Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way, 2nd Floor
PO Box 8366
Madison WI 53708-8366

Phone: 608-266-2112
Web: http://dsps.wi.gov
Email: dsps@wisconsin.gov

Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
August 31, 2023

Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. ***A quorum of the Board may be present during any committee meetings.***

AGENDA

9:00 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1)

B. Approval of Minutes of June 15, 2023 (2)

C. Administrative Rule Matters – Discussion and Consideration (3-78)
1) Phar 15, Relating to Compounding Pharmaceuticals (4-62)
2) Phar 1, 5, 7, 10 and, 19, Relating to Registration of Pharmacy Technicians (63-78)
3) Pending or Possible Rulemaking Projects

D. Public Comments

ADJOURNMENT

NEXT MEETING: OCTOBER 26, 2023

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
MEETING MINUTES
JUNE 15, 2023

PRESENT: Susan Kleppin, Tiffany O'Hagan, John Weitekamp

EXCUSED: Anthony Peterangelo

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 9:02 a.m. A quorum was confirmed with three (3) members present.

ADOPTION OF AGENDA

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to adopt the Agenda as published. Motion carried unanimously.

ADJOURNMENT

MOTION: Tiffany O'Hagan moved, seconded by John Weitekamp, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 9:45 a.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**08/18/23** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board Rules Committee

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
08/31/23	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Phar 15, Relating to Compounding Pharmaceuticals** 2. **Phar 1, 5, 7, 10 and, 19, Relating to Registration of Pharmacy Technicians** 3. **Pending or Possible Rulemaking Projects**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

10) Describe the issue and action that should be addressed:

Attachments:

1. Phar 15 Preliminary Rule Draft
2. Wisc. Admin Code Chapter Phar 15
3. May NABP Presentation Slides
4. Language from Other States on Flavoring
5. Phar 1, 5, 7, 10 , 19 Preliminary Rule Draft with EmR Public Hearing Comments

Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

11) Authorization

Nilajah D. Hardin — 08/18/23

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — **Date**

Directions for including supporting documents:

1. **This form should be attached to any documents submitted to the agenda.**
2. **Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.**
3. **If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate chapter Phar 15, relating to Compounding Pharmaceuticals.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.01 (16), Stats.

Statutory authority: ss. 15.08 (5) (b), and 450.02 (3) (d) and (e), Stats.

Explanation of agency authority:
Section 15.08 (5) (b), Stats. states that "The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.02 (3) (d), Stats. says that the board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

Section 450.02 (3) (e), Stats. provides that the board "may promulgate rules establishing minimum standards for the practice of pharmacy."

Related statute or rule: N/A

Plain language analysis:
The Pharmacy Examining Board recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate by reference United States Pharmaceopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020.

Summary of, and comparison with, existing or proposed federal regulation:
The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compounded drugs in response to an order that is not patient specific. The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: For patient-specific prescriptions, sterile and unsterile pharmaceutical compounding is governed by the USP 42-NF 37 from the 2019 USP Compounding Compendium, except for USP Chapter 800. Additionally, all pharmacies that compound drugs must maintain a set of minimum standards and equipment. These requirements include a specific area for compounding materials, accurate scales or measuring equipment, a separate area for compounding, a record keeping system for tracking compounded drugs, drug distribution procedures, and labelling. Additional requirements for sterile compounding include current reference materials, pharmacist availability at all times to answer patient and health care professional questions, and emergency medications for adverse drug reactions to compounded sterile drugs. [Illinois Administrative Code s. 1330.640]. In Illinois, the definition of "compounding" excludes flavorings [225 Illinois Compiled Statutes 85 s. 3 (o)].

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. Additionally, Iowa includes requirements for the use of flavoring agents. These requirements include that pharmacist may add flavoring in the amount of not more than percent of the total volume of the drug. The beyond-use date of the flavored drug must be no greater than 14 days and the pharmacist must document that a flavoring agent was added ot a drug. Compliance with USP Chapter 825 is not required, however Iowa does have its own rules for radiopharmaceuticals and nuclear pharmacy [Iowa Administrative Code ss.657.16 and 657.20].

Michigan: Michigan requires a pharmacy that provides compounding services to be licensed as a pharmacy and authorized to provide compounding services. The pharmacy must be accredited through a national accrediting organization and be in compliance with USP standards [Michigan Compiled Laws s. 333.17748]. In Michigan, the definition of "compounding" does not include flavoring agents that are nonallergenic, inert, and not more than 5% of the drug's total volume [Michigan Administrative Rules R 338.501 (1) (e)].

Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow USP chapter 795 standards. Pharmacies compounding sterile drug preparations are required to follow USP chapter 797 standards. [Minnesota Administrative Rules s.6800.3300]

Summary of factual data and analytical methodologies: In addition to the four adjacent states listed above, the Pharmacy Examining Board also reviewed statutes and regulations regarding compounding pharmaceuticals from other states including Arizona, California, Colorado, Connecticut, Idaho, Kentucky, Lousiana, Massachusetts, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule will be posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

Effect on small business:
These rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public

hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

Section 1. Chapter Phar 15 is repealed and recreated to read:

Chapter Phar 15
PHARMACEUTICAL COMPOUNDING, SAFE HANDLING OF HAZARDOUS DRUGS, AND RADIOPHARMACEUTICALS

Phar 15.01 Definitions. In this chapter:
(1) "USP-NF" means the United States Pharmacopeia-National Formulary published by the United States Pharmacopeial Convention.

Phar 15.02 Incorporation of Standards. (1) PHARMACEUTICAL COMPOUNDING - NONSTERILE PREPARATIONS. USP-NF general chapter 795, published on November 1, 2022, is incorporated by reference into this chapter, subject to the following exceptions:
(a) Nonsterile compounding does not include the addition of nonallergenic, therapeutically inert flavoring agents to a conventionally manufactured drug product that are not more than 5% of the product's total volume.
(b)
(2) PHARMACEUTICAL COMPOUNDING - STERILE PREPARATIONS. USP-NF general chapter 797, published on November 1, 2022, is incorporated by reference into this chapter.
(3) SAFE HANDLING OF HAZARDOUS DRUGS. USP-NF general chapter 800, published on December 1, 2019, is incorporated by reference into this chapter.
(4) RADIOPHARMACEUTICALS. USP-NF general chapter 825, published on December 1, 2020, is incorporated by reference into this chapter.

Note: Copies of the above standards are on file in the offices of the legislative reference bureau. A copy of the USP-NF can be purchased from the United States Pharmacopeial Convention at https://usp.org.

Phar 15.03 Compliance. Noncompliance with ch. Phar 15 may be considered a violation of s. Phar 10.03 and may result in disciplinary action by the Board against a licensee.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Commented [NH1]: Any other exceptions?

Commented [NH2]: Unprofessional Conduct Violations https://docs.legis.wisconsin.gov/code/admin_code/phar/10.pdf

Chapter Phar 15

COMPOUNDING PHARMACEUTICALS

Note: Chapter Phar 15 is shown as repealed and recreated by CR 16–085, effective November 1, 2018, Register April 2018 No. 748.

Phar 15.01 Intent. The intent of this chapter is to create a state regulatory standard that aligns with compounding standards found in the United States Pharmaceopeia (USP) general chapters lower than the number 1000.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11−1−18.

Phar 15.015 Definitions. In this chapter:

(1) "Active pharmaceutical ingredient" or "API" means any substance or mixture of substances intended to be used in the compounding of a drug preparation and that, when used in the compounding of a drug preparation, becomes an active ingredient in the preparation intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

(2) "Added substances" means ingredients that are necessary to compound a drug preparation that are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation.

(3) "Adverse drug event" means an injury resulting from the use of a drug.

(4) "Beyond use date" or "BUD" means one of the following:

(a) The date after which a non−sterile compounded preparation shall not be used.

(b) The date and time after which a sterile compounded preparation shall not be used.

(5) "Certificate of analysis" means a report from the supplier of a component, container, or closure that accompanies the component, container, or closure and contains the specifications and results of all analyses and a description.

(6) "Chemical stability" means each active pharmaceutical ingredient retains its chemical integrity and labeled potency, within specified limits.

(7) "Classified area" means a space that maintains an air cleanliness classification based on the International Organization for Standardization (ISO).

(8) "Component" means any active pharmaceutical ingredient, or added substances used in the compounding of a drug preparation.

(9) "Compounding" means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug delivery device, or a device in accordance with a prescription, or medication order. Compounding does not include repackaging. Compounding includes any of the following:

(a) Preparation of drug dosage forms for both human and animal patients.

(b) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(c) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients. Notwithstanding this paragraph, the reconstituting, mixing, or storage and beyond use dating that is performed for non−sterile preparations in accordance with the directions contained in approved labeling provided by the manufacturer is not compounding.

(d) Preparation of drugs or devices for the purposes of, or as an incident to, research, teaching, or chemical analysis.

(10) "Container−closure system" means the sum of packaging components that together contain and protect a dosage form, including primary packaging components and secondary packaging components.

(11) "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 68 degrees to 77 degrees Fahrenheit or 20 degrees to 25 degrees Celsius.

(12) "FDA" means the United States food and drug administration.

(13) "Freezer" means a place in which the temperature is maintained between −13 degrees and 14 degrees Fahrenheit or −25 degrees and −10 degrees Celsius.

(14) "Microbiological stability" means sterility or resistance to microbial growth is retained according to specified requirements and antimicrobial agents that are present retain effectiveness within specified limits.

(15) "NF" means the National Formulary.

(16) "Physical stability" means the original physical properties, including appearance, palatability, uniformity, dissolution, and suspendability, are retained.

(17) "Refrigerator" means a cold place in which the temperature is maintained between 36 degrees and 46 degrees Fahrenheit or 2 degrees and 8 degrees Celsius.

(18) "Stability" means the extent to which a compounded preparation retains, within specified limits and through its beyond use date, the same properties and characteristics that it possessed at the time of compounding.

(19) "Therapeutic stability" means the therapeutic effect remains unchanged.

(20) "Toxicological stability" means no significant increase in toxicity occurs.

(21) "USP" means the United States Pharmacopeia.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18; **CR 22–007: am. (11), (13), (17) Register July 2022 No. 799, eff. 8–1–22.**

Subchapter I — General

Phar 15.10 Facilities. A pharmacist engaged in compounding shall ensure all of the following:

(1) An area designated for compounding.

(2) Orderly placement of compounding equipment, materials, and components in order to minimize the potential for compounding errors.

(3) The compounding area is maintained in a clean and sanitary condition.

(4) The compounding area is easily accessible to all of the following:

(a) Hot and cold running water, exclusive of the bathroom sink.

(b) Soap or detergent.

(c) Single–use towels.

(5) All compounding equipment, materials, and components shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage areas.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.11 Equipment and Drug Preparation Containers. (1) A pharmacy shall possess equipment and drug preparation containers or packaging appropriate to the type of compounding performed at the pharmacy.

(2) Equipment and drug preparation containers or packaging used in compounding shall be of appropriate design and capacity, and shall be suitably stored in a manner to facilitate use, cleaning, maintenance, and protect it from contamination.

(3) Equipment and drug preparation containers or packaging used in compounding drug products shall be of suitable composition and may not be reactive, additive, adsorptive, or absorptive so as to alter the stability of the compounded preparation.

(4) Equipment used in compounding shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, according to written policies and procedures, in order to reduce bioburden and reduce the opportunity for cross–contamination.

(5) All equipment utilized in compounding preparations shall be inspected, maintained, calibrated, and validated at appropriate intervals, consistent with manufacturer's recommendations, to ensure the accuracy and reliability of equipment performance. Records shall be kept indicating the equipment was inspected, maintained, calibrated, and validated.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.12 Records of compounding. The managing pharmacist shall ensure written or electronic compounding documentation to systematically trace, evaluate, and replicate the compounding steps throughout the process of a preparation. The compounding documentation shall be maintained for a period of 5 years after the date of the last refill. The compounding documentation shall include all of the following:

(1) Official or assigned name, strength, and dosage form of the preparation.

(2) List of all APIs and added substances and their quantities.

(3) Vendor or manufacturer, lot number and expiration date of each APIs and added substances.

(4) Equipment and supplies needed to prepare the preparation.

(5) Mixing instructions pertinent to the replication of the preparation as compounded.

(6) Compatibility and stability information, including references or laboratory testing.

(7) Container or container–closure system used in dispensing.

(8) Packaging and storage requirements.

(9) Quality control procedures.

(10) Sterilization method when using non–sterile ingredients to make a sterile preparation.

(11) Total quantity compounded.

(12) Name of the person who prepared the preparation.

(13) Name of the person who performed the quality control procedures.

(14) Name of the person who approved the preparation.

(15) Date of preparation.

(16) Assigned control or prescription number.

(17) Assigned BUD.

(18) Copy of the label to dispense final product.

(19) Documentation of any adverse reactions or preparation problems reported by the patient or caregiver.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.13 Quality control. (1) One or more pharmacists shall complete a verification of all the following before dispensing:

(a) Written procedures were followed in the compounding process.

(b) Preparation instructions were followed.

(c) Finished preparation appears as expected.

(d) Label includes all required elements.

(e) Quality control procedures were completed.

(f) Compounding records are complete.

(2) A pharmacist shall investigate any discrepancies found during any of verifications and take appropriate corrective action before dispensing.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.14 Training, Policies, and Procedures. (1) TRAINING. All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained and competency is assessed for the type of compounding conducted. It is the responsibility of the managing pharmacist to ensure personnel training and competency assessments are completed and documented.

(2) POLICIES AND PROCEDURES. The pharmacy and managing pharmacist shall establish written policies and procedures governing all of the following:

(a) Personnel qualifications and training, responsibilities, and competencies.

(b) Personal hygiene, garb, garbing, and personal protective gear.

(c) Use and maintenance of compounding facilities and equipment, including applicable certifications.

(d) Environmental monitoring.

(e) Cleaning and disinfection of compounding area.

(f) Component selection.

(g) Sterilization and depyrogenation, if pharmacy does sterilization and depyrogenation.

(h) Documentation requirements.

(i) Establishing BUD.

(j) Reporting of adverse drug events.

(k) A risk management program, including documentation of incidents, adverse drug reactions and product contamination.

(L) A quality assurance program.

(m) Maintaining the integrity of any classified work areas.

(n) Handling small and large spills of antineoplastic agents and other hazardous substances.

(o) Notification to patients or practitioners of a preparation which is recalled when there is potential for patient harm.

(3) REVIEW OF POLICIES AND PROCEDURES. The policy and procedures shall be reviewed at least once every 36 months and shall be updated, on a continuous basis, to reflect current practice. Documentation of the review shall be made available to the board upon request.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18; correction in (2) (o) made under s. 35.17, Stats., Register April 2018 No. 748.

Phar 15.15 Labeling. The label of a compounded preparation shall include all of the following:

(1) Labeling requirements in s. Phar 7.02 and 8.08.

(2) Storage conditions if other than controlled room temperature.

(3) BUD.

(4) Special handling instructions, when applicable.

(5) Indication that the preparation is compounded unless administered by health care personnel.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.16 Component Selection. (1) Active pharmaceutical ingredients or added substances used in compounding shall be manufactured by an FDA registered facility or accompanied by a certificate of analysis.

(2) APIs and added substances shall meet USP or NF monograph specifications when monographs are available. A pharmacist shall use professional judgement in selection of APIs if USP or NF grade is not available.

(3) All components shall be stored and handled consistent with the manufacturer's labeling or USP or NF monographs and in a manner that prevents contamination and deterioration.

(4) A pharmacist compounding for human use may not use components that have been withdrawn or removed from the market for safety or efficacy reasons by the FDA. A pharmacist compounding for food producing animal use may not use components prohibited for use in food producing animals.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.17 Non–patient specific compounding. Compounded preparations dispensed or distributed to a practitioner pursuant to a non–patient specific order to be administered by a practitioner or practitioner's agent shall meet all of the following:

(1) The order shall include the name and address of the practitioner, drug, strength, quantity, and the purpose of the compounded preparation.

(2) The label shall include the practitioner's name in place of the patient's name and state "For Practitioner Administration Only — Not for Dispensing or Distribution." If the sterility or integrity of the compounded preparation is not maintained after the initial opening of the container, the label shall state "Single–Dose Only."

(3) The pharmacist shall record the name and address of the location the compounded preparation was dispensed or distributed, and the lot number and BUD of all preparations dispensed or distributed to the practitioner.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Subchapter II — Non–sterile Compounding

Phar 15.20 Component Selection. (1) Components with an expiration date from the manufacturer or distributor may be used before the expiration date provided all of the following:

(a) The component is stored in its original container under conditions to avoid decomposition.

(b) There is minimal exposure of the remaining component each time component is withdrawn from the container.

(2) Components without an expiration date assigned by the manufacturer or supplier shall be labeled with the date of receipt and assigned a conservative expiration date, not to exceed three years after receipt, based upon the nature of the component and its degradation mechanism, the container in which it is packaged and the storage conditions.

(3) Components transferred to another container which shall provide integrity that is minimally equivalent to the original container and shall be identified with all of the following:

(a) Component name.

(b) Original supplier.

(c) Lot or control number.

(d) Transfer date.

(e) Expiration date.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.21 Assigning BUD. (1) The BUD shall not be later than the expiration date on the container of any component.

(2) Only in the absence of stability information that is applicable to a specific drug product and preparation, the maximum BUD for a non–sterile compounded drug preparation that is packaged in a tight, light–resistant container is as follows:

(a) For nonaqueous formulations stored at controlled room temperature, the BUD shall not be later than the time remaining until the earliest expiration date of any active pharmaceutical ingredient or 6 months, whichever is earlier.

(b) For water–containing oral formulations, the BUD shall not be later than 14 days when stored in a refrigerator.

(c) For water–containing semisolid mucosal liquid, topical, or dermal formulations, stored at controlled room temperature, the BUD shall not be later than 30 days.

(3) Assignment of BUD shall include an assessment of the need for antimicrobial agents or storage in a refrigerator to protect against bacteria, yeast, and mold contamination introduced during or after the compounding process.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Subchapter III — Sterile Compounding

Phar 15.30 Definitions. In this subchapter:

(1) "Ante area" means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, labeling and other high particulate generating activities are performed. The ante–area is the transition area between the unclassified area of the facility and the buffer area.

(2) "Buffer area" means an ISO Class 7 or ISO Class 8 if using an isolator or cleaner area where the primary engineering control that generates and maintains an ISO Class 5 environment is physically located.

(3) "Category 1" means a compounded sterile preparation compounded with a primary engineering control in a segregated compounding area.

(4) "Category 2" means a compounded sterile preparation compounded with a primary engineering control in a classified area.

(5) "Clean" means to physically remove debris, dirt, dust, and other impurities from surfaces or objects using a cleaning agent with a detergent.

(6) "Compounded sterile preparation" means a compounded final preparation intended to be sterile through the BUD.

(7) "Compounded stock solution" means a compounded solution to be used in the preparation of multiple units of a finished compounded sterile preparation.

(8) "Critical site" means a location that includes any component or fluid pathway surfaces or openings that are exposed and at risk of direct contact with air, moisture, or touch contamination.

(9) "Disinfect" means the killing of microorganisms when used according to the disinfectant's label.

(10) "HEPA" means high–efficiency particulate air.

(10m) "High–risk level compounded sterile preparations" means preparations compounded from non–sterile ingredients or from ingredients that are incorporated using non–sterile equipment before terminal sterilization, or from commercially manufactured sterile products that lack effective antimicrobial preservatives and whose preparation, transfer, sterilization, and packaging is performed in air quality worse than ISO class 5 for more than one hour. High–risk level compounded sterile preparations include water containing preparations that are stored for more than six hours before terminal sterilization.

(11) "ISO Class 5" means conditions in which the air particle count is no greater than a total of 3,520 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA–filtered air.

(12) "ISO Class 7" means conditions in which the air particle count is no greater than a total of 352,000 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA–filtered air.

(13) "ISO Class 8" means conditions in which the air particle count is no greater than a total of 3,520,000 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA–filtered air.

(14) "Isolator" means an enclosure that provides HEPA–filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. An isolator uses only decontaminated interfaces or rapid transfer ports for materials transfer.

(14g) "Low–risk level compounded sterile preparations" means preparations compounded with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, products, components, and devices. The low–risk level sterile compounding process involves only transfer, measuring, and mixing, using no more than three commercially manufactured sterile products, and not more than two entries into one sterile container or package to make the compounded sterile preparations.

(14r) "Medium–risk level compounded sterile preparations" means preparations compounded under low–risk level conditions but which require multiple individual or small doses of sterile products to be combined or pooled to prepare compounded sterile preparations that will be administered either to multiple patients or to one patient on multiple occasions. The medium–risk level sterile compounding process includes complex aseptic manipulations other than single volume transfer, and requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

(15) "Primary engineering control" means a device or zone that provides an ISO Class 5 environment for sterile compounding.

(16) "Restricted access barrier system (RABS)" means an enclosure that provides HEPA–filtered ISO Class 5 unidirectional air that allows for the ingress or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. RABS include compounding aseptic isolators and compounding aseptic containment isolators.

(17) "Sterility assurance level of 10^{-6}" means an equivalent to a probability that one unit in a million is nonsterile.

(18) "Segregated compounding area" means a designated, unclassified space, area, or room that contains a primary engineering control.

(19) "Urgent use compounded sterile preparation" means a preparation needed urgently for a single patient and preparation of the compounded sterile preparation under Category 1 or Category 2 requirements would subject the patient to additional risk due to delays.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18; **CR 22–007: cr. (10m), (14g), (14r) Register July 2022 No. 799, eff. 8–1–22.**

Phar 15.31 Facility design and environmental controls. (1) GENERAL. Facilities shall meet all of the following requirements:

(a) Be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

(b) Be accessible only to designated personnel.

(c) Have a heating, ventilation, and air conditioning system controlling the temperature and humidity.

(2) SEGREGATED COMPOUNDING AREA. A segregated compounding area shall meet all of the following requirements:

(a) Be located in an area away from unsealed windows and doors that connect to the outdoors, or significant traffic flow.

(b) Be located in an area which is not adjacent to construction sites, warehouses, and food preparation areas.

(c) Have a defined perimeter.

(d) Locate the primary engineering control at least one meter from any sink.

(3) CLASSIFIED AREA. A classified area shall meet all of the following:

(a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, and nonshedding.

(b) Work surfaces shall be constructed of smooth, impervious materials. All work surfaces shall be resistant to damage from cleaning and sanitizing agents.

(c) Junctures where ceilings meet walls shall be covered, caulked, or sealed to avoid cracks and crevices in which microorganisms and other contaminate can accumulate. All areas in ceilings and walls where the surface has been penetrated shall be sealed.

(d) Ceilings that consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.

(e) Walls shall be constructed of a durable material, panels locked together and sealed or of epoxy–coated gypsum board.

(f) Floors shall have a covering that shall be seamless or have heat–welded seams and coving to the sidewall. There shall be no floor drains.

(h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush, and sealed.

(i) Carts shall be constructed of stainless steel wire, nonporous plastic or sheet metal with cleanable casters.

(j) Tacky mats may not be used in a classified area.

(k) HEPA filters and unidirectional airflow shall be used to maintain the appropriate airborne particulate classification.

(L) The classified area shall measure not less than 30 air changes per hour of which at least half shall be HEPA–filtered fresh air.

(m) For classified areas physically separated through the use of walls, doors, and pass–throughs, a minimum differential positive pressure of 0.02–inch water column is required to separate each classified area. If a pass–through is used, only one door shall be opened at a time. A pressure gauge or velocity meter shall be used to monitor the pressure differential or airflow between classified areas with results documented at least daily.

(mm) For classified areas not physically separated, no sterile compounded preparation may be compounded using any ingredient that was at any time non–sterile in a classified area not physically separated and all of the following shall be met:

1. The buffer and ante areas shall be designated with a line of demarcation.

2. The principle of displacement airflow shall be used with an air velocity of 40 feet per minute or more from the buffer area across the entire plane of the line of demarcation.

(n) Devices and objects essential to compounding shall be located at an appropriate distance from the primary engineering control.

(p) The ante area shall meet all of the following requirements:

1. Be capable of maintaining an ISO Class 8 air or higher.

2. Have a sink with running hot and cold running water.

(q) The buffer area shall meet all of the following requirements:

1. Be capable of maintaining an ISO Class 7 air or better.

2. Only contain any of the following:

a. Items, including furniture, equipment, and supplies, that are required for the tasks to be performed in the buffer area.

b. Items that are smooth, impervious, free from cracks and crevices, nonshedding, and easily cleaned and disinfected.

c. Items that have been cleaned and disinfected immediately prior to their being placed in the buffer area.

3. Does not contain any sinks.

4. Does not contain any course cardboard, external shipping containers, and nonessential paper.

(4) PRIMARY ENGINEERING CONTROL. The primary engineering control shall be certified by an independent, qualified individual certified by the Controlled Environment Testing Association's National Board of Testing or another Board approved entity prior to initial use and then every six months. It shall also be certified when any of the following occurs:

(a) Redesign of the facility.

(b) Replacement of the primary engineering control.

(c) Relocation of the primary engineering control.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.32 Personnel hygiene, garbing and protective gear. (1) Personnel suffering from rashes, sunburn, oozing tattoos or sores, conjunctivitis, active respiratory infection, or other active communicable disease shall be excluded from working in compounding areas until the condition is resolved.

(2) All personnel who engage in compounding sterile preparations shall comply with all of the following requirements before entering the compounding area:

(a) Remove personal outer garments, all cosmetics, exposed jewelry and piercings, headphones, ear buds, and cell phones.

(b) Abstain from eating, chewing gum or drinking in the compounding area or bringing food, gum, or drink into the compounding area.

(c) Artificial nails, nail extenders or nail polish may not be worn while working in the compounding area. Nails shall be neat and trim.

(d) Don personnel protective equipment and perform hand hygiene in the following order:

1. Low–lint, disposable shoe covers.

2. Low–lint, disposable covers for head and facial hair that cover the ears and forehead and face masks.

3. Eye shields, if required due to working with irritants or hazardous drugs.

4. Wash hands and forearms up to the elbows with unscented soap and water for at least 30 seconds. Hands and forearms to the elbows shall be completely dried using either lint–free disposable towels or wipes.

5. Don low lint disposable gown or overalls.

6. Prior to donning sterile gloves, hand antisepsis shall be performed using an alcohol–based hand rub with sustained antimicrobial activity following the manufacturers labeled instructions and application times.

(3) Gloves on hands and gauntlet sleeves on RABS shall be routinely inspected for holes, punctures, or tears and shall be replaced immediately if any are detected. Sterile gloves shall be donned over the RABS gloves.

(4) Disinfection of contaminated gloved hands shall be accomplished by wiping or rubbing sterile 70% isopropyl alcohol on all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Routine application of sterile 70% isopropyl alcohol shall occur throughout the compounding process and whenever non–sterile surfaces, including vials, counter tops, chairs, and carts, are touched.

(5) When compounding personnel exit the buffer or segregated compounding area, a gown may be removed and retained in the ante area or segregated compounding area if not visibly soiled, to be worn again during the same work shift. Coveralls, shoe covers, hair and facial hair covers, face masks, eye shields, and gloves shall be replaced with new ones before re–entering the compounding area.

(6) Garbing items, including gowns, shall be segregated and stored before use in an enclosure to prevent contamination.

(7) Visibly soiled gowns shall be changed immediately.

(8) Gloves shall be sterile and powder free and tested by the manufacturer for compatibility with alcohol disinfection.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.33 Cleaning and Disinfecting the Compounding Area and Supplies. (1) Compounding personnel are responsible determining the cleaning and disinfecting products to be used and for ensuring that the frequency of cleaning and disinfecting compounding area is done.

(2) Compounding personnel shall clean in accordance with the following:

(a) Primary engineering control work surfaces, counters, floors and work surfaces in the buffer zone area, ante room and segregated compounding areas daily.

(b) Walls, ceilings and storage shelving monthly.

(c) When a spill occurs or the surface is visibly soiled.

(d) Sporicidal agents shall be used at least weekly to clean compounding areas.

(3) Compounding personnel shall disinfect in accordance with the following:

(a) Primary engineering control work surfaces at the beginning and end of each compounding business day and before each batch, but not longer than 4 hours following the previous disinfection when ongoing compounding activities are occurring.

(b) When microbial contamination is known to have been or is suspected of having been introduced into the compounding area.

(4) All cleaning and disinfecting practices and policies for the compounding area shall be included in written standard operating procedures and shall be followed by all compounding and environmental services personnel.

(5) Cleaning, detergents and disinfection agents shall be selected and used with consideration of compatibilities, effectiveness, and inappropriate or toxic residues. The selection and use of disinfectants shall be guided by microbicidal activities, inactivation by organic matter, residue, and shelf life. Disinfectants shall have antifungal, antibacterial and antiviral activity. Sporicidal agents shall be used at least weekly to clean compounding areas.

(6) Storage sites for compounding ingredients and supplies shall remain free from dust and debris.

(7) Floors, walls, ceiling, and shelving in the classified and segregated compounding areas are cleaned when no aseptic operations are in progress. Cleaning shall be performed in the direction from cleanest to dirtiest areas.

(8) All cleaning tools and materials shall be low–lint and dedicated for use in the buffer room, ante room and segregated compounding areas. If cleaning tools and materials are reused, procedures shall be developed based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned.

(9) Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent delivered from a spray bottle or other suitable delivery method. After the disinfectant is wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.

(10) Entry points on bags and vials shall be wiped with small sterile 70% isopropyl alcohol swabs or comparable method for disinfecting, allowing the isopropyl alcohol to dry before piercing stoppers with sterile needles and breaking necks of ampules. The surface of the sterile 70% isopropyl alcohol swabs used for disinfecting entry points of sterile package and devices may not contact any other object before contacting the surface of the entry point. Particle generating material may not be used to disinfect the sterile entry points of packages and devices.

(11) When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 primary engineering control without the need to disinfect the individual sterile supply items.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18; **CR 22–007: am. (10) Register July 2022 No. 799, eff. 8–1–22.**

Phar 15.34 Immediate–use compounded sterile preparations. Immediate–use compounded sterile preparations are exempt from the requirements described for low–risk level, Category 1, and Category 2 compounding sterile preparations only when all the following criteria are met:

(1) The compounding process involves simple transfer of not more than three commercially manufactured sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or product of sterile infusion solution or administration container or device.

(2) Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

(3) During preparation, aseptic technique is followed and, if not immediately administered, the finished compound sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix–ups with other compound sterile preparations, and direct contact of outside surfaces.

(4) Administration begins not later than 4 hours following the start of the preparation.

(5) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared it, and the exact 4–hour BUD and time.

(6) If administration of the compounded sterile preparation has not begun within 4 hours following the start of preparation, it shall be promptly, properly, and safely discarded.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18; **CR 22–007: r. and recr. Register July 2022 No. 799, eff. 8–1–22.**

Phar 15.35 Sterilization methods. (1) Sterilization methods employed shall sterilize while maintaining its physical and chemical stability and the packaging integrity of the compounding sterile preparations. The efficacy of sterilization and depyrogenation of container closure systems performed in the pharmacy shall be established, documented, and reproducible.

(2) Pre–sterilization requirements shall meet all of the following:

(a) During all compounding activities that precede terminal sterilization, including weighing and mixing, compounding personnel shall be garbed and gloved in the same manner as when performing compounding in an ISO Class 5 environment. All pre–sterilization procedures shall be completed in an ISO Class 8 or better environment.

(b) Immediately before use, all nonsterile measuring, mixing, and purifying devices used in the compounding process shall be thoroughly rinsed with sterile, pyrogen–free water and then thoroughly drained or dried.

(3) Sterilization shall be performed utilizing one of the following methods:

(a) *Sterilization by filtration.* Sterilization by filtration involves the passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent. Filtration may not be used when compounding a suspension when the suspended particles are removed by the filter being used. This method shall meet all of the following:

1. Sterile filters used to sterile filter preparations shall meet all of the following requirements:

a. Be pyrogen–free and have a nominal pore size of 0.22 microns.

b. Be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the compounded sterile preparations will be filtered.

c. Be chemically and physically stable at the compounding pressure and temperature conditions.

d. Have sufficient capacity to filter the required volumes.

e. Yield a sterile filtrate while maintaining pre–filtration pharmaceutical quality, including strength of ingredients of the specific compounded sterile preparations.

2. The filter dimensions and liquid material to be sterile filtered shall permit the sterilization process to be completed rapidly without the replacement of the filter during the filtering process.

3. When compounded sterile preparations are known to contain excessive particulate matter, one of the following shall occur:

a. A pre–filtration step using a filter of larger nominal pore size.

b. A separate filter of larger nominal pore size placed upstream of the sterilizing filter to remove gross particulate contaminants before the compounding sterile compound is passed through the sterilizing grade filter.

4. Sterilization by filtration shall be performed entirely within an ISO Class 5 or better air quality environment.

5. Filter units used to sterilize compounded sterile preparations shall be subjected to the manufacturers' recommended post–use integrity test.

(b) *Sterilization by steam heat*. The process of thermal sterilization using saturated steam under pressure shall be the method for terminal sterilization of aqueous preparations in their final, sealed container closure system. The effectiveness of steam sterilization shall be established and verified with each sterilization run or load by using biological indicators, physicochemical indicators and integrators. This method shall meet all of the following:

1. All materials shall be directly exposed to steam under adequate pressure for the length of time necessary, as determined by use of appropriate biological indicators, to render the items sterile. The duration of the exposure period shall include sufficient time for the compounded sterile preparation to reach the sterilizing temperature.

2. The compounded sterile preparation and other items shall remain at the sterilizing temperature for the duration of the steril-

ization period. The sterilization cycle shall be designed to achieve a sterility assurance level of 10^{-6}.

3. Compounded sterile preparations shall be placed in trays which allow steam to reach the compounded sterile preparations without entrapment of air. Paper, glass, and metal devices or items shall be wrapped in low lint protective fabric, paper, or sealed in envelopes that will permit steam penetration and prevent post sterilization microbial contamination.

4. Immediately before filling ampules and vials, solutions shall be passed through a filter having a nominal pore size of not larger than 1.2 microns for removal of particulate matter.

5. Sealed containers shall be able to generate steam internally. Stoppered and crimped empty vials shall contain a small amount of moisture to generate steam. Deep containers, including beakers and graduated cylinders, shall be placed on their sides to prevent air entrapment or have a small amount of water placed in them.

6. Porous materials and items with occluded pathways shall only be sterilized by steam if the autoclave chamber has cycles for dry goods.

7. The steam supplied shall be free of contaminants and generated using clean water.

8. The seals on the doors of autoclave chambers shall be examined visually every day they are used for cracks or damage and the seal surfaces shall be kept clean.

9. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.

10. Materials in direct contact with the compounded sterile preparation shall undergo a depyrogenation process before being sterilized using steam heat unless the materials used are certified to be pyrogen–free.

(c) *Sterilization by dry heat.* Dry heat sterilization shall be used only for those materials that cannot be sterilized by steam or filtration. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and temperature sensing devices. This method shall meet all of the following:

1. The duration of the exposure period shall include sufficient time for the compounding sterile preparation or items to reach the sterilizing temperature. The compounded sterile preparation and items shall remain at the sterilizing temperature for the duration of the sterilization period.

2. Heated air shall be evenly distributed throughout the chamber.

3. Sufficient space shall be left between materials to allow for good circulation of the hot air.

4. The oven shall be equipped with temperature controls and a timer.

5. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.

6. Materials shall first undergo a depyrogenation process before being sterilized using dry heat, unless the materials used are certified to be pyrogen–free.

(4) Dry heat depyrogenation shall be used to render glassware and other thermostable containers pyrogen free. The duration of the exposure period shall include sufficient time for the items to reach the depyrogenation temperature. The items shall remain at the depyrogenation temperature for the duration of the depyrogenation period. The effectiveness of the dry heat depyrogenation cycle shall be established and verified annually using endotoxin challenge vials to demonstrate that the cycle is capable of achieving at least a 3–log reduction in endotoxins.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.36 Inspection, sterility testing and antimicrobial effectiveness. (1) PHYSICAL INSPECTION. (a) At the completion of compounding, the compounded sterile preparation shall be inspected by performing all of the following:

1. Visually inspect the container closure for leakage, cracks in the container, or improper seals.

2. Visually check the compounded sterile preparation for phase separation.

3. Each individual injectable unit shall be inspected against a lighted white background and a black background for evidence of visible particulates or other foreign matter or discoloration.

(b) For compounded sterile preparations which will not be dispensed promptly after preparation, an inspection shall be conducted immediately before it is dispensed for any defects, including precipitation, cloudiness, or leakage, which may develop during storage.

(c) Compounded sterile preparations with any observed defects shall be immediately discarded or marked and segregated from acceptable units in a manner that prevents them from being dispensed.

(2) STERILITY TESTING. (a) The membrane filtration method shall be used for sterility testing unless it is not possible due to the compounded sterile preparation formulation. The direct inoculation of the culture method shall be used when the membrane filtration method is not possible.

(b) If a preparation may be needed before the results of sterility testing have been received, the pharmacy shall daily observe the incubating test specimens and immediately recall the dispensed preparations when there is any evidence of microbial growth in the test specimens. The patient and the prescriber to whom a potentially contaminated compounded sterile preparation was administered shall be notified immediately of the potential risk.

(c) Positive sterility test results shall prompt a rapid and systematic investigation into the causes of the sterility failure, including identification of the contaminating organism and any aspects of the facility, process or personnel that may have contributed to the sterility failure. The investigation and resulting corrective actions shall be documented.

(d) All Category 2 compounded sterile preparations made from one or more nonsterile ingredients, except those for inhalation and ophthalmic administration, shall be tested to ensure that they do not contain excessive bacterial endotoxins.

(e) Notwithstanding par. (d), a compounded sterile preparation does not need to be tested for bacterial endotoxins if the material is stored under cool and dry conditions and one of the following:

1. The certificate of analysis for the nonsterile ingredient lists the endotoxins burden, and that burden is found acceptable.

2. The pharmacy has predetermined the endotoxins burden of the nonsterile ingredient and that burden is found acceptable.

(3) ANTIMICROBIAL EFFECTIVENESS. Compounded sterile preparations containing a preservative added by the compounder shall pass an antimicrobial effectiveness testing with the results obtained on the specific formulation before any of the compounded sterile preparation is dispensed. The test may be conducted only once on each formulation in the particular container–closure system in which it will be stored or dispensed. The antimicrobial effectiveness test shall occur at one of the following times:

(a) At the completion of the sterility test.

(b) At the time of preparation for compounded sterile preparations which have not undergone a sterility testing.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.37 Beyond use dating. (1) Sterility and stability considerations shall be taken into account when establishing a BUD. Either Category 1 and 2, or low, medium, and high–risk compounding preparation standards may be used, but not a combination of the two within the same pharmacy. The following

dates and times for storage and initiation of administration of the compounded sterile preparations shall apply:

(a) For compounded sterile preparations including components from conventionally manufactured products, the BUD shall not exceed the shortest expiration of any of the starting components. If the compounded sterile preparation includes non–conventionally manufactured products, the BUD may not exceed the shortest BUD of any of the starting components.

(b) For Category 1 compounded sterile preparations, one of the following:

1. May not exceed 12 hours when the preparation is stored at controlled room temperature.

2. May not exceed 24 hours when the preparation is stored in a refrigerator.

(c) For aseptically processed Category 2 processed sterile preparations, one of the following:

1. No sterility testing performed or sterility testing not passed, and prepared with one or more nonsterile starting components, one of the following:

a. Within 1 day when the preparation is stored at controlled room temperature.

b. Within 4 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

2. No sterility testing performed or sterility testing not passed, and prepared with only sterile starting components, one of the following:

a. Within 4 days when the preparation is stored at controlled room temperature.

b. Within 10 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

3. Sterility testing performed and passed, one of the following:

a. Within 30 days when the preparation is stored at controlled room temperature.

b. Within 45 days when the preparation is stored in a refrigerator.

c. Within 60 days when the preparation is stored in a freezer.

(d) For Category 2 compounded sterile preparations, terminally sterilized by a validated procedure, one of the following:

1. No sterility testing performed or sterility testing not passed, one of the following:

a. Within 14 days when the preparation is stored at controlled room temperature.

b. Within 28 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

2. Sterility testing performed and passed, one of the following:

a. Within 45 days when the preparation is stored at controlled room temperature.

b. Within 60 days when the preparation is stored in a refrigerator.

c. Within 90 days when the preparation is stored in a freezer.

(2) The BUD established in sub. (1) may not be exceeded or extended for compounded sterile preparations without verifiable supporting valid scientific sterility and stability information that is directly applicable to the specific preparation or compound.

(3) For compounded sterile preparations which have been assigned a BUD based upon storage in a freezer, the integrity of the container–closure system with the specific compounded sterile preparation in it shall have been demonstrated for 45 days at frozen storage. The container–closure integrity test may be conducted only once on each formulation in the specific container closure–system in which it will be stored or dispensed.

(4) When a preservative is added, the compounded sterile formulation shall pass antimicrobial effectiveness testing that shall include inoculation of standardized microorganisms, incubation serial sampling, and calculation of the changes in colony forming unit concentrations in terms of log reduction. The results of antimicrobial effectiveness testing shall be obtained before any of the compounded sterile preparation is dispensed. Preservatives shall not be used as a substitute for good compounding practices.

(5) For low–risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 48 hours when the preparation is stored at controlled room temperature.

(b) Within 14 days when the preparation is stored in a refrigerator.

(c) Within 45 days when the preparation is stored in a freezer.

(d) For products prepared in an airflow workbench not located in a buffer area, administration shall begin within 12 hours or less of preparation.

(6) For medium–risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 30 hours when the preparation is stored at controlled room temperature.

(b) Within 9 days when the preparation is stored in a refrigerator.

(c) Within 45 days when the preparation is stored in a freezer.

(7) For high–risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 24 hours when the preparation is stored at controlled room temperature.

(b) Within 3 days when the preparation is stored in a refrigerator.

(c) Within 45 days when the preparation is stored in a freezer.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18; **CR 22–007: am. (1) (intro.), (c) (intro.), 1. (intro.), a., b., 2. (intro.), a., b., 3., r. (1) (c) 4., 5., am. (1) (d) 1. (intro.), 2., r. (1) (d) 3., 4., cr. (5) to (7) Register July 2022 No. 799, eff. 8–1–22; correction in (6) (b), (7) (b) made under s. 35.17, Stats. July 2022 No. 799.**

Phar 15.38 Training and evaluation. (1) GENERAL. The managing pharmacist, pharmacists, pharmacy technicians, pharmacy interns and pharmacy externs compounding sterile preparations shall successfully complete didactic or practical training. The didactic or practical training shall be done before any compounding personnel initially prepares compounded sterile preparations and annually thereafter and shall include all of the following:

(a) Hand hygiene and garbing.

(b) Cleaning and disinfection.

(c) Measuring and mixing.

(d) Aseptic manipulation.

(e) Cleanroom behavior.

(f) Sterilization and depyrogenation.

(g) Use of equipment.

(h) Documentation.

(i) Use of primary engineering controls.

(2) EVALUATION. Compounding personnel shall successfully complete an initial and annual evaluation which includes all of the following:

(a) Visual observation of hand hygiene and garbing.

(b) Visual observation of aseptic technique.

(c) Gloved fingertip and thumb sampling.

(d) Media–fill tests.

(3) GLOVED FINGERTIP. Successfully gloved and thumb sampling is measured by samplings resulting in zero colony–forming units no fewer than three times. Sampling shall be performed on

sterile gloves inside of an ISO Class 5 primary engineering control. Gloved fingertip and thumb sampling in a RABS or an isolator shall be taken from the sterile gloves placed over the gauntlet gloves. When gloved fingertip sample results exceed action levels defined by the pharmacy, a review of hand hygiene and garbing procedures, glove and surface disinfection procedures and work practices shall be performed and documented.

(5) RECORDS. The pharmacy shall maintain written policies and procedures for the initial and ongoing training and evaluation of persons involved in compounding sterile preparations. Documentation of all training, assessments, gloved fingertip tests and media–fill simulations shall be maintained by the pharmacy for 5 years and made available to the Board upon request.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

What's New with *USP* General Chapters ⟨795⟩ and ⟨797⟩?

Brenda Jensen, CPhT, CNMT, MBA

Brian Serumaga, PhD, M Pharm, MPH

May 11, 2023

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Financial Disclosures

- Our speaker Brian Serumaga declares that he does not have a relevant affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this continuing pharmacy education (CPE) activity within the past 24 months.
- Our speaker Brenda Jensen declares that she has a current affiliation or financial arrangement with an ineligible company as an owner of Compounding Consultants, LLC.
- Brian Serumaga is employed by USP, and Brenda Jensen is chair of the 2020-2025 Compounding Expert Committee.
- Additionally, NABP staff involved in the planning of this activity do not have an affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of NABP's CPE program within the past 24 months.
- All relevant financial relationships have been mitigated.

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Learning Objectives

1. Describe the revisions to General Chapter ⟨795⟩ *Pharmaceutical Compounding—Nonsterile Preparations*, including updates to the beyond-use dates
2. Describe the revisions to General Chapter ⟨797⟩ *Pharmaceutical Compounding—Sterile Preparations*, including updates to the beyond-use dates
3. Explain the difference between requirements and recommendations in the *USP* General Chapters

3

3

Assessment Questions

1. When do USP standards become official?

A. As soon as they are published in the *Pharmacopeial Forum*

B. Generally, six months after being published in the *Pharmacopeial Forum*

C. As soon as they are published in the *USP–NF*

D. Generally, six months after being published in the *USP–NF*

4

4

Assessment Questions

2. The current official version of USP ⟨797⟩ was last revised in

A. 2008

B. 2015

C. 2019

D. 2022

5

5

Assessment Questions

3. Category 1 compounded sterile preparations (CSPs) in USP ⟨797⟩ are restricted to

A. Sterile to sterile compounding only

B. CSPs that are assigned a BUD of no more than 6 hours when stored at room temperature

C. CSPs that are assigned a BUD of no more than 24 hours when stored under refrigeration

D. Non-hazardous CSPs only

6

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Assessment Questions

4. Which of the following standards are available for compounders in the Compounding Compendium?

A. General Chapter ⟨795⟩ *Pharmaceutical Compounding—Nonsterile Preparations*

B. General Chapter ⟨797⟩ *Pharmaceutical Compounding—Sterile Preparations*

C. USP Compounded Preparation Monographs

D. All of the above

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USP Overview

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2020 – 2025 Compounding Expert Committee

Chair: Brenda Jensen, MBA, Owner and Compounding Pharmacy Consultant, Compounding Consultants, LLC
Vice Chair: Vanessa Pinheiro, MS, BS Pharm, Pharmacist and Consultant, Medisca and LP3 Network

EC Member	Affiliation
Lisa Ashworth, BS Pharm	Compounding Specialist and Clinical Pharmacist, Children's Health System of Texas
Phil Ayers, PharmD	Chief, Clinical Pharmacy Services, Mississippi Baptist Medical Center
Gus Bassani, PharmD	Chief Scientific Officer, PCCA
Suzanne Blevins, BSc	Laboratory Director, Aerobiology Laboratory
Brett Cordes, DVM	Veterinarian, Private Practice
Gigi Davidson, BS Pharm	Veterinary Pharmacy Consultant, VetPharm Consulting, LLC
Edmund Elder, PhD, BS Pharm	Director, Zeeh Pharmaceutical Experiment Station, University of Wisconsin-Madison
Kevin Hansen, PharmD, MS	Assistant Director of Pharmacy, Cone Health
Patricia Kienle, MPA, BS Pharm	Director, Accreditation and Medication Safety, Cardinal Health
Elizabeth Rebello, MD, BS Pharm	Professor and Anesthesiologist, University of Texas MD Anderson Cancer Center
Rick Rhoads, PharmD	Director of Compounding, University Compounding Pharmacy
Robert Shrewsbury, PhD	Associate Professor, UNC Eshelman School of Pharmacy
Connie Sullivan, BS Pharm	President and CEO, National Home Infusion Association

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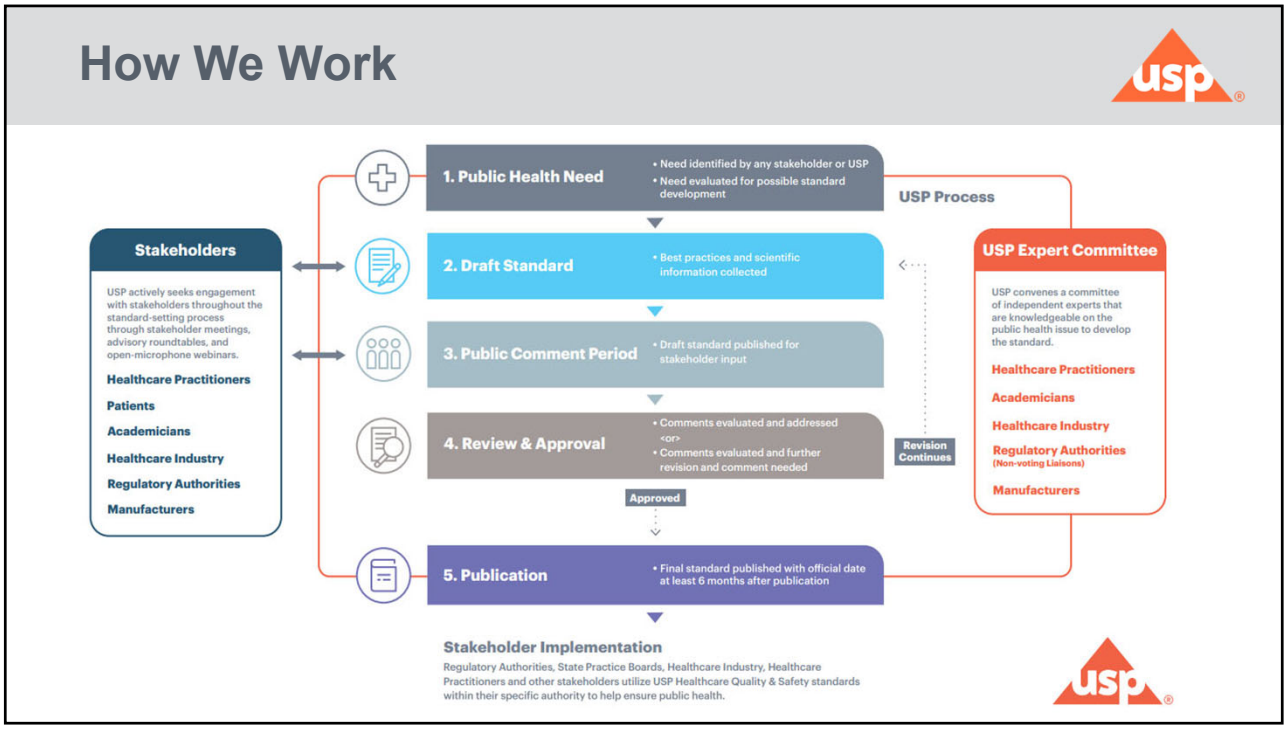
How We Work
Stakeholders
USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.
Healthcare Practitioners
Patients
Academicians
Healthcare Industry
Regulatory Authorities
Manufacturers
1. Public Health Need
• Need identified by any stakeholder or USP
• Need evaluated for possible standard development
2. Draft Standard
• Best practices and scientific information collected
3. Public Comment Period
• Draft standard published for stakeholder input
4. Review & Approval
• Comments evaluated and addressed <or>
• Comments evaluated and further revision and comment needed
Approved
5. Publication
• Final standard published with official date at least 6 months after publication
USP Process
Revision Continues
USP Expert Committee
USP convenes a committee of independent experts that are knowledgeable on the public health issue to develop the standard.
Healthcare Practitioners
Academicians
Healthcare Industry
Regulatory Authorities
(Non-voting Liaisons)
Manufacturers
Stakeholder Implementation
Regulatory Authorities, State Practice Boards, Healthcare Industry, Healthcare Practitioners and other stakeholders utilize USP Healthcare Quality & Safety standards within their specific authority to help ensure public health.

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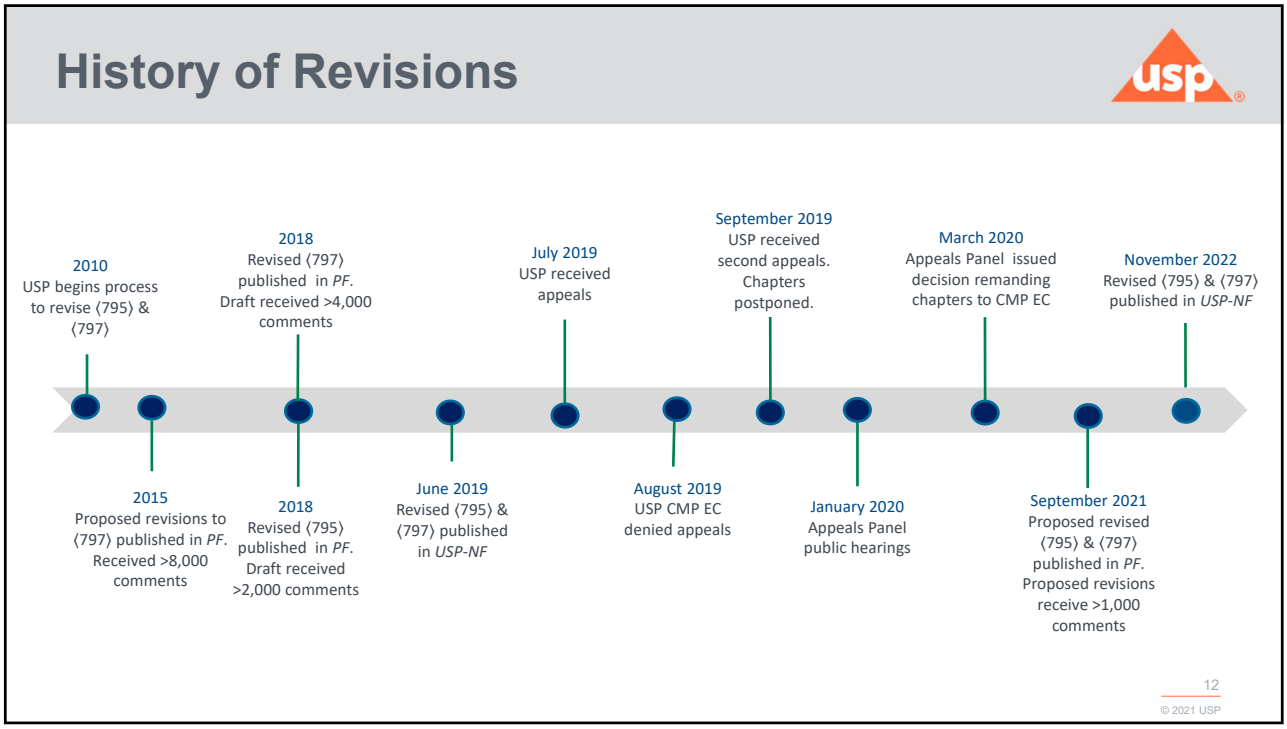
History of Revisions
2010
USP begins process to revise ⟨795⟩ & ⟨797⟩
2015
Proposed revisions to ⟨797⟩ published in PF. Received >8,000 comments
2018
Revised ⟨797⟩ published in PF. Draft received >4,000 comments
2018
Revised ⟨795⟩ published in PF. Draft received >2,000 comments
June 2019
Revised ⟨795⟩ & ⟨797⟩ published in USP-NF
July 2019
USP received appeals
August 2019
USP CMP EC denied appeals
September 2019
USP received second appeals. Chapters postponed.
January 2020
Appeals Panel public hearings
March 2020
Appeals Panel issued decision remanding chapters to CMP EC
September 2021
Proposed revised ⟨795⟩ & ⟨797⟩ published in PF. Proposed revisions receive >1,000 comments
November 2022
Revised ⟨795⟩ & ⟨797⟩ published in USP-NF
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Approach to Revisions

- Stakeholder Engagement
  - Reviewed feedback, including *PF* public comments and issues raised in the appeals
  - Held stakeholder semi-structured interviews (May 2020)
  - Roundtable session (July 28, 2020)
  - Open forum (September 15, 2020)
- Identified key stakeholder engagement discussion topics as a framework
- Also had general considerations throughout the review process
  - Scientifically robust, risk-based approach to assigning beyond-use dates (BUDs)
  - Physical and chemical stability considerations
  - Sterility assurance in ⟨797⟩
  - Operational implications
  - Balancing the need for patient access to cost-effective compounded preparations with rigorous quality standards
  - Implications on regulatory oversight and enforcement

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Overview of Revised General Chapter ⟨795⟩ *Pharmaceutical Compounding—Nonsterile Preparations*

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⟨795⟩ Overview

Chapter Outline

1. Introduction and Scope
2. Personnel Training and Evaluation
3. Personal Hygiene and Garbing
4. Buildings and Facilities
5. Cleaning and Sanitizing
6. Equipment and Components
7. Master Formulation and Compounding Records
8. Release Inspections and Testing
9. Labeling
10. Establishing Beyond-Use Dates
11. SOPs
12. Quality Assurance and Quality Control
13. CNSP Packaging and Transporting
14. Documentation

- Glossary

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⟨795⟩ Revisions

Section 1. Introduction and Scope

- Scope
  - Added information on types of Compounded Nonsterile Preparations (CNSPs)
- Hazardous Drugs
  - Removed all information on handling of hazardous drugs and added references to General Chapter ⟨800⟩ *Hazardous Drugs—Handling in Healthcare Settings*
- Affected Personnel and Settings
  - Added roles and responsibility of the designated person
    - Designated person = One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs

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Flavoring

- Nonsterile compounding is defined 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
- Adding components (such as flavors) not stipulated in the labeling to conventionally manufactured products is compounding as defined in ⟨795⟩ and has been within the scope of ⟨795⟩ since the chapter was first published in 2004
- Flavors are organic chemicals with reactive functional groups including acids, alcohols, aldehydes, amides, amines, esters, ketones, and lactams
- The effect of adding these substances, even in very small quantities or concentrations, to conventionally manufactured products is unpredictable due to the potential for a variety of chemical reactions
- USP Resource: "⟨795⟩: Adding Flavor to Conventionally Manufactured Nonsterile Products"

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⟨795⟩ Revisions

Section 2. Personnel Training and Evaluation

- Added guidance on training and core competencies
- Included steps in training procedures

Section 3. Personal Hygiene and Garbing

- Added Box on Hand Hygiene Procedures
- Included description of garb and glove requirements
  - Gloves are required for all compounding activities
  - Other garb must be used as appropriate for the type of compounding

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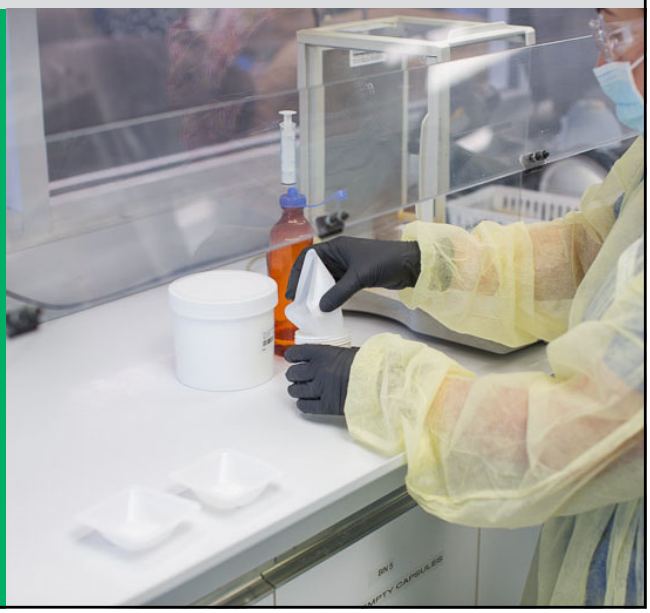
⟨795⟩ Revisions

Section 4. Buildings and Facilities

- Added requirement for a designated area for nonsterile compounding
- Area must be well lit and be maintained in a clean, orderly, sanitary condition and in a good state of repair

Section 5. Cleaning and Sanitizing

- New table on minimum frequencies for cleaning and sanitizing surfaces in nonsterile compounding areas, including:
  - Work surfaces
  - Floors
  - Walls
  - Ceilings
  - Storage Shelving



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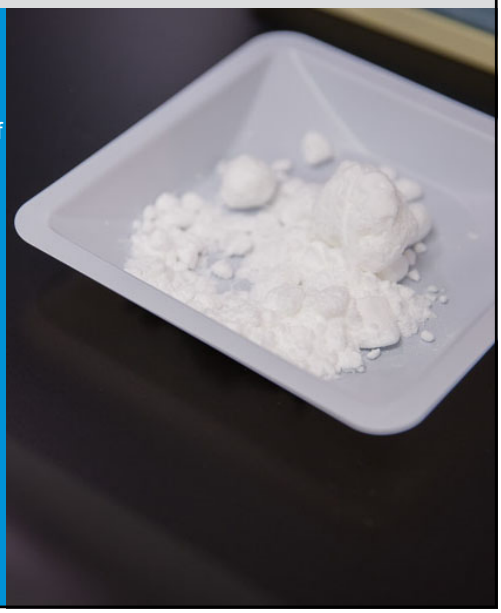
⟨795⟩ Revisions

Section 6. Equipment and Components

- Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (eg, APIs, added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device
  - Containment ventilated enclosures (CVEs) and biological safety cabinets (BSCs) must be cleaned and sanitized
  - CVE or BSC must be certified at least annually
- Components
  - In the United States, active pharmaceutical ingredients (APIs) must be manufactured by an FDA-registered facility
    - Each API must be accompanied by a valid Certificate of Analysis (COA)
  - In the United States, all components other than APIs should be obtained from an FDA-registered facility
  - Packaging systems of components that lack a vendor's expiration must not be used after 3 years from the date of receipt



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⟨795⟩ Revisions

Section 7. Master Formulation And Compounding Records

- Boxes include required elements of Master Formulation Records and Compounding Records

Section 8. Release Inspections and Testing

- Confirm CNSP and labeling match Compounding Records
- Visual inspections to determine if physical appearance is as expected
- Other tests to ensure quality (eg, pH, assays)

Section 9. Labeling

- Requirements for *labels* (labeling on the immediate container)
- Requirements for *labeling* (all matter on container or in any packaging system or wrapper)

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⟨795⟩ Revisions

Section 10. Establishing Beyond-Use Dates

- Terminology
  - Expiration Date applies to conventionally manufactured drug products
  - BUD applies to CNSPs calculated in terms of hours, days, or months
- Parameters to consider
  - Water activity (a_w)
  - Chemical and physical stability
  - Compatibility of container closure system
  - Degradation of container closure system
  - Potential for microbial proliferation
  - Deviations from essential compounding steps and procedures

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⟨795⟩ Revisions

Section 10. Establishing Beyond-Use Dates

- *Table 4. BUD Limit by Type of Preparation in the **Absence** of a USP–NF Compounded Preparation Monograph or CNSP-Specific Stability Information* [a]

Type of Preparation	BUD (days)	Storage Temperature [b]
Aqueous Dosage Forms ($a_w \geq 0.60$)		
Nonpreserved aqueous dosage forms [c]	14	Refrigerator
Preserved aqueous dosage forms [c]	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms ($a_w < 0.60$)		
Oral liquids (nonaqueous) [d]	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms [e]	180	Controlled room temperature or refrigerator

a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table (see *10.4 CNSPs Requiring Shorter BUDs*).
b See *Packaging and Storage Requirements* ⟨659⟩.
c An aqueous preparation is one that has an a_w of ≥ 0.6 (eg, emulsions, gels, creams, solutions, sprays, or suspensions).
d A nonaqueous oral liquid is one that has an a_w of < 0.6.
e Other nonaqueous dosage forms that have an a_w of < 0.6 (eg, capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges).

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⟨795⟩ Revisions

Nonaqueous Dosage Forms: $a_w < 0.6$			Aqueous Dosage Forms: $a_w \geq 0.6$		
Dosage Form	Description	a_w	Dosage Form	Description	a_w
Animal treat	Animal treat (oil flavor)	0.507	Animal treat	Animal treat with 15%–18% aqueous flavor	0.716
Capsule (oil filled)	Olive oil encapsulated	0.468	Cream	Cream vehicle (oil in water emulsion, petrolatum free)	0.968
Capsule (powder filled)	Powder base encapsulated	0.435	Cream	Emollient cream (petrolatum and mineral oil)	0.984
Gel (glycol based)	Propylene glycol, ethoxy diglycol, or hydroxypropyl cellulose gel	0.056	Cream	Cream (oil in water emulsion with natural oils)	0.989
Lollipop (sorbitol based)	Sorbitol-based lollipop	0.460	Foam	Foaming surfactant solution	0.983
Ointment	Hydrophilic petrolatum	0.396	Gel (water based)	Alcohol-free aqueous gel	0.990
Ointment	Polyethylene and mineral oil gel base	0.459	Gel (water based)	Hydroxypropyl methylcellulose (HPMC) gel	1.000
Oral solution (glycol based)	20% Polyethylene glycol and 80% propylene glycol	0.009	Lotion	Lotion (oil in water emulsion)	0.986
Oral solution (oil based)	Medium chain triglycerides oil	0.338	Nasal spray	Nasal spray	0.991
Oral suspension (fixed oil)	Fixed oil with thickener	0.403	Oral solution (water based)	Low-sucrose syrup vehicle	0.906
Powder for inhalation	Encapsulated powder for inhalation	0.402	Oral solution (water based)	90% Water and 10% glycerin	0.958
Stick	Lip balm	0.181	Oral suspension (water based)	Oral suspension base	0.992
Suppository	Polyethylene glycol base	0.374	Rinse	Polymer gel with 30% water	0.960
Suppository	Fatty acid base	0.385	Shampoo	Shampoo	0.976
Tablet (compressed)	Compressed tablet	0.465	Simple syrup	Simple syrup	0.831
Tablet (triturate)	Tablet triturate (lactose and/or sucrose)	0.427	-	-	-
Troche or lozenge (gelatin based)	Gelatin troche or lozenge with NMT 3% aqueous flavor	0.332	-	-	-
Troche or lozenge (glycol based)	Polyethylene glycol troche or lozenge with NMT 3% aqueous flavor	0.571	-	-	-

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⟨795⟩ Revisions

2008 Currently Official Chapter	Revised Chapter
Water-containing oral formulations = **14 days** Water-containing topical/dermal and mucosal liquids and semisolid formulations = **30 days** Nonaqueous formulations = **6 months**	Nonpreserved aqueous dosage forms ($a_w \geq 0.60$) = **14 days** Preserved aqueous dosage forms ($a_w \geq 0.60$) = **35 days** Oral liquids (nonaqueous) ($a_w < 0.60$) = **90 days** Other nonaqueous dosage forms ($a_w < 0.60$) = **180 days**

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⟨795⟩ Revisions

Section 10. Establishing Beyond-Use Dates

- In the **Presence** of CNSP-Specific Stability Information
  - BUD may be extended up to a maximum of 180 days
  - Stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the container closure that will be used
  - An aqueous CNSP must be tested for ⟨51⟩ antimicrobial effectiveness at the end of the BUD
    - Bracketing can be utilized to provide flexibility
  - If compounding from a *USP–NF* compounded preparation monograph, the BUD must not exceed the BUD specified in the monograph
- Shorter BUDs may be required
  - If components have an earlier expiration date or BUD
  - If ingredients are known to be susceptible to decomposition

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⟨795⟩ Revisions

Section 11. SOPs

Section 12. Quality Assurance and Quality Control

- Quality Assurance = set of written processes that, at a minimum, verifies, monitors, and reviews the adequacy of the compounding process
- Quality Control = observation of techniques and activities that demonstrate that requirements are met
- SOPs for complaint receipt, acknowledgement, and handling
- Review of adverse events

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⟨795⟩ Revisions

Section 13. CNSP Packaging and Transporting

Section 14. Documentation

Glossary

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Overview of Revised General Chapter ⟨797⟩ *Pharmaceutical Compounding—Sterile Preparations*

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⟨797⟩ Revisions

Chapter Outline

1. Introduction and Scope
2. Personnel Training and Evaluation
3. Personal Hygiene and Garbing
4. Facilities and Engineering Controls
5. Certification and Recertification
6. Microbiological Air and Surface Monitoring
7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA
8. Introducing Items into the SEC and PEC
9. Equipment, Supplies, and Components
10. Sterilization and Depyrogenation
11. Master Formulation and Compounding Records
12. Release Inspections and Testing
13. Labeling
14. Establishing Beyond-Use Dates
15. Use of Conventionally Manufactured Products as Components
16. Use of CSPs as Components
17. SOPs
18. Quality Assurance and Quality Control
19. CSP Handling, Storage, Packaging, Shipping, and Transport
20. Documentation
21. Compounding Allergenic Extracts

- Glossary

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⟨797⟩ Intent

- Serve as the minimum standards for the preparation of compounded sterile preparations (CSPs) for human and animal drugs
- To minimize harm, including death, from:
  - Microbial contamination (nonsterility)
  - Excessive bacterial endotoxins
  - Variability from the intended strength of correct ingredients
  - Physical and chemical incompatibilities
  - Chemical and physical contaminants
  - Use of ingredients of inappropriate quality
- Requires aseptic techniques, processes, and procedures when preparing any sterile medication to minimize:
  - Contact with nonsterile surfaces
  - Introduction of particulate matter or biological fluids
  - Mix-ups with other products or CSPs

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⟨797⟩ Revisions

Administration is out of the scope of the chapter

- Sterile compounding is defined as:
  - Combining,
  - Admixing,
  - Diluting,
  - Pooling,
  - Reconstituting,
  - Repackaging, or
  - Otherwise altering a drug or bulk drug substance to create a sterile preparation

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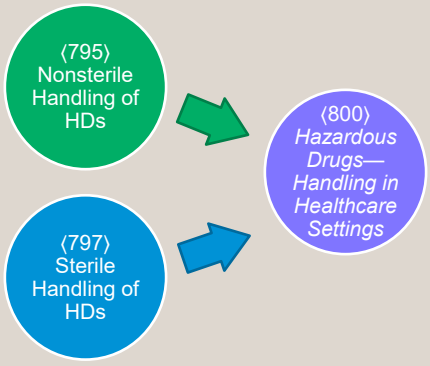
⟨797⟩ Revisions

Scope

- *Removes* provisions for handling of hazardous drugs
  - Compounded sterile hazardous drugs *are subject to* ⟨800⟩



- *Removes* provisions for radiopharmaceuticals
  - Compounding radiopharmaceuticals *are subject to* ⟨825⟩ *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*

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⟨797⟩ Revisions

Alternative Technologies

- The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited as long as they are noninferior to those described herein and validated for the intended purpose (eg, *Validation of Alternative Microbiological Methods* ⟨1223⟩ and *Validation of Compendial Procedures* ⟨1225⟩).

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⟨797⟩ Revisions

Immediate-Use CSPs

Requirements for Immediate-Use CSPs
Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (eg, approved labeling, stability and compatibility studies).
The preparation involves not more than 3 different sterile products.
Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
Administration begins within 4 hours following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-hour time period within which administration must begin.

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⟨797⟩ Revisions

Preparation Per Approved Labeling

- Clarifies that compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer
- Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is out of scope of this chapter only if:
  - The product is prepared as a single dose for an individual patient; and
  - The approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time
- Proprietary bag and vial systems
  - Docking and activation in accordance with the manufacturer's labeling for *immediate* administration to an individual patient is not considered compounding and may be performed outside of an ISO Class 5 environment
  - Docking for *future activation* and administration is considered compounding and must be performed in accordance with this chapter, with the exception of *14. Establishing Beyond-Use Dates*. BUDs for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling

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⟨797⟩ Revisions

Categories of CSPs

- High-Risk
- Medium-Risk
- Low-Risk
- Low-Risk With 12-Hour BUD

Category 1 CSPs	Category 2 CSPs	Category 3 CSPs
• Must be prepared in a PEC that may be located in an unclassified segregated compounding area • Assigned a BUD of ≤ 12 hours at controlled room temperature or ≤ 24 hours when refrigerated	• Must be prepared in a cleanroom suite • May be assigned a BUD of > 12 hours at controlled room temperature or > 24 hours if refrigerated	• Have additional requirements that must be met at all times • May be assigned a BUD longer than established for Category 2 CSPs, up to 180 days

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⟨797⟩ Revisions

Assigning Longer BUDs Than in the Chapter*

2008 Last Official Chapter	2015 Revision Proposed in *PF*	2018 Revision Proposed in *PF*	2019 Revision Published in *USP-NF* (subsequently remanded)	Revised Chapter
BUDs could be assigned up to the duration indicated by appropriate information sources for the same or similar formulations and by personal experience	The ability to assign longer BUDs was not described	BUDs could be assigned up to a maximum of 90 days if supported by stability data	BUDs could only be assigned up to the limits described in the chapter	Category 3 describes the requirements a compounding site must ensure at all times for assigning longer BUDs than those established for Category 2 CSPs, up to a maximum of 180 days

* If there is a compounded preparation monograph for a particular CSP formulation, the BUD in the monograph can be assigned if the CSP is prepared according to the monograph and all monograph requirements are met, including sterility testing.

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⟨797⟩ Revisions

Personnel Training and Evaluation

Knowledge and Competency of Core Skills

Garbing Competency Evaluation

- Visual observation
- Gloved fingertip and thumb sampling of both hands

Aseptic Manipulation Competency Evaluation

- Visual observation
- Media-fill testing
- Gloved fingertip and thumb sampling on both hands
- Surface sampling of the direct compounding area

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⟨797⟩ Revisions

Personnel Qualifications

	2008 Last Official Chapter	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	Revised Chapter
Visual observation of hand hygiene and garbing	Annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs
Gloved fingertip and thumb sampling	**Low/Medium-Risk CSPs:** Annually **High-Risk CSPs:** Semi-annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs as part of garbing competency and aseptic competency
Media-fill testing	**Low/Medium-Risk CSPs:** Annually **High-Risk CSPs:** Semi-annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs

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⟨797⟩ Revisions

Minimum Garbing Requirements

2008 Last Official Chapter	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	Revised Chapter
• Gown • Dedicated shoes or shoe covers • Head and facial hair covers • Face masks • Sterile gloves	Determined based on: • Category • Type of PEC Included: • Gown or coveralls • Disposable covers for shoes • Disposable covers for head and facial hair • Sterile gowns or sleeves • Sterile gloves	• Gown • Disposable covers for shoes • Disposable covers for head and facial hair • Face mask • Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves	• Gown • Disposable covers for shoes • Disposable covers for head and facial hair • Face mask • Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves	• Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (eg, gown or coverall) • Low-lint covers for shoes • Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair • Low-lint face mask • Sterile powder-free gloves • If using a RABS, (ie, a CAI or CACI), disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve

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⟨797⟩ Revisions

Minimum Garbing Requirements

Revised Chapter – Category 3
If the facility compounds Category 3 CSPs, additional garbing requirements must be continuously met in the buffer room in which Category 3 CSPs are prepared. The following additional garbing requirements must be followed in the buffer room where Category 3 CSPs are prepared for all personnel regardless of whether Category 3 CSPs are compounded on a given day: 1. Do not allow any exposed skin in the buffer room (ie, face and neck must be covered). 2. All low-lint outer garb must be sterile, including the use of sterile sleeves over gauntlet sleeves when a RABS is used. 3. Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle. 4. The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.

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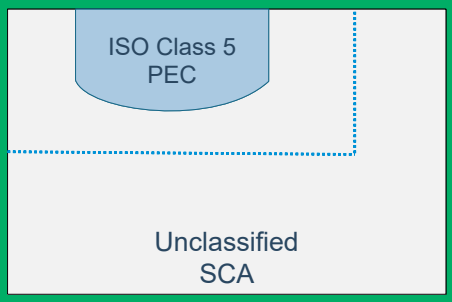
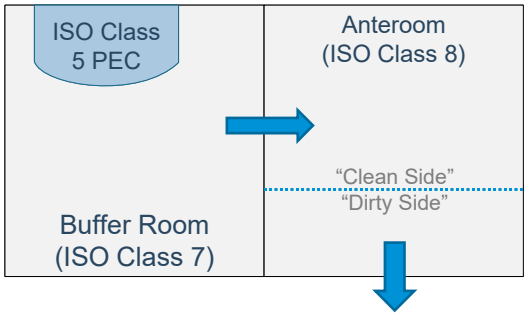
⟨797⟩ Revisions

Minimum PEC Placement

Category 1 CSPs



Category 2 or 3 CSPs



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⟨797⟩ Revisions

Certification and Recertification

- During dynamic operating conditions
- Required every 6 months
- Includes:
  - Airflow testing
  - HEPA filter integrity testing
  - Total particle count testing
  - Dynamic airflow smoke pattern test

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⟨797⟩ Revisions

Microbiological Air and Surface Monitoring

	2008 Last Official Chapter	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	Revised Chapter
Viable air sampling	Every 6 months	Monthly	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Monthly
Surface sampling	Periodically	Monthly	Monthly	Monthly	**Category 1 & 2:** Monthly **Category 3:** Weekly

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⟨797⟩ Revisions

Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA

- Frequencies specified for separate activities
  - Cleaning
  - Disinfecting
  - Applying a sporicidal disinfectant
- Cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads)
  - Must be low-lint
  - Should be disposable
  - Reusable cleaning tools must be dedicated for use

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⟨797⟩ Revisions

Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA

- Cleaning, disinfecting, and sporicidal agents used within the PEC must be sterile
- Cleaning and disinfecting supplies used in the PEC must be sterile with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC
- Reusable cleaning tools must be made of cleanable materials (eg, handles should not be made of wood or any other porous material) and must be cleaned and disinfected before and after each use

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Component Selection

- Conventionally manufactured sterile products should be used when available and appropriate for the intended CSP
- Active pharmaceutical ingredients:
  - Must comply with the criteria in the *USP–NF* monograph, if one exists
  - Must have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality
  - In the United States, must be manufactured by an FDA-registered facility
  - Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction
- Components other than APIs:
  - Must comply with the criteria in the *USP–NF* monograph, if one exists
  - Must be accompanied by documentation (eg, COA, labeling) that includes the specifications and test results and shows that the component meets the specifications
  - In the United States, should be manufactured by an FDA-registered facility
  - Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction

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Terminal Sterilization Methods and Aseptic Processing

- A CSP may be prepared by the following methods:
  - Terminal sterilization is the preferred method of sterilization
    - Steam
    - Dry heat
    - Irradiation

    Probability of a nonsterile unit (PNSU) of 10^{-6}
  - Aseptic processing
    - Compounding with only sterile starting ingredient(s), or
    - Compounding with nonsterile ingredient(s) followed by sterilization by filtration

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Master Formulation and Compounding Records

Master Formulation Record

- Required for
  - All CSPs prepared from nonsterile ingredient(s)
  - CSPs prepared for more than one patient

Compounding Record

- Required for
  - All Category 1, Category 2, and Category 3 CSPs
  - Immediate-use CSPs prepared for more than one patient
- May be in the form of a prescription or medication order or label
- May be stored electronically through an ACD, workflow management system, or other similar equipment
  - As long as it is retrievable and contains the required information

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Release Inspections and Testing

Visual Inspection

Sterility Testing

- Required for **Category 2** CSPs assigned a BUD that requires sterility testing, and for all **Category 3** CSPs
- **The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units**
- If the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in *USP* ⟨71⟩, *Table 3*, additional units must be compounded to perform sterility testing
  - If between 1 and 39 CSPs, test a number of units equal to 10% of CSPs prepared
  - If >40 CSPs, test based on *USP* ⟨71⟩, *Table 3*
- If an alternative method is used for sterility testing, the method must be validated (see ⟨1223⟩) and demonstrated to be suitable for that CSP formulation

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Release Inspections and Testing

Bacterial Endotoxins Testing

- Required for
  - **Category 2** injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing
  - **Category 3** injectable CSPs compounded from one or more nonsterile component(s)
- **Category 2** CSPs assigned a BUD that does not require sterility testing but compounded from one or more nonsterile component(s) **should** be tested

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Establishing Beyond-Use Dates

Quality factors

- Chemical and physical stability properties of the drug and/or its formulation
- Materials of composition of the container closure system and compatibility of the container closure system with the final preparation (eg, leachables, interactions, adsorption, and storage conditions)

Sterility factors

- Conditions of the environment in which the CSP is prepared
  - Cleanroom suite or SCA
- Aseptic processing and sterilization method
- Starting components
  - Sterile or nonsterile starting ingredients
- Whether or not sterility testing is performed
- Storage conditions
  - Packaging and temperature

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Category 1 CSP BUD Limits

Storage Conditions	
Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)
≤ 12 hours	≤ 24 hours

2008 Last official ⟨797⟩

Low-Risk Level CSP in SCA — **12 hours**

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Category 2 CSP BUD Limits

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days

2008 Last official ⟨797⟩

High-Risk Level CSPs	1 day	3 days	45 days

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Category 2 CSP BUD Limits

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days

2008 Last official ⟨797⟩

Medium-Risk Level CSPs	30 hours	9 days	45 days
Low-Risk Level CSPs	48 hours	14 days	45 days

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Category 2 CSP BUD Limits

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

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Category 3 CSP BUD Limits

Preparation Characteristics	Storage Conditions		
Compounding Method	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (-25°–10°)
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	60 days	90 days	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs	90 days	120 days	180 days

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Additional Requirements for Category 3 CSPs

- Category 3 CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for
  - Personnel qualification
  - Use of sterile garb
  - Frequency of applying sporicidal disinfectants
  - Frequency of environmental monitoring
  - Stability determination
- The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units

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Multiple-Dose CSPs

- A multiple-dose CSP must be prepared as a Category 2 or Category 3 CSP
- For preserved aqueous multiple-dose CSPs, antimicrobial effectiveness testing must be passed in accordance with *USP* ⟨51⟩
- Time within which multiple-dose preserved CSPs must be used:
  - Whichever is shorter:
    - BUD limit assigned based on if CSP is compounded as Category 2 or Category 3
    - Up to 28 days after container is initially entered or punctured, if supported by ⟨51⟩ testing
- Time within which multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs must be used:
  - BUD limit assigned based on if CSP is compounded as Category 2 or Category 3, and
  - Discarded 24 hours after first opening if stored at room temperature, or 72 hours if refrigerated

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⟨797⟩ Revisions

Use of Conventionally Manufactured Products as Components

- Addresses the time within which an entered or punctured conventionally manufactured product must be used

Type of Container	Time within which product must be used
Single-Dose Container	ISO Class 5 → 12 hours
Multiple-Dose Container	28 days
Pharmacy Bulk Package	As specified by the manufacturer

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Use of CSPs as Components

- Addresses the use of CSPs (eg, multiple-dose CSPs, single-dose CSPs, and compounded stock solutions) as components to prepare final CSPs

Type of Container	Time within which product must be used
Single-Dose CSP and CSP Stock Solution	ISO Class 5 → 12 hours
Multiple-Dose CSP	28 days

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Notification and Recall

- If a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to:
  - Immediately notify the prescriber
  - Recall any unused dispensed CSPs and quarantine any stock remaining
  - Investigate if other lots are affected and recall if necessary
- An SOP for recall must contain procedures:
  - To determine the severity and the urgency
  - To determine the distribution of any affected CSP
  - To identify patients who have received the CSP
  - For disposal and documentation of the recalled CSP
  - To investigate and document the reason for failure

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Compounding Allergenic Extracts

Licensed allergenic extracts:

- Section applicable only when:
  - The compounding process involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances; and
  - Manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials

Provisions include:

- Personnel Qualifications
  - Gloved fingertip and thumb sampling every 12 months
  - Media-fill testing every 12 months
- Facilities
  - ISO Class 5 PEC
  - Dedicated allergenic extract compounding area (AECA)
- Establishing BUDs
  - No later than the earliest expiration date of any component
  - Must not exceed 1 year
- Documentation
  - Compounding records

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Next Steps

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Next Steps

- The Compounding Expert Committee decided to delay the implementation of the revised chapters until November 1, 2023
- Sign up for updates to ⟨795⟩, ⟨797⟩, and other topics related to USP Healthcare Quality and Safety Standards
  - *https://www.usp.org/hqs-signup-form*
- Attend the Compounding Expert Committee's Official Meetings
  - *https://callforcandidates.usp.org/node/32481*

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Assessment Questions

1. When do USP standards become official?

A. As soon as they are published in the *Pharmacopeial Forum*

B. Generally, six months after being published in the *Pharmacopeial Forum*

C. As soon as they are published in the *USP–NF*

D. Generally, six months after being published in the *USP–NF*

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Assessment Questions

2. The current official version of USP ⟨797⟩ was last revised in

A. 2008

B. 2015

C. 2019

D. 2022

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Assessment Questions

3. Category 1 compounded sterile preparations (CSPs) in USP ⟨797⟩ are restricted to

A. Sterile to sterile compounding only

B. CSPs that are assigned a BUD of no more than 6 hours when stored at room temperature

C. CSPs that are assigned a BUD of no more than 24 hours when stored under refrigeration

D. Non-hazardous CSPs only

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Assessment Questions

4. Which of the following standards are available for compounders in the Compounding Compendium?

A. General Chapter ⟨795⟩ *Pharmaceutical Compounding – Nonsterile Preparations*

B. General Chapter ⟨797⟩ *Pharmaceutical Compounding – Sterile Preparations*

C. USP Compounded Preparation Monographs

D. All of the above

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Thank You

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Stay Connected

Sign up for updates: *https://www.usp.org/hqs-signup-form*

Email questions to CompoundingSL@USP.org

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Newly Approved Rules on Flavoring, in Promulgation

Connecticut
This language was approved by the Connecticut Board of Pharmacy in 2023 and is a reiteration of their existing rule.

- (c) The addition of a flavoring agent in accordance with subsections (a) and (b) of this section shall be exempt from the requirements established in subsections (a) to (m), inclusive, of section 20-633b, as amended by this act, any regulations adopted pursuant to subsection (o) of section 20-633b, as amended by this act, and United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding –Nonsterile Preparations, and Chapter 800, Hazardous Drugs, as both may be amended from time to time.

Nebraska
This language was approved by the Nebraska Board of Pharmacy in 2023 and is a reiteration of their existing rule.

- (4) Any authorized person splitting a scored tablet along scored lines or adding flavoring to a commercially available drug product is not engaged in compounding.

Tennessee
This language was approved by the Tennessee Board of Pharmacy in 2023 and is entirely new.

- (2) Solely adding flavoring to medications is not considered compounding. (3) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5. Authority: T.C.A. §§ 63-10-216, 63-10-304, and 63-10-30.

Vermont
This language was approved by the Vermont Board of Pharmacy in 2023 and is entirely new.

- Addition of flavoring agents to conventionally manufactured products is not considered compounding; provided that the flavoring agent is inert and does not alter the product's concentration beyond USP's accepted level of variance, and that the pharmacy labels the product with an expiration date and storage instructions consistent with any effect on stability caused by the addition of flavoring. The addition of flavoring must be documented as part of the prescription record, reconstitution log, or other similar documentation. The documentation shall include the agent's flavor, manufacturer, lot number, and expiration date.

STATE FLAVORING LANGUAGE CURRENT AS OF JUNE 2023

ARIZONA

https://pharmacy.az.gov/resources/substantive-policies

https://drive.google.com/file/d/11DHc9aSw8fkIosNjP_bAwlZY-wTJ4gBG/view

1. A pharmacist may add flavoring agents, up to a maximum of five (5) percent (%) of the total volume, to a prescription at the request of a patient, the patient's care-giver, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented and maintain electronic or manual documentation of the flavoring agent and quantity added. Documentation of beyond-use-dates longer than fourteen days, including the flavoring agent and quantity added, shall be maintained by the pharmacy electronically or manually and made available to agents of the Board on request.

2. The addition of flavoring agents over five (5) percent (%) of the total volume to a prescription requires the permission of the prescriber and compliance with the requirements of the Current Good Compounding Practices rule (A.A.C. R4-23-410).

3. A pharmacist may not add flavoring to an over-the-counter product at the request of a patient or patient's care-giver unless the pharmacist first obtains a prescription for the over-the-counter product from the patient's

CALIFORNIA

https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf

Article 4.5 Compounding 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.

COLORADO

https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=9470&fileName=3%20CCR%2071 9-1

3.00.55 Prescription Flavoring. A flavor additive may be incorporated into a non-sterile prescription under the following conditions: a. The patient, patient's caregiver, or practitioner who authorized the original prescription shall authorize the flavoring of each new and, if applicable, refilled prescription; b. The flavor additive shall in no way compromise the stability, safety, or efficacy of the dispensed drug. c. No expired flavor additive shall be incorporated into a prescription. No flavor additive shall be incorporated which will expire prior to utilization by the patient, based on the practitioner's directions for use. d. For flavoring additives that do not have expiration dates assigned by the manufacturer or supplier, a pharmacist shall clearly and legibly label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the flavoring additive. In no

event shall the labeled date of receipt or assigned expiration date be later altered after originally labeling the container. e. The following information shall be recorded and maintained in a suitable hard-copy or electronic dispensing record for a period of two years from the date of flavoring the corresponding new or refilled prescription. This record shall be made available, in printed form, for the Board or its representatives immediately upon the request of the Board or its representatives. 1) Additive's flavor; 2) Flavor additive's manufacturer 3) Flavor additive's lot number (if available); and 4) Flavor additive's expiration date. f. The pharmacist responsible for conducting the final evaluation of a new or refilled prescription shall also be responsible for the flavoring of the prescription as specified in subsections a., b., and c. of this Rule 3.00.55. g. The pharmacist manager shall be responsible for subsection d. of this Rule 3.00.55 and the maintenance of records as specified in subsection e. of this Rule 3.00.55.

CONNECTICUT

https://www.cga.ct.gov/current/pub/chap_400j.htm#sec_20-617a

Sec. 20-617a. Flavoring agent added to prescription product. (a) For purposes of this section, "flavoring agent" means an additive used in food or drugs when such additive: (1) Is used in accordance with good manufacturing practice principles and in the minimum quantity required to produce its intended effect, (2) consists of one or more ingredients generally recognized as safe in food and drugs, has been previously sanctioned for use in food and drugs by the state or the federal government, meets United States Pharmacopeia standards or is an additive permitted for direct addition to food for human consumption pursuant to 21 CFR 172, (3) is inert and produces no effect other than the instillation or modification of flavor, and (4) is not greater than five per cent of the total weight of the product.

(b) A flavoring agent may be added to a prescription product by: (1) A pharmacist upon the request of the prescribing practitioner, patient for whom the prescription is ordered or such patient's agent, or (2) a pharmacist acting on behalf of a hospital, as defined in section 19a-490.

(P.A. 12-12, S. 1.)

IDAHO

https://bop.idaho.gov/wp-content/uploads/2021/08/Idaho_Pharmacy_Laws_Unofficial_Copy.pdf

700. COMPOUNDING DRUG PREPARATIONS. Any compounding that is not permitted herein is considered manufacturing. (7-1-21)T 01. Application. This rule applies to any person, including any business entity, authorized to engage in the practice of non-sterile compounding, sterile compounding, and sterile prepackaging of drug products in or into Idaho, except these rules do not apply to: (7-1-21)T a. Compound positron emission tomography drugs; (7-1-21)T b. Radiopharmaceutics; (7-1-21)T c. The reconstitution of a non-sterile drug or a sterile drug for immediate administration; (7-1-21)T d. The addition of a flavoring agent to a drug product; and (7-1-21)T e. Product preparation of a non-sterile, non-hazardous drug according to the manufacturer's FDA approved labeling. (7-1-21)T

STATE FLAVORING LANGUAGE CURRENT AS OF JUNE 2023

ILLINOIS

https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1318&ChapterID=24

(o) "Compounding" means the preparation and mixing of components, excluding flavorings, (1) as the result of a prescriber's prescription drug order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice or (2) for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing.

IOWA

https://www.legis.iowa.gov/docs/iac/chapter/657.20.pdf

Compounding does not include the use of a flavoring agent to flavor a drug pursuant to rule 657—20.13(124,126,155A), nor does it include mixing or reconstituting a drug according to the product's manufacturer label.

"Flavoring agent" means a therapeutically inert, nonallergenic substance consisting of inactive ingredients that is added to a drug to improve the drug's taste and palatability.

657—20.13(124,126,155A) Use of flavoring agents. A flavoring agent may be added to a drug at the discretion of the pharmacist or upon the request of the prescriber, the patient, or the patient's agent. The pharmacist may add flavoring agents not to exceed 5 percent of the total volume of the drug to which the flavoring agents are added. The pharmacist shall label the flavored drug with a beyond-use date no greater than 14 days past the date the flavoring agent is added if the drug is required to be stored in a refrigerator. A different beyond-use date or alternate storage conditions may be indicated if such variation is supported by peer-reviewed medical literature. The pharmacist shall electronically or manually document that a flavoring agent was added to a drug, and such documentation shall be made available for inspection and copying upon the request of the board or an agent of the board.

KENTUCKY

https://apps.legislature.ky.gov/law/kar/201/002/076.pdf

201 KAR 2:076. Compounding.

Section 2. (1) All non-sterile compounded preparations shall be compounded pursuant to United States Pharmacopeia (USP) 795, unless specified portions submitted by a pharmacist have been waived by the board. Notwithstanding any USP guidance to the contrary, the addition of flavoring to a drug shall not be considered non-sterile compounding, if the additive:

(a) Is inert, nonallergenic, and produces no effect other than the instillation or modification of flavor; and (b) Is not greater than five (5) percent of the drug product's total volume.

STATE FLAVORING LANGUAGE CURRENT AS OF JUNE 2023

LOUISIANA

http://www.pharmacy.la.gov/assets/docs/GuidanceDocuments/PPM_I.A.31_AdditionFlavorsMedications_2019-1113.pdf

Louisiana Board of Pharmacy Policies & Procedures

Title: Addition of Flavors to Medications- Policy No. I.A.31

Resolved, that the Board adopt an enforcement policy, such that the addition of nonallergenic and inert flavoring agents to commercially available liquid oral products resulting in a change in the final product volume of less than 5% shall not require a prescriber's order or a full compounding log.

MASSACHUSSETTS

Flavoring agents added to commercially available products must be documented as part of the prescription record, reconstitution log, or other similar documentation.

In the case of any flavoring agent(s) added to conventionally manufactured non-sterile drug products, the compounding record may also serve as the master formulation record. The following information must be documented and be readily retrievable:

- date of preparation;
- prescription number;
- name, vendor / manufacturer / NDC, lot number, and expiration date of each component;
- all relevant calculations and quantities/volumes of additives (e.g., water, flavoring agent(s), etc.);
- BUD and storage requirements; and
- identifier (e.g., name, initials, etc.) of individual who prepared the product (e.g., reconstitution, etc.).

MICHIGAN

https://www.michigan.gov/-/media/Project/Websites/lara/bpl/Folder41/4-8-2020_Pharmacy_Full_Approved_Minutes_with_attachments.pdf?rev=1895ca8fd73348c88042c19076c7234d

(e) "Compounding" does not include any of the following: (i) Except as provided in section 17748c of the code, MCL 333.17748c, the compounding of a drug product that is essentially a copy of a commercially available product. (ii) The reconstitution, mixing, or other similar act that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product. (iii) The compounding of allergenic extracts or biologic products. (iv) Flavoring agents added to conventionally manufactured and commercially available liquid medications. Flavoring agents must be nonallergenic and inert, not exceeding 5% of a drug product's total volume.

STATE FLAVORING LANGUAGE CURRENT AS OF JUNE 2023

MISSISSIPPI

https://www.sos.ms.gov/adminsearch/ACProposed/00024335b.pdf

C. For the purpose of this Article, the combining of commercially manufactured, ready to-use products shall be exempt from USP 795 compounding standards under the following conditions: i. No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used; ii. All products used are FDA approved; iii. Compounding is not done in anticipation of medication orders; iv. Must follow USP 795 beyond use dates (BUDs); v. A valid prescription shall serve as the compounding record; vi. The prescription label shall comply with the labeling requirements as set forth in Article XIV of these regulations and also include: (1) Name of Preparation; (2) Strength and concentration of each component; 2 (3) Beyond Use Date; (4) Special storage requirements, if applicable; and (5) Cautionary auxiliary labels, if applicable.

MISSOURI

https://pr.mo.gov/boards/pharmacy/practiceguide.pdf

H.12 FLAVORING

Licensees may flavor a legend product unless the prescriber indicates otherwise. OTC products may only be flavored by prescription. Licensees should indicate that the product was flavored on the patient's container and the added flavoring must be documented in the pharmacy's prescription record (e.g., in a flavoring book or in the prescription record). As defined by the Board's rules, flavoring does not constitute compounding. Licensees may not flavor a prescription dispensed by another pharmacy.

NEBRASKA

https://nebraskalegislature.gov/laws/statutes.php?statute=38-2867.01

(4) Any authorized person splitting a scored tablet along scored lines or adding flavoring to a commercially available drug product is not engaged in compounding.

NEW HAMPSHIRE

http://www.gencourt.state.nh.us/rsa/html/XXX/318/318-mrg.htm

"Compounding" shall not include the reconstitution of powdered formulations before dispensing or the addition of flavoring. "Compounding" shall not include the simple addition of flavoring, nor shall it include the preparation of a single dose of a nonhazardous commercially available drug or licensed biologic for administration within 2 hours of preparation to an individual patient when done in accordance with the manufacturer's approved labeling or instructions consistent with that labeling.

NEW JERSEY

https://www.njconsumeraffairs.gov/regulations/Chapter-39-State-Board-of-Pharmacy.pdf

c) A compounding record shall not be required for:

1) Mixing, reconstituting, or assembling a drug according to the product's labeling or the manufacturer's directions; and

2) Product flavoring.

NORTH CAROLINA

http://www.ncbop.org/faqs/pharmacist/faq_NEWUSP795.htm

Adding flavoring to Conventionally Manufactured Products

Q. Is adding flavoring to a conventionally manufactured product considered compounding?

A. USP considers adding flavoring to a conventionally manufactured product to fall within the scope of compounding, because there are known instances when flavoring components have destabilized a product. If a pharmacy adds flavoring to a manufactured product it must take into account the manufacturer's Beyond Use Date (BUD) and the effect on stability caused by adding flavoring. If a flavoring component is added to a manufactured product that does not contain a preservative (e.g.: reconstitution of amoxicillin oral suspension) the BUD is 14 days refrigerated or shorter if indicated in the manufacturer's labeling. If a flavoring component is added to a manufactured product that contains a preservative (e.g. pyridostigmine oral solution), then the BUD is 35 days in controlled room temperature or refrigerated or shorter if indicated in the manufacturer's labeling. The addition of flavoring including the flavor manufacturer or product, lot number, and expiration date must be documented in the patient record notes for the prescription.

OHIO

https://codes.ohio.gov/ohio-administrative-code/rule-4729:7-2-01

A pharmacy engaged in the following shall not be required to comply with the provisions of this chapter:

(1) The preparation of non-hazardous, conventionally manufactured non-sterile products in accordance with the directions contained in the approved labeling provided by the product's manufacturer. A pharmacist shall perform the final check of the product.

(2) The preparation of radiopharmaceuticals as defined in agency 4729 of the Administrative Code.

(3) Sterile compounded drug preparations in accordance with rule 4729:7-2-02 of the Administrative Code.

(4) The addition of a flavoring agent to a conventionally manufactured drug product.

PENNSYLVANIA

https://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Pharmacy/Pages/default.aspx

At the October 22, 2019 Pennsylvania State Board of Pharmacy (Board) Meeting, the Board discussed issues related to USP's decision to delay implementation of the revisions to chapters 795 and 797 pending resolution of appeals. The following decisions were approved by the Board and placed on record:

1. The Board is enforcing USP 795 and 797 as *currently* written. Board Regulation Section 27.601 was finalized on June 22, 2019 and requires compliance with section 503a of the federal Food,

Drug and Cosmetic Act, federal regulations promulgated thereunder and the *current* version of the USP chapters governing compounding.

2. The Board is delaying the enforcement of USP 800 until the appeals of certain provisions of the revised USP 795 and 797 are resolved. While enforcement of USP 800 is being delayed, pharmacies should do their best to comply with the requirements of USP 800, including the sections related to the handling of hazardous medications, as these requirements will be enforced at some time in the future, dependent on resolution of the appeals of the revised USP 795 and 797.
3. The Board voted to adopt the following position and will be amending its regulations to reflect this information:

The definition of "compounding" does not include the unencumbered flavoring of conventionally manufactured medications provided that the flavors used are inert, tested and do not alter a medication's concentration beyond USP's accepted level of variance.

SOUTH CAROLINA

https://llr.sc.gov/bop/PFORMS/InspectionForms/Non-Sterile%20Compounding%20Pharmacy.pdf

Simple compounding that does not precipitate the application of this form include: 1) Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer; 2) Making twenty or less compounds of an oral liquid or topical dosage form utilizing five or less non-hazardous APIs over any 30 day period (not exempt from 40-43-86(CC)(6), "Formulas and Logs Maintained").

SOUTH DAKOTA

https://doh.sd.gov/boards/pharmacy/minutes/9-12-19minutes.pdf

USP <795>; USP <797>; USP <800>: Tyler Laetsch, Pharm.D., Pharmacy Inspector

• USP 795 and USP 797 published June 1, 2019 for go live date of December 1, 2019.

• USP 795 clarifications – Flavoring antibiotic suspensions is not compounding, simple reconstitution of antibiotics with water is not compounding; however, combining two creams or preparing a magic mouthwash is compounding and USP 795 must be followed including the restriction for carpet in the compounding area (Board may propose to allow extra time for compliance) and the BUD changes

TEXAS

https://www.pharmacy.texas.gov/files_pdf/TSBP%20Rules_MASTER%20FILE.pdf

(H) A pharmacist may add flavoring to a prescription at the request of a patient, the patient's agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented. Documentation of

beyond-use-dates longer than fourteen days shall be maintained by the pharmacy electronically or manually and made available to agents of the board on request. A pharmacist may not add flavoring to an over-the-counter product at the request of a patient or patient's agent unless the pharmacist obtains a prescription for the over-the-counter product from the patient's practitioner.

UTAH

https://rules.utah.gov/wp-content/uploads/r156-17b.pdf

Flavoring Rule Utah Admin Code R156-17b-102

(13) "Compounding," as defined in Subsection 58-17b-102(18), in accordance with 21 U.S.C. 353a(e) Pharmacy Compounding, does not include:

(a) mixing, reconstituting, or other such acts that are performed in accordance with directions in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling; or

(b) the addition of flavoring agents to conventionally manufactured and commercially prepared available liquid medications, if the flavoring agents:

(i) are therapeutically inert; and

(ii) do not exceed 5% of a preparation's total volume.

WEST VIRGINIA

https://casetext.com/regulation/west-virginia-administrative-code/agency-15-pharmacy/title-15-legislative-rule-board-of-pharmacy/series-15-01-licensure-and-practice-of-pharmacy/section-15-1-2-definitions

2.1.7.c. The following are not "compounding" and are exempt from USP 795 Compounding Standards:

2.1.7.c.1. the reconstitution of a drug pursuant to a manufacturer's directions;

2.1.7.c.2. the act of tablet splitting, crushing, or capsule opening, including those hazardous medications listed in NIOSH List Tables 2 and 3;

2.1.7.c.3. upon the request of the prescribing practitioner and/or the patient for whom the prescription is ordered or such patient's agent, the addition of therapeutically inert, nonallergenic flavoring agents to a commercially manufactured product, not in excess of five percent (5%) of the preparation's total volume;

WYOMING

https://wyoleg.gov/arules/2012/rules/ARR18-098P.pdf

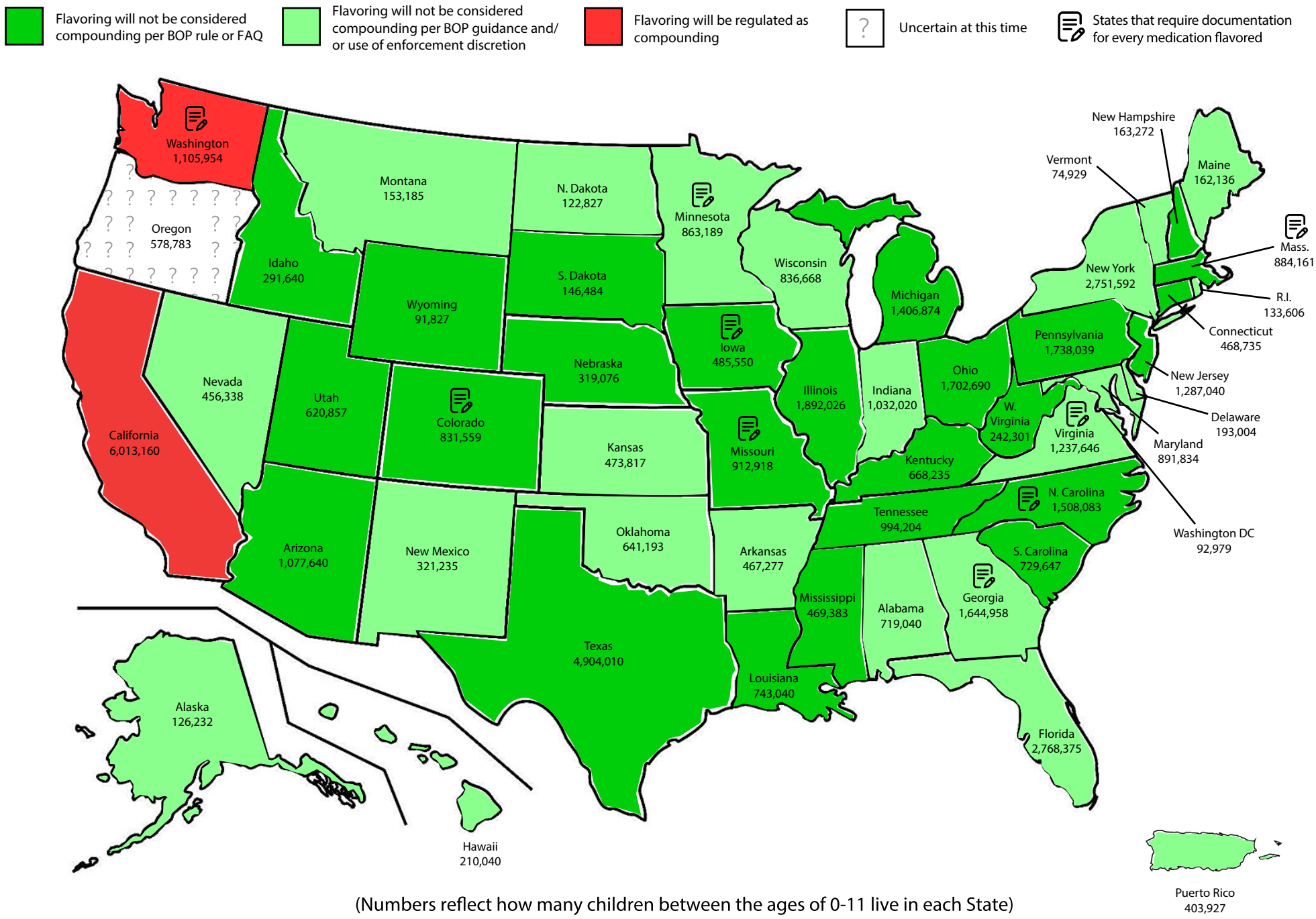
Compounding does not include mixing, reconstituting, adding flavoring or other such

acts that are performed in accordance with directions contained in approved labeling provided

by the product’s manufacturer and other manufacturer directions consistent with the labeling.

ANTICIPATED **BOARD OF PHARMACY POSITIONS** TOWARDS **FLAVORING** ON NOVEMBER 1, 2023

(STATUS AS OF May 31, 2023)



(Numbers reflect how many children between the ages of 0-11 live in each State)

Data Source: Population Division, U.S. Census Bureau

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Pharmacy Examining Board to amend Phar 1.01, 1.02 (intro), 1.02 (Note), 7.07 (2), 7.14 (2), (2) (b), (2) (c) 3. and 6., (2) (d) 1. and 2., (2) (e), (3) (a) and (b), (4) (a), (b), (c), and (d), (5), (6) (a) 1. and 2, 7.43 (7), ch. Phar 7 subch. V (title), 7.62 (title), (1), (2), (3) (intro.), (5), (6), and (7), 10.03 (2), (17), and (19); create Phar 1.01 (11m), 5.07, 7.60 (intro.) and (3), and ch. Phar 19; and repeal Phar 7.14 (2) and 7.62 (3) (a) to (d), relating to registration of pharmacy technicians.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.68, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), (d), and (e). Stats

Explanation of agency authority:
Section 15.08 (5) (b), Stats. states that "The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.02 (3) (a), Stats. allows the board to "promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

Section 450.02 (3) (d), Stats. says that the board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

Section 450.02 (3) (e), Stats. provides that the board "may promulgate rules establishing minimum standards for the practice of pharmacy."

Related statute or rule: 2021 Wisconsin Act 100

Plain language analysis: The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 100.

Summary of, and comparison with, existing or proposed federal regulation: The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains requirements for licensure of registered pharmacy technicians, as well as for pharmacists and pharmacies. Registered pharmacy technicians in Illinois have to be at least 16 years old, is attending or has graduated from high school or has a high school equivalency certificate and must complete the requirements to become a licensed registered certified pharmacy technician. A licensed registered certified pharmacy technician must be at least 18 and as of January 1, 2024, have graduated from a pharmacy technician training program or obtained documentation from the pharmacist-in-charge at the pharmacy where they are employed that they have successfully completed a nationally accredited training program. [225 Illinois Complied Statutes ch. 85 s. 9 and 9.5]. The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include application requirements for both registered and registered certified pharmacy technicians, as well as rules for their training and education [Illinois Administrative Code s. 1330.200-1330.220].

Iowa: **Iowa**: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. Title IV Chapter 155A of the Iowa Code includes the statutory requirements for pharmacy technician registration, licensure of pharmacists and pharmacies, and prescription drug orders, among other requirements. In Iowa pharmacy technicians must register with the Iowa Board and the responsibility for their actions is with the licensed pharmacist who is supervising them [Iowa Code ch.155A s.6A]. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and also include requirements for pharmacy technicians. Among those requirements, the chapter includes registration procedures, training, delegation and practice, national certification, as well as unethical conduct and discipline [657 Iowa Administrative Code ch. 3].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for pharmacy in Michigan, among several other occupations. Also included in those regulations are the statutory requirements for licensure and practice of pharmacy technicians. [Michigan Compiled Laws s. 333.17739]. The Michigan Administrative Rules also include requirements for pharmacy technicians administered by the Michigan Department of Licensing and Regulatory Affairs in conjunction with the Michigan Board. These rules include licensure, examination, training, and approved education program requirements for pharmacy technicians [Michigan Administrative Rules R 338.3561-338.3665].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes the regulations for pharmacy in Minnesota. These rules include requirements for pharmacy technician registration, education, training, and supervision [Minnesota Administrative Rules part 6800.3850]. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes pharmacy regulations and requirements for pharmacy technicians. This statute specifically clarifies the nature of the supervisory relationship of the pharmacist to the technician, as well as how many technicians each individual pharmacist may supervise. [Minnesota Statutes 151.102].

Summary of factual data and analytical methodologies:
The Board reviewed the statutory changes from 2021 Wisconsin Act 100 and updated or created Wisconsin Administrative Code Chapters Phar 1, 5, 7, 10 and 19 accordingly.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule will be posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission: Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 1.01, 1.02 (intro.), and 1.02 (Note) are amended to read:

Phar 1.01 Authority. Rules in chs. Phar 1 to ~~17~~19 are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats, and ch. 450, Stats.

Phar 1.02 (intro.) As used in ch. Par 1 to ~~17~~19.

Phar 1.02 (Note) The board office is located at ~~1400 East Washington Avenue~~ 4822 Madison Yards Way Madison, WI ~~53707~~53705.

SECTION 2. Phar 1.01 (11m) is created to read:

Phar 1.01 (11m) "Pharmacy technician" means a person registered by the board under s. 450.068, Stats.

SECTION 3. Phar 5.07 is created to read:

Phar 5.07 Pharmacy Technicians. (1) All requirements for renewal and reinstatement of a pharmacy technician registration are specified in chapter Phar 19. **(2)** No pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is eligible to be registered as a pharmacy technician.

SECTION 4. Phar 7.07 (2); 7.14 (title); 7.14 (1) (a), (b) and (d); and 7.14 (2) are amended to read:

Phar 7.07 (2) For all prescription drug product or device dispensing, the prescription record shall identify the pharmacist responsible for each part of the final check. If sub. (1) (a) or (b) is completed by ~~delegate-check-delegate~~ pharmacy product verification technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the ~~delegate~~ pharmacy product verification technician performing the check.

Phar 7.14 (title) ~~Delegate-check-Delegate~~ Pharmacy Product Verification Technician-check-Pharmacy Technician.

Phar 7.14 (1) (a) "~~Delegate~~ Pharmacy product verification technician" means a ~~person~~ registered pharmacy technician to whom the pharmacist has delegated the task of product verification.

Phar 7.14 (1) (b) "~~Delegate-check-delegate~~ Pharmacy product verification technician-check- pharmacy technician" means the process in which ~~one delegate~~ a pharmacy product verification technician conducts the task of product verification of technical dispensing functions completed by ~~an unlicensed individual~~ a pharmacy technician. A ~~delegate~~ pharmacy product verification technician may not conduct product verification as part of the final check of their own product preparation.

Phar 7.14 (1) (d) ""Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a ~~delegate~~ pharmacy product verification technician and ensuring for direct supervision of the ~~delegate~~ pharmacy product verification technician.

Phar 7.14 (2) ~~DELEGATE~~ PHARMACY PRODUCT VERIFICATION TECHNICIAN QUALIFICATIONS. A
pharmacist may delegate the product verification of a prescription or chart order to a ~~delegate~~ pharmacy technician who meets all of the following:

SECTION 5. Phar 7.14 (2) (a) is repealed.

SECTION 6. Phar 7.14 (2) (b), (2) (c) 3. and 6., (2) (d) 1. and 2., and (2) (e); 7.14 (3) (a) and (b); 7.14 (4) (a), (b), (b) 1., (c), and (d); 7.14 (5); and 7.14 (6) (a) 1. and 2. are amended to read:

Phar 7.14 (2) (b) Completed an accredited pharmacy technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

Phar 7.14 (2) (c) 3. Eligible ~~medications~~ products for ~~delegate-check-delegate~~ pharmacy product verification technician-check-pharmacy technician.

Phar 7.14 (2) (c) 6. A practical training designed to assess the competency of the ~~delegate~~ pharmacy technician prior to starting the validation process. The practical training shall include simulation of at least 2 occurrences of each of the following:

Phar 7.14 (2) (d) 1. The ~~delegate~~ pharmacy technician being validated shall make a product verification on the work of a pharmacist or ~~unlicensed person~~ another pharmacy technician for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.

Phar 7.14 (2) (d) 2. A pharmacist shall audit 100% of the product verifications made by the ~~delegate~~ pharmacy technician during the validation process.

Phar 7.14 (2) (e) Notwithstanding pars. ~~(a)~~ (b) to (d), ~~a delegate~~ an individual who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the ~~delegation~~ pharmacy product verification technician qualifications unless the ~~delegate~~ individual fails to meet the quality assurance standards under sub. (4).

Phar 7.14 (3) (a) *Institutional pharmacies.* The ~~delegate~~ pharmacy product verification technician may do the product verification in an institutional pharmacy if all of the following requirements are met:

Phar 7.14 (3) (b) *Community pharmacies.* The ~~delegate~~ pharmacy product verification technician may do the product verification in a community pharmacy if all of the following requirements are met:

Phar 7.14 (4) (a) A minimum of 5% of each ~~delegate's~~ pharmacy product verification technician's verifications shall be audited by a licensed pharmacist. The accuracy of each ~~delegate~~ pharmacy product verification technician shall be tracked individually.

Phar 7.14 (4) (b) A record of each ~~delegate-check-delegate~~ pharmacy product verification technician-check-pharmacy technician audit shall include all of the following:

Phar 7.14 (4) (b) 1. Name of the pharmacy product verification ~~delegate~~ technician.

Phar 7.14 (4) (c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each ~~delegate~~'s pharmacy product verification technician's previous 12 months accuracy and correctness of ~~delegate-check-delegate~~ pharmacy product verifications including a review of the quality assurance log.

Phar7.14 (4) (d) A ~~delegate~~ pharmacy product verification technician shall be revalidated if the ~~delegate~~ individual fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed ~~delegate- check-delegate product~~ verifications within the last 6 months.

Phar 7.14 (5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the ~~delegate-check-delegate~~ pharmacy product verification by technicians which shall be made available to the board upon request.

Phar 7.14 (6) (a) 1. All validation records of each ~~delegate~~ pharmacy product verification technician that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

Phar 7.14 (6) (a) 2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising ~~delegate-check-~~ ~~delegate~~ pharmacist, indicating the name of the supervising ~~delegate-check-delegate~~ pharmacist, and the dates the supervision responsibilities begin and end.

SECTION 7. Phar 7.43 (7) is amended to read:

Phar 7.43 (7) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), (gm), or (i), Stats., shall meet the following requirements to remote dispense:

SECTION 8. chapter Phar 7 subchapter V (title) is amended to read:

Subchapter V – Unlicensed ~~Persons~~ Pharmacy Staff

SECTION 9. Phar 7.60 (intro) and (3) are created to read:

Phar 7.60 Definitions. In this subchapter:

Phar 7.60 (3) "Pharmacy staff" means any staff practicing in the pharmacy who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats.

SECTION 10. Phar 7.62 (title), (1), (2), (3), (3) (intro.) are amended to read:

Phar 7.62 (title) Unlicensed ~~persons~~ Pharmacy staff.

Phar 7.62 (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f), (g) or (gm), Stats.

Phar 7.62 (2) A pharmacist shall provide ~~general~~ direct supervision of unlicensed ~~personnel~~ pharmacy staff. A pharmacist shall be available to the unlicensed pharmacy staff person for consultation either in person or contact by telecommunication means.

Phar 7.62 (3) An unlicensed pharmacy staff person may not ~~do any of the following:~~ engage in the practice of pharmacy as defined in s. 450.01 (16), Stats., or the practice of a pharmacy technician as defined in Phar 19.02.

SECTION 11. Phar 7.62 (3) (a) to (d) are repealed.

SECTION 12. Phar 7.62 (5), (6), and (7) are amended to read:

Phar 7.62 (5) A managing pharmacist shall provide training to or verify competency of an unlicensed pharmacy staff person prior to the unlicensed pharmacy staff person performing a delegated act.

Commented [HND1]: Public Comment (DeBisschop): "Throughout Phar, where technicians are intended to be included, I ask the board to consider including not just 450.03(1)(gm) – which is techs who have applied but before registration granted – but also 450.03(1)(e), which is where the authority for pharmacy technicians is located in this section."

Public Comment (PSW): "This section refers to who can remote dispense; it does not currently include pharmacy technicians as written. This may be an oversight, as those who have applied to be a technician are included, and the new remote dispensing rules allow technicians to remote dispense. We recommend that those practicing under ... [1]

Commented [HND2]: Public Comment (DeBisschop): "Suggest creating a separate section for those practicing under 450.03(1)(f), (g), and as interns under Phar 17.02(4), to be as clear as possible regarding their supervision and roles. I realize that technicians are the focus, but, as written, it is difficult to distinguish students' and interns' roles, authority, and supervision from technicians."

Commented [HND3]: Public Comment (DeBisschop): "Phar 7.60(3) defining pharmacy staff is confusing, as it defines this as "any staff practicing in the pharmacy who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats." This is confusing since those practicing pharmacy under these statutes are not licensed or registered."

Public Comment (PSW): Suggested language - ... [2]

Commented [HND4]: Public Comment (DeBisschop): "I ask the board to consider defining "unlicensed pharmacy staff" (or a similar term) to be as clear as possible and exclude all who are intended to be excluded. To my understanding, these are supposed to be cashiers, clerks, drivers, and others who are not trained or delegated any pharmacy practice acts. Technicians are "unlicensed," and not excluded in Phar 7.60(3), yet it appears they are ... [3]

Commented [NH5]: Public Comment (DeBisschop): "consider adding interns as defined in Phar 17.02(4) to the statement in Phar 7.62(1) for greater clarity"
"P3/4 students who are working in a pharmacy outside of pharmacy school are covered in 7.62(1)."
"P1/2 students who are working in a pharmacy outside of pharmacy school are not covered explicitly and currently must register as technicians under these rules. " ... [4]

Commented [HND6]: Public Comment (DeBisschop): "I ask the board to consider ensuring definitions of general and direct supervision are applicable to all of Phar 7 and any other chapters necessary."

Commented [HND7]: Public Comment (DeBisschop): "I ask the board to **consider including delivery of a drug or device to a patient as a permitted task for pharmacy staff**. Currently under the Emergency Rule, this remains within the "practice of pharmacy" defined in 450.01(16); thus, as staff may not practice pharmacy, they may not deliver or transfer a drug to another. This would imply that anyone handing another person a drug (like a cashier o ... [5]

Phar 7.62 (6) The managing pharmacist shall determine which acts may be delegated in a pharmacy. The managing pharmacist has a duty to notify all pharmacists practicing in that pharmacy which acts may be delegated to specific unlicensed ~~persons~~ pharmacy staff. This record shall be provided to the board upon request.

Phar 7.62 (7) A pharmacist may delegate to an unlicensed pharmacy staff person any delegated act approved by the managing pharmacist pursuant to sub. (3).

SECTION 13. Phar 10.03 (2), (17), and (19) are amended to read:

Phar 10.03 (2) Engaging in any pharmacy practice which constitutes a danger to the health, welfare, or safety of patient or public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist or pharmacy technician which harmed or could have harmed a patient;

Phar 10.03 (17) Having a pharmacist license or pharmacy technician registration revoked or suspended in another state or United States jurisdiction or having been subject to other disciplinary action by the licensing authority thereof;

Phar 10.03 (19) Practicing without a current license or registration.

SECTION 14. Chapter Phar 19 is created to read:

Chapter Phar 19
REGISTRATION OF PHARMACY TECHNICIANS

Phar 19.01 Registration. (1) No person may engage in the practice of a pharmacy technician or use the title "pharmacy technician" or "pharmacy tech" unless the person is registered as a pharmacy technician by the Board.

(2) A person applying for a pharmacy technician registration shall satisfy all of the following:

(a) Submit a completed application form.

Note: Instructions for applications are available on the department of safety and professional services' website at http://dsps.wi.gov.

(b) Pay the fee determined by the Department under s. 440.05 (1), Stats.

(c) Subject to ss. 111.321, 111.322, and 111.335, stats., the applicant does not have an arrest or conviction record.

(d) The applicant satisfies one of the following:

1. Is at least 18 years of age and has graduated from high school or has attained high school graduation equivalency as determined by the department of public instruction.

2. Is enrolled in a youth apprenticeship program for pharmacy technicians

Commented [HND8]: Public Comment (DeBisschop): "I request to consider explicitly stating in Phar 19 that registered technicians can operate under general supervision."
"In some cases, it appears that P1s and P2s on rotation in pharmacy school can be under general (Phar 17), in others direct (EmR, Phar 7.62 (2). Can this be clarified?"
"Regarding the communication modes used during supervision – Phar 7.62(2) allows in person or through telecommunication means for direct supervision. Its implied this is permitted for general supervision through remote dispensing site regulations. I ask the board to clarify if both means of communication could be used for both types of supervision at any time, or only with certain roles or tasks."
"Phar 7.62 (5)-(7) provides rules for managing pharmacist training, delegating, and verifying competency of tasks for pharmacy staff. I ask the board to consider doing the same for registered technicians in Phar 19."

Public Comment (PSW): "Given that the law intends to register pharmacy technicians, not students completing practicum hours that may or may not be counted toward the internship requirement, we would request that the rule is clear that all student pharmacists are exempt from the requirement to register as a pharmacy technician. "

that is on the list of youth apprenticeship programs approved by the department of workforce development under s. 106.13 (2m), Stats.

(3) A person who has applied for a registration as a pharmacy technician and whose practice as a pharmacy technician is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board and during the period before which the board takes final action on the persons application may practice as a pharmacy technician.

Phar 19.02 Scope of Practice. A pharmacy technician may administer vaccines as authorized under s. 450.035 (2h), Stats., perform technical dispensing functions, compounding, packaging, labeling and storage, pharmacy and inventory management, and other activities involved in the practice of pharmacy delegated by a pharmacist. A pharmacy technician may not perform any of the following:

(1) Except as allowed under Phar 7.14, provide the final verification for the accuracy, validity, completeness, or appropriateness of the filled prescription or medication order.
(2) Complete the drug utilization review under s. Phar 7.03.
(3) Administer any prescribed drug products, or devices under s. 450.035 (1t), Stats.
(4) Provide patient specific counseling or consultation.
(5) Make therapeutic alternate drug selections.
(6) Provide supervision to other pharmacy technicians or pharmacy support personnel.

Commented [HND9]: Public Comment (DeBisschop): "I ask the board to clarify this rule to exclude job-related supervision and tech-check tech activities."

Phar 19.03 Renewal and Reinstatement. (1) RENEWAL.

(a) A person with an expired pharmacy technician registration may not reapply for a registration using the initial application process.

(b) A person renewing their pharmacy technician registration shall do all of the following:

1. Submit a completed renewal application.

   Note: Instructions for renewal applications are available on the department of safety and professional services' website at http://dsps.wi.gov.

2. Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats. and any applicable late renewal fee.

(c) Notwithstanding sub. (b), if a pharmacy technician fails to obtain renewal on or before the applicable renewal date, the board may suspend the pharmacy technician's registration.

(2) REINSTATEMENT. A registration holder who has unmet disciplinary requirements and failed to renew the registration within 5 years or whose registration has been surrendered or revoked may apply to have the registration reinstated in accordance with all of the following:

(a) Evidence of completion of the requirements under s. 19.02 (2).

(b) Evidence of completion of any disciplinary requirements.

Phar 19.04 Change of Address, Employer, or Name. Pursuant to ss. 440.11 (1) and 450.068 (3), each pharmacy technician shall notify the department of an address change or change of employer within 10 days of the change, and a name change within 30 days of the change.

Note: Instructions for providing notification of address change, change of employer, or a name change are available on the department of safety and professional services' website at http://dsps.wi.gov.

SECTION 15. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Page 7: [1] Commented [HND1] Hardin, Nilajah - DSPS 7/10/2023 12:19:00 PM

Public Comment (DeBisschop): "Throughout Phar, where technicians are intended to be included, I ask the board to consider including not just 450.03(1)(gm) – which is techs who have applied but before registration granted – but also 450.03(1)(e), which is where the authority for pharmacy technicians is located in this section."

Public Comment (PSW): "This section refers to who can remote dispense; it does not currently include pharmacy technicians as written. This may be an oversight, as those who have applied to be a technician are included, and the new remote dispensing rules allow technicians to remote dispense. We recommend that those practicing under 450.03(e) (i.e., pharmacy technicians) may also remote dispense"

Page 7: [2] Commented [HND3] Hardin, Nilajah - DSPS 7/10/2023 12:24:00 PM

Public Comment (DeBisschop): "Phar 7.60(3) defining pharmacy staff is confusing, as it defines this as "any staff practicing in the pharmacy who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats." This is confusing since those practicing pharmacy under these statutes are not licensed or registered."

Public Comment (PSW): Suggested language -
"Phar 7.60 (3) "Pharmacy staff" means any staff ~~practicing~~ in the pharmacy who are not ~~otherwise~~ licensed ~~, or~~ registered, or practicing under s. 450.03 (1) (f), (g), or (gm), Stats."

Page 7: [3] Commented [HND4] Hardin, Nilajah - DSPS 7/10/2023 12:23:00 PM

Public Comment (DeBisschop): "I ask the board to consider defining "unlicensed pharmacy staff" (or a similar term) to be as clear as possible and exclude all who are intended to be excluded. To my understanding, these are supposed to be cashiers, clerks, drivers, and others who are not trained or delegated any pharmacy practice acts. Technicians are "unlicensed," and not excluded in Phar 7.60(3), yet it appears they are supposed to be excluded from the provisions of this chapter. Perhaps a different term would be clearer? Two options I can think of might be "uncredentialed pharmacy staff" or "pharmacy support personnel" (as they are referred to in Phar 19.02(6)."

Page 7: [4] Commented [NH5] Hardin, Nilajah - DSPS 7/10/2023 12:13:00 PM

Public Comment (DeBisschop): "consider adding interns as defined in Phar 17.02(4) to the statement in Phar 7.62(1) for greater clarity"
"P3/4 students who are working in a pharmacy outside of pharmacy school are covered in 7.62(1)."
"P1/2 students who are working in a pharmacy outside of pharmacy school are not covered explicitly and currently must register as technicians under these rules. "
"Consider explicitly allowing P1/2 students, when not practicing as interns, and under appropriate supervision, to practice under the authority of 450.03(1)(i), which allows "any person, other than a pharmacy technician, who is providing services as directed, supervised, and inspected by a pharmacist who has the power to direct, decide, and oversee the implementation of the services rendered"
"Currently, new graduates, who have applied for licensure but have not yet had action taken on their license, are not statutorily defined as well and must register as pharmacy technicians. I ask the board to consider explicitly allowing these individuals, under appropriate supervision, to practice pharmacy under this statute (450.03(1)(i)) as well."
"Throughout Phar, where technicians are intended to be included, I ask the board to consider including not just 450.03(1)(gm) – which is techs who have applied but before registration granted – but also 450.03(1)(e), which is where the authority for pharmacy technicians is located in this section."

Page 7: [5] Commented [HND7] Hardin, Nilajah - DSPS 7/10/2023 12:25:00 PM

Public Comment (DeBisschop): "I ask the board to **consider including delivery of a drug or device to a patient as a permitted task for pharmacy staff**. Currently under the Emergency Rule, this remains within the "practice of pharmacy" defined in 450.01(16); thus, as staff may not practice pharmacy, they may not deliver or transfer a drug to another. This would imply that anyone handing another person a drug (like a cashier or delivery driver in their duties) would have to be registered as a technician. Expressly permitting this action would avoid that"

Date: March 1, 2023

To: Pharmacy Examining Board

From: Michael DeBisschop, Pharm.D.

Re: Feedback on Emergency Rule 2303

Thank you for allowing me to express my comments on the rulemaking process around pharmacy technician registration. I appreciate the board's work in this area, since defining roles and responsibility of all our various pharmacy professionals is no easy task. Although these rules are designed to ensure appropriate roles and authority of technicians to practice pharmacy, they do, by their nature, also then define other adjacent roles, such as student pharmacists, interns, and other unlicensed or unregistered personnel in the pharmacy.

Through teaching pharmacy law, and precepting students in different years, I help prepare students pharmacists for their practice both during enrollment in pharmacy school and after graduation. My overall goal is to provide students with experiences that make them the best pharmacist they can be, as well as to help them pass the MPJE for licensure. Please note that the comments in this document are my own personal opinions and do not represent those of my employer.

I am grateful for the opportunity to provide comments and suggestions in the following areas:

1. **I respectfully request that the board ensure that it is clear in the rules that interns, and, to the extent statutorily possible, recent graduates who have applied for pharmacist licensure and students of all years are not subject to technician registration.** This has been a source of confusion that I have heard of from pharmacists.
    - **a.** Exemption from registration is established for interns (as defined in Phar 17) in 7.62(3) as an exception to a prohibition, which is confusing to a reader. **I ask the board to consider adding interns as defined in Phar 17.02(4) to the statement in Phar 7.62(1) for greater clarity.**
    - b. P3/4 students who are working in a pharmacy outside of pharmacy school are covered in 7.62(1).
    - **c.** P1/2 students who are working in a pharmacy outside of pharmacy school are not covered explicitly and currently must register as technicians under these rules. I believe this does not send a forward thinking and modern message about Wisconsin pharmacy education and practice. Our first and second years undergo clinical training early in their curriculum and should have the opportunity to practice these skills to the extent determined by their employer, not the state. Work is an important part of the education and professionalization of these future pharmacists. **Consider explicitly allowing P1/2 students, when not practicing as interns, and under appropriate supervision, to practice under the authority of 450.03(1)(i), which allows "any person, other than a pharmacy technician, who is providing services as directed, supervised, and inspected by a pharmacist who has the power to direct, decide, and oversee the implementation of the services rendered**" to engage in the practice of pharmacy without licensure. This will differentiate this group from pharmacy technicians.

    d. Currently, new graduates, who have applied for licensure but have not yet had action taken on their license, are not statutorily defined as well and must register as pharmacy technicians. I ask the board to **consider explicitly allowing these individuals, under appropriate supervision, to practice pharmacy under this statute (450.03(1)(i)) as well.**
2. Throughout Phar, where technicians are intended to be included, **I ask the board to consider including not just 450.03(1)(gm) – which is techs who have applied but before registration granted – but also 450.03(1)(e),** which is where the authority for pharmacy technicians is located in this section. An example of this would be the remote dispensing site delegation under Phar 7.43(7).
3. Section V of Phar 7 is extremely difficult to parse due to the way in which it is written.
    a. **I ask the board to consider ensuring definitions of general and direct supervision are applicable to all of Phar 7 and any other chapters necessary**, as possible.
    b. **I ask the board to consider defining "unlicensed pharmacy staff" (or a similar term) to be as clear as possible and exclude all who are intended to be excluded**. To my understanding, these are supposed to be cashiers, clerks, drivers, and others who are not trained or delegated any pharmacy practice acts. Technicians are "unlicensed," and not excluded in Phar 7.60(3), yet it appears they are supposed to be excluded from the provisions of this chapter. Perhaps a different term would be clearer? Two options I can think of might be "uncredentialed pharmacy staff" or "pharmacy support personnel" (as they are referred to in Phar 19.02(6).
    c. Phar 7.60(3) defining pharmacy staff is confusing, as it defines this as "any staff practicing in the pharmacy who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats." This is confusing since those practicing pharmacy under these statutes are not licensed or registered.
    d. I ask the board to **consider including delivery of a drug or device to a patient as a permitted task for pharmacy staff**. Currently under the Emergency Rule, this remains within the "practice of pharmacy" defined in 450.01(16); thus, as staff may not practice pharmacy, they may not deliver or transfer a drug to another. This would imply that anyone handing another person a drug (like a cashier or delivery driver in their duties) would have to be registered as a technician. Expressly permitting this action would avoid that.
    e. **Suggest creating a separate section for those practicing under 450.03(1)(f), (g), and as interns under Phar 17.02(4),** to be as clear as possible regarding their supervision and roles. I realize that technicians are the focus, but, as written, it is difficult to distinguish students' and interns' roles, authority, and supervision from technicians.
4. I ask the board to clearly define which roles require general and direct supervision:
    a. I request to consider **explicitly stating in Phar 19 that registered technicians can operate under general supervision.**
    b. In some cases, it appears that P1s and P2s on rotation in pharmacy school can be under general (Phar 17), in others direct (EmR, Phar 7.62 (2). **Can this be clarified?**
    c. Regarding the communication modes used during supervision – Phar 7.62(2) allows in person or through telecommunication means for direct supervision. Its implied this is permitted for general supervision through remote dispensing site regulations. **I ask the**

board to clarify if both means of communication could be used for both types of supervision at any time, or only with certain roles or tasks.

5. Phar 7.62 (5)-(7) provides rules for managing pharmacist training, delegating, and verifying competency of tasks for pharmacy staff. **I ask the board to consider doing the same for registered technicians in Phar 19.**
6. As currently written, Phar 19.02(6) prohibits a technician from providing supervision to another technician or support personnel. Many techs act as supervisors to other techs as a job function. In addition, tech-check-tech involves a level of supervision in inspecting the practice of another. I believe the intent is to prevent a tech from supervising pharmacy practice of another tech, which is appropriate. **I ask the board to clarify this rule to exclude job-related supervision and tech-check tech activities.**

Thank you for taking these items into consideration in development of the permanent rules. I really appreciate the board's hard work and the difficulty involved in parsing out appropriate roles, responsibilities, and authority while remaining flexible and fostering modern pharmacy practice. Please do not hesitate to reach out with any questions.

Pharmacy Society of Wisconsin

DATE: March 2, 2023
TO: John Weitekamp, Chairman
Members, Pharmacy Examining Board (PEB)
FROM: Danielle Womack, Vice President of Public Affairs
Pharmacy Society of Wisconsin
SUBJECT: EmR 2303: Pharmacy Technician Registration

On behalf of the Pharmacy Society of Wisconsin's more than 4,000 members, I would like to thank you for the opportunity to share our thoughts on Emergency Rule 2303, relating to pharmacy technician registration.

The Pharmacy Society of Wisconsin is dedicated to advancing pharmacy practice with the ultimate purpose of enhancing patients' lives. Therefore, we appreciate the Pharmacy Examining Board's work in implementing 2021 Wisconsin Act 100, which requires the registration of pharmacy technicians.

Upon reviewing the emergency rule, we respectfully suggest some changes based on feedback from our membership. These changes will bring more clarity to the chapter for technicians while ensuring that the intent of the legislation is carried out. Below are the changes that PSW respectfully and specifically requests.

- **Students:** There have been many questions regarding how the emergency rule applies to students enrolled in schools of pharmacy. As currently written, student pharmacists completing hours for the licensure internship requirement are not required to register, but other students working in a pharmacy must register. While we are working closely with the schools to share this information and have created an FAQ and visual guide, the handling of this group of learners has generated much confusion. Most schools have not previously counted introductory pharmacy practice experience (IPPE) rotations as hours for the licensure internship requirement." Therefore, student pharmacists completing these IPPE rotations and their experiential practice sites have raised concerns about registering as pharmacy technicians to complete experiential requirements early in their pharmacy school curriculum.

  Additionally, student pharmacists may wear multiple hats at various times when employed by an organization – serving as a technician on the weekend, an intern during the week, and an experiential learner on a rotation. The complexity for the student pharmacist, the school of pharmacy, and the practice site can potentially impact staffing and patient care. I have attached the flowchart we created for students; the chart's complexity demonstrates the rule's complexity.

  Given that the law intends to register pharmacy technicians, not students completing practicum hours that may or may not be counted toward the internship requirement, we would request that the rule is clear that all student pharmacists are exempt from the requirement to register as a pharmacy technician.

- **Phar 7.60 (3):** This section defines pharmacy staff but refers to some individuals as registered or licensed who are not registered or licensed under the law. We would suggest the language be revised to state:

  Phar 7.60 (3) "Pharmacy staff" means any staff ~~practicing~~ in the pharmacy who are not ~~otherwise~~ licensed, ~~or~~ registered, or practicing under s. 450.03 (1) (f), (g), or (gm), Stats.

701 Heartland Trail
Madison, WI 53717
t: 608.827.9200 f: 608.827.9292
info@pswi.org www.pswi.org

- **Phar 7.43**: This section refers to who can remote dispense; it does not currently include pharmacy technicians as written. This may be an oversight, as those who have applied to be a technician are included, and the new remote dispensing rules allow technicians to remote dispense. We recommend that those practicing under 450.03(e) (i.e., pharmacy technicians) may also remote dispense.

To reiterate, our goal, like that of the PEB, is to advance pharmacy practice while ensuring patient safety, and we appreciate the PEB's diligence and work in implementing regulations regarding pharmacy technician registration. Thank you again for allowing me to submit comments on behalf of more than 4,000 Pharmacy Society of Wisconsin members.