re-use.

Members of the public were provided an opportunity to comment.

A representative from Sutter Health commented in Sacramento regarding (b) referencing a closed system processing device seemed to intersect with USP 800 and was curious if that could be interpreted not specific to hazardous drugs. The representative inquired of a requirement being added specifically around closed system processing device noting there was no definition in the current regulations

regarding closed system processing device and could be added. Dr. Acosta provided closed system processing devise was provided in USP. Dr. Serpa added while the Board was attempting to not have duplication, there were examples where it has repeated to ensure clarity.

There were no commenters via WebEx.

Members were provided the opportunity to comment.

President Oh agreed with Member Barker that clarification would be helpful and it was noted.

Chairperson Serpa referenced Section 1735.4 Building and Facilities where proposed the current section would be repealed and a new section added.

~~**1735.4. Labeling of Compounded Drug Preparations**~~
~~(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:~~

~~(1) Name of the compounding pharmacy and dispensing pharmacy (if different);~~
~~2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;~~
~~(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;~~
~~(4) The beyond use date for the drug preparation;~~
~~(5) The date compounded; and~~
~~6) The lot number or pharmacy reference number.~~

~~(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.~~

~~(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.~~

~~(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).~~

~~(e) All hazardous agents shall bear a special label which states "Chemotherapy -Dispose of Properly" or "Hazardous – Dispose of Properly."~~

~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.~~

1735.4. Building and Facilities

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

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.
(b) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.
(c) No CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in USP Chapter 795 or the pharmacy's written SOPs referenced in section 1735.11.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301, 4306.5 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate.

Members were provided the opportunity to comment.

President Oh inquired about (b) being a huge undertaking for facilities. Dr. Acosta provided some facilities use this water already and noted large amount of contaminates in tap water.

Members of the public were provided an opportunity for comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa referenced Section 1735.5 Cleaning and Sanitizing where proposed the current section would be repealed and a new section added.

~~**1735.5. Compounding Policies and Procedures**~~
~~(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.~~

~~(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.~~

~~(c) The policies and procedures shall include at least the following:~~
~~1) Procedures for notifying staff assigned to compounding duties of any changes in policies .~~
~~2) A written plan for recall of a dispensed compounded drug preparation where subsequent demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).~~
~~3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in , and for training on these procedures as part of the staff training and competency evaluation process.~~
~~(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.~~
~~(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.~~
~~(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.~~
~~(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.~~
~~8) Dates and signatures accompanying any revisions to the policies and procedures approved by pharmacist-in-charge.~~
~~9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.~~
~~10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.~~
~~(11) Policies and procedures for proper garbing when compounding with hazardous products. shall include when to utilize double shoe covers.~~
~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127, and 4301, Business and Professions Code~~

1735.5. Cleaning And Sanitizing

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

(a) In addition to the documentation requirements in USP Chapter 795, the facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include a record of the identity of the person completing the cleaning and sanitizing as well as the product name of the cleaning and sanitizing agents used.

(b) Any cleaning or sanitizing agents used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa agreed with the documentation requirements.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa referenced Section 1735.6 Equipment and Components where proposed the current section would be repealed and a new section added.

~~**1735.6. Compounding Facilities and Equipment**~~

~~(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.~~

~~(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.~~

~~c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.~~

~~(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.~~

~~(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:~~

~~(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and~~
~~2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and~~
~~(3) A) For sterile compounding, each BSC or CACI shall also be externally exhausted. y~~
~~(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant HEPA filter in series or be externally exhausted.; For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.~~

~~Each PEC in the room shall also be externally vented; and~~

~~4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.~~
~~(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.~~

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

1735.6. Equipment And Components

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

(a) Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specifications.

(b) Any component used to compound a CNSP shall be used and stored in accordance with all federal laws and regulations and industry standards including the manufacturers' specifications and requirements.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa believed that

such requirements would go without saying but regrettably have been advised by staff, that this was not always the case.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa referenced Section 1735.7 Master Formulation and Compounding Records where proposed the current section would be repealed and a new section added.

~~**1735.7. Training of Compounding Staff**~~

~~(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.~~

~~(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.~~

~~(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.~~

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

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:

(1) The referenced source material (e.g., peer reviewed article, published scientific book) used to support the assigned beyond-use date (BUD); 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.

(2) Instructions for storage and handling of the CNSP.

(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 and time of preparation. The time of preparation is the time when compounding the CNSP started, which also determines when the assigned BUD starts.

(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.

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

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted there was a change in terms from the prior version of USP from master formula to master formulation. Dr. Serpa agreed that documentation on the referenced sourced material must be maintained and appreciated the flexibility to allow the prescription document to serve as the master formulation record. Dr. Serpa recalled seeing several enforcement-related matters that involved violations with compounding records. Dr. Serpa appreciated the specificity in the draft language and believed it provided clarity to the regulated public.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment.

A representative of Sutter Health commented in Sacramento regarding (c) (4) agreeing with the statement noting the number in USP mentions "if other than one or default to one" and recommended adding as Sutter Health's records default to one. The representative commented about the statement "that every single volume would require its own unique master formulation" versus being referenced within the master formulation for different amounts and appreciated clarification. SI Panella-Spangler advised it was addressed in USP FAQ #44.

A commenter from WebEx appreciated working with the Board and staff on new regulations noting a step forward to harmonize with USP. The commenter made the following comments: (a)(2) noting it was important to include that but there were times where there was no stability data adding it could be interpreted to mean that stability data is required even if assigning a BUD within the limits in Table 4 of USP 795 and recommended saying "if it exists"; (c)(1) clarifying the date and time of the preparation adding if BUD was listed in hours, the date and time of preparation was needed because most of the time the BUD was listed in days; and (c)(4) including the number of units made and the volume or weight of each unit and recommended "if immediately packaged into final dispensing containers after compounding."

Dr. Acosta expressed concern about "if it exists" for (a)(1) and could work on the verbiage. Dr. Acosta advised date and time of preparation was to harmonize with USP 797 but doesn't normally get down to the hours on non-sterile preparation so verbiage could be developed there. Dr. Acosta noted (c)(4) was more of a dispensing feature.

Chairperson Serpa recommended discussing changes to (a)(1) and (c)(1) but agreed (c)(4) was dispensing or possibly repackaging. Members were provided the opportunity to comment. Board staff would work offline to address verbiage for (a)(1) and (c)(1).

Chairperson Serpa referenced Section 1735.8 Release Inspections and Testing where proposed the current section would be repealed and a new section added.

~~**1735.8. Compounding Quality Assurance**~~

~~(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.~~

~~(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.~~

~~(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.~~

~~(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.~~

~~(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.~~

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

1735.8. Release Inspections and Testing

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.
A pharmacist performing or supervising the nonsterile compounding by other authorized personnel is responsible for the integrity, quality, and labeled strength of a CNSP until the beyond-use date indicated on the label provided the patient or the patient's agent follows the label instructions provided on the CNSP for storage and handling after receiving the CNSP.
Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4036.5, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted it should be well understood that a pharmacist was responsible and appreciated clearly stating as such.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa referenced Section 1735.9 Labeling which was a proposed new section.

1735.9. Labeling

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

(a) A CNSPs label shall also include the following:
(1) Route of intended administration, and

(2) Name of compounding facility and dispensing facility (if different).

(b) A CNSPs Labeling shall also include:

(1) Any special handling instructions,

(2) Any applicable warning statements, and

(3) Name, address, and phone number of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded.

(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa highlighted there was a difference between a label and labeling.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa referenced Section 1735.10 Establishing Beyond-Use Dates which was a proposed new section.

1735.10. Establishing Beyond-Use Dates

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

(a) Beyond-use dates (BUDs) assigned with only a date shall expire at 11:59 p.m. on that date.

(b) A CNSP's BUDs shall not exceed:

(1) The chemical and physical stability data of the active pharmaceutical ingredient (API) and any added component in the preparation,

(2) The compatibility and degradation of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),

(3) The shortest remaining expiration date or BUD of any of the starting components, or,

(4) The potential for microbial proliferation in the CNSP.

(c) If a licensee chooses to use antimicrobial effectiveness testing results provided by an current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources, the reference (including the raw data and testing method suitability), shall be readily retrievable in accordance with Business and Professions Code section 4081 in its entirety for three years from the last date the CNSP was dispensed.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa appreciated the very clear language in section (a) and noted regrettably, there had been many enforcement-related matters that include violations where the BUD of the preparation exceeds the expiration date of one of the ingredients used.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa referenced Section 1735.11 Standard Operating Procedures (SOPs) which was a proposed new section.

1735.11. Standard Operating Procedures (SOPs)

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

(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall:

(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

(2) In addition to the SOPs required in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, SOPs must also be developed to describe the following:

(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) Procedures for handling, compounding, and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdictional standards.

(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.

(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPS as described in this article.

(b) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the facility's SOPs. The SOPs shall be updated any time changes are made to compounding processes, facility changes or other changes occur that impact the CNSP. Such SOP changes shall be disseminated to the affected staff prior to implementation.

(c) Failure to follow written SOPs shall constitute a basis for enforcement action.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa appreciated the cross-reference to USP Chapter 1163 providing clarity to the licensees about the requirement and believed the specified elements as well as frequency of review were appropriate for SOPs. Dr. Serpa noted failure to follow SOPs was a basis for enforcement action, which Dr. Serpa believed should go without saying; however, to ensure everyone has a clear understanding, Dr. Serpa was agreeable to explicitly stating it in the proposed language.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa referenced Section 1735.12 Quality Assurance and Quality Control which was a proposed new section.

1735.12. Quality Assurance And Quality Control

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

(a) The quality assurance program shall also comply with section 1711 and the standards contained in USP Chapter 1163, entitled *Quality Assurance in Pharmaceutical Compounding*. In addition to compliance with those standards, the program shall include in its SOPs the following:
  (1) A written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.
  (2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(b) The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint or the occurrence of an adverse drug event involving a CNSP.

(c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa appreciated the cross references to other sections again providing more clarity to licensees. Dr. Serpa noted many of the requirements included in this section go the Board's core consumer protection function including mandating review of adverse events.

Members were provided the opportunity to comment.

President Oh inquired about (a)(2) and requested the intent to be explained. Dr. Acosta advised current law related to mostly to acute care so when something patient-specific was dispensed and it would go to a nursing unit to be held to the actual administration time, the refrigerators in the nursing units or medication rooms would need to have the temperatures within range so it was stored appropriately. Dr. Serpa added it also includes the pharmacy itself (e.g., when it is 110 degrees in California).

Members of the public were provided the opportunity to comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa referenced Section 1735.13 Package and Transport which was a proposed new section.

1735.13. Packaging and Transporting

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

There shall be written procedures recorded in the facility's SOPs (as described in Section 1735.11) describing validated processes for storage, shipping containers and transportation of temperature sensitive CNPSs to preserve quality standards for integrity, quality and labeled strength.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa believed the incorporation of procedures for storage, shipping containers, and transportation of temperature sensitive preparations was essential especially where medications were mailed or delivered.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa referenced Section 1735.14 Documentation which was a proposed new section.

1735.14. Documentation

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

(a) Facilities shall maintain each record required by USP Chapter 795 or this article, in a readily retrievable form, for at least three years from the date the record was created or relied upon to meet the requirements of this article.
(b) Records created shall be created and maintained in a manner to provide an "audit trail" to the Board that includes a detailed, chronological record of all revisions and updates made by the facility's personnel of each record document in accordance with this section. To meet the "audit trail" requirement of this section, each record must include the original document created, each subsequent version of that document showing change to the original document, an identification of individual who made the change, and the date of each change.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4105, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

Chairperson Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa added this section emphasized that documentation required must be maintained in a readily retrievable form for three years, similar to other pharmacy records, and established audit trail provisions necessary to understand document history.

Members were provided the opportunity to comment.

President Oh expressed concern about a pharmacy open for 10 years may have a large and hard to maintain audit trail. Dr. Acosta advised the law requires three years. Ms. Sodergren provided this might be an area where the FAQ may be helpful.

Members of the public were provided the opportunity to comment; however, there were no comments in Sacramento or via WebEx.

Chairperson Serpa thanked all for participation in the meeting and provided an overview of the summary of the identified changes:

- 1735 (d) – diluent
- 1735.1 (e) – subdivision needed a correction
- 1735.3 (e) – germicidal detergent
- 1735.7 (a)(1) – regarding reference source materials
- 1735.7 (c)(1) – date and time of preparation
- 1735.10 (a) – BUD dates
- 1735.14 – FAQ record requirement be explained

Chairperson Serpa advised the agenda item for Enforcement Statistics was added in error and would not be discussed.

VII. Future Committee Meeting Dates

Chairperson Serpa reminded the next meeting was scheduled for March 23, 2023, noting the meeting would also be conducted in person, in Sacramento and members of the public were welcome to attend either in person or via WebEx. Dr. Serpa advised the Board respectfully requested that individuals attending in person follow COVID protocols.

VIII. Adjournment

The meeting adjourned at 11:39 a.m.