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

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Tony Evers, Governor
Dawn B. Crim, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI 53705
Contact: Brad Wojciechowski (608) 266-2112
December 2, 2021

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. Administrative Rule Matters – Discussion and Consideration (2)

1) Phar 8, Relating to Controlled Substance Requirements **(3-32)**
2) Phar 15, Relating to Compounding Pharmaceuticals **(33-52)**
3) Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

****

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 at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. 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 deaf or hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, 608-266-2112, or the Meeting Staff at 608-266-5439.

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**	**11/18/21** 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?
12/02/21	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Phar 8, Controlled Substance Requirements** 2. **Phar 15, Compounding Pharmaceuticals** 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 8 Current Rule Draft
2. Phar 8 Clearinghouse Report
3. Phar 8 Public Comments
4. Phar 8 Redlined Text (with Comments included)
5. Phar 15 Redlined Draft Text
6. USP BUD Reference for the 2021 Proposed Revisions to <797>

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

11) Authorization

Nilajah D. Hardin — 11/18/21

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 RULE-MAKING 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 ch. Phar 8 relating to requirements for controlled substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.31, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (2), 450.02 (3) (a), (b) (d) and (e), and 961.31, Stats.

Explanation of agency authority:

Section 15.08 (5) (b) provides that the board "[s]hall 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 (2) states that the board "shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05."

Section 450.02 (3) provides that "[t] board may promulgate rules:

(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

(b) Establishing security standards for pharmacies.

…

(d) Necessary for the administration and enforcement of this chapter and ch. 961.

(e) Establishing minimum standards for the practice of pharmacy."

Section 961.31 gives the Pharmacy Examining Board authority to "promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state."

Related statute or rule: N/A

Plain language analysis:

This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. The rule project simplifies recordkeeping requirements for controlled substances, removes restrictions on receipt of prescriptions via facsimile machine, partial dispensing, renewals, labeling, and emergency kits in long-term care facilities.

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.

Comparison with rules in adjacent states:

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.600 to 68/1330.800 outlines requirements for pharmacy standards and pharmacy operations. Illinois law requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA (IL 68/1330.710). Illinois administrative rule requires that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years (IAC 3100.360). Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription (IAC 3100.400).

Iowa: The Iowa Pharmacy Board requires a pharmacy to maintain controlled substance records for at least 2 years and to segregate Schedule I and II drug records from other controlled substance records (Iowa Admin. Code 657-10.36). Iowa also requires that pharmacies keep a perpetual inventory of all Schedule II drugs on hand (Iowa Admin. Code 657-10.18). Iowa only requires a pharmacist to report theft or loss of controlled substances to the Pharmacy Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to merely report to the DEA (Iowa Admin. Code 657-10.21). Iowa also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate

administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Iowa Admin. Code 657-10.26).

Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the DEA within 10 days. There does not appear to be a separate requirement to report it to the Pharmacy Board (Mich. R 338.3141). Inventory must be taken of all controlled substances at least annually (Mich. R 338.3151 and 338.3152). Controlled substance records must be retained for at least 5 years, with the first 3 in hard copy form and in the last 2 may be kept electronically. Michigan also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Michigan R 338.3164 and 338.3165).

Minnesota: Minnesota requires a perpetual inventory of Schedule II substances which must be reconciled monthly (Minn. Admin. Code 6800.4600). Pharmacists must report loss or theft of controlled substances to the DEA immediately. There is no requirement that a separate report be made to the state (Minn. Admin. Code 6800.4800). All prescription information must be maintained for at least 2 years (Minn. Admin. Code 6800.3100).

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board completed a comprehensive review of ch. Phar 8, Requirements for Controlled Substances, in order to identify and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices. The board also evaluated ch. Phar 8 for ways to reduce the regulatory impact on pharmacies without negatively impacting public safety.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

A fiscal estimate and economic impact analysis are attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8306; phone (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, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on October 20, 2021 at 9:00 a.m. to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter Phar 8 is repealed and recreated to read:

Chapter Phar 8
REQUIREMENTS FOR CONTROLLED SUBSTANCES

Phar 8.01 Federal registration and compliance with federal, state, and local laws and regulations.
(1) FEDERAL REGISTRATION REQUIRED. To possess, manufacture, distribute, dispense, or conduct research with controlled substances in this state, pharmacies and pharmacists shall register with the drug enforcement administration as required under federal law.
(2) CONTROLLED SUBSTANCES AUTHORIZATION UNDER FEDERAL REGISTRATION. As provided under s. 961.32 (1m) (a), Stats., pharmacies and pharmacists registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, and conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the provisions of ch. 961, Stats.
(3) COMPLIANCE WITH LAWS AND REGULATIONS. Failure to register with the drug enforcement administration or otherwise comply with applicable federal, state, and local laws and regulations relating to possessing, manufacturing, distributing, dispensing, or conducting research with controlled substances constitutes unprofessional conduct for purposes of s. 450.10, Stats.

Note: The United States Department of Justice Drug Enforcement Administration has published a pharmacist's manual, which provides an informational outline of the federal Controlled Substances Act. It can be found online at: https://www.deadiversion.usdoj.gov/pubs/manuals/index.html.

Phar 8.02 Purpose of issue of prescription order. Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

Phar 8.03 Valid prescription requirements. (1) A pharmacist may not dispense controlled substances for a prescription the pharmacist knows, or reasonably should know, is not a valid prescription under applicable federal, state, and local laws and regulations.

(2) An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid. A pharmacist knowingly dispensing pursuant to such a purported order, as well as the practitioner issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.
(3) As provided under s. 961.38 (4r), Stats., a pharmacist is immune from any civil or criminal liability and from discipline under s. 450.10, Stats., for any act taken by the pharmacist in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.

Phar 8.04 Notification of suspicious orders for and theft or loss of controlled substances. A pharmacy or pharmacist shall notify the board of a suspicious order or series of orders for controlled substances or the theft or loss of controlled substances on the same day notification is required to be provided to the drug enforcement administration. Notification to the board shall include all information required to be provided in the notification to the drug enforcement administration.

Phar 8.05 Recordkeeping. Records required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats., shall be maintained for at least 5 years from the date the drug was received, manufactured, distributed, or dispensed or, for a record that is subject to s. 961.385, Stats., until the name of a person to whom a drug is dispensed is delivered to the controlled substances board under s. 961.385, Stats., whichever is sooner. Records shall be readily retrievable, easily readable, and available for inspection by authorized persons for at least 5 years from the date of such record. An electronic recordkeeping system shall have the capability of producing a printout of records as required under this section. The pharmacist-in-charge shall oversee monthly inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.

Phar 8.06 Identification card requirement under s. 450.11 (1b), Stats. (1) DEFINITION. In this section and s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community−based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.
(2) IDENTIFICATION CARD REQUIREMENT. As provided under s. 450.11 (1b) (b) and (e), Stats., a controlled substance included in schedule II or III of ch. 961, Stats., may not be dispensed, and may not be delivered to a representative of the ultimate user, without an identification card belonging to the person to whom the drug is being dispensed or delivered. An identification card is not required if any of the following applies:
(a) The drug is administered or dispensed directly to the ultimate user by a practitioner.
(b) The pharmacist or other person dispensing or delivering the drug has personal knowledge of the person to whom the drug is dispensed or delivered, and that the person is the ultimate user or the ultimate user's authorized representative.
(c) The drug is delivered to a health care facility to be administered in the health care facility.

Phar 8.07 Dispensing schedule II controlled substances in emergency situations under s. 961.38 (2), Stats. (1) DEFINITION. For purposes of dispensing a schedule II controlled substance under s. 961.38 (2), Stats., "emergency situation" means a situation in which the prescribing practitioner determines all of the following:

(a) Immediate administration of the schedule II controlled substance is necessary for proper treatment of the patient.
(b) No appropriate alternative treatment is available, including the administration of a drug that is not a schedule II controlled substance.
(c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.
(2) REQUIRED NOTIFICATION. A dispensing pharmacist shall notify the board of the failure of a prescribing practitioner to deliver a written prescription within 7 days after authorizing an emergency oral prescription for a schedule II controlled substance. The notification shall be provided to the board on the same day notification is required to be provided to the drug enforcement administration and shall include all information required to be provided in the notification to the drug enforcement administration.

Phar 8.08 Dispensing and sale of pseudoephedrine products. The dispensing and sale of pseudoephedrine products shall meet all applicable federal, state, and local laws and regulations relating to schedule V controlled substances, including all the following requirements:
(1) The requirements under ss. 961.23 and 961.38 (4), Stats., for dispensing schedule V controlled substances.
(2) The requirements under s. 961.235, Stats., for records relating to sales of pseudoephedrine products.

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)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
09/01/21

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 8

4. Subject
Requirements for Controlled Substances

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☒ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
The objective of the proposed rule is to complete a comprehensive review of Phar 8, Requirements for Controlled Substances and make revisions to ensure the chapter is statutorily compliant with state and federal law and are current with professional standards and practices.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted for 14 days on the Department of Safety and Professional Services' website to solicit comments on the potential economic impact. No comments were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
No econonmic or fiscal impacts are anticipated for specific businesses, business sectors, public utility rate payers, local governmental units, or the state's economy as a whole. A total of $1,107.54 in one time costs are anticipated to be absorbed within the operating budget of the Department of Safety and Professional Services.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The Board intends to modernize Phar 8 to bring it in line with current pharmacy standards and practices. The Board will evaluate reducing the regulatory impact on pharmacies without negatively impacting public safety. The board will also incorporate minimum standards to prevent controlled substance diversion.

16. Long Range Implications of Implementing the Rule
This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. The rule project simplifies recordkeeping requirements for controlled substances, removes restrictions on receipt of prescriptions via facsimile machine, partial dispensing, renewals, labeling, and emergency kits in long-term care facilities.

17. Compare With Approaches Being Used by Federal Government

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.600 to 68/1330.800 outlines requirements for pharmacy standards and pharmacy operations. Illinois law requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA (IL 68/1330.710). Illinois administrative rule requires that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years (IAC 3100.360). Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription (IAC 3100.400).

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Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the DEA within 10 days. There does not appear to be a separate requirement to report it to the Pharmacy Board (Mich. R 338.3141). Inventory must be taken of all controlled substances at least annually (Mich. R 338.3151 and 338.3152). Controlled substance records must be retained for at least 5 years, with the first 3 in hard copy form and in the last 2 may be kept electronically. Michigan also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Michigan R 338.3164 and 338.3165).

Minnesota: Minnesota requires a perpetual inventory of Schedule II substances which must be reconciled monthly (Minn. Admin. Code 6800.4600). Pharmacists must report loss or theft of controlled substances to the DEA immediately. There is no requirement that a separate report be made to the state (Minn. Admin. Code 6800.4800). All prescription information must be maintained for at least 2 years (Minn. Admin. Code 6800.3100).

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

This document can be made available in alternate formats to individuals with disabilities upon request.

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

LCRC
FORM 2

Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **21-071**

AN ORDER to repeal and recreate ch. Phar 8, relating to requirements for controlled substances.

Submitted by **PHARMACY EXAMINING BOARD**

09-01-2021 RECEIVED BY LEGISLATIVE COUNCIL.
09-27-2021 REPORT SENT TO AGENCY.

SG:SM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☑ NO ☐

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☑ NO ☐

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE RULE 21-071

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Council Staff and the Legislative Reference Bureau, dated November 2020.]

1. Statutory Authority

The rule should cite ss. 450.11 (1b) (a) 1. and 961.38 (2), Stats., as additional sources of statutory authority. Section 450.11 (1b) (a) 1., Stats., authorizes the board to identify additional types of health care facilities for the purposes of identification card requirements under s. Phar 8.06 (1) of the proposed rule, and s. 961.38 (2), Stats., authorizes the board to define "emergency situations" for the purposes of dispensing schedule II controlled substances under s. Phar 8.07 of the proposed rule.

2. Form, Style and Placement in Administrative Code

Section Phar 8.05 appears to contain a number of different requirements relating to recordkeeping and recordkeeping systems. Consider organizing the material into subsections for clarity and readability.

4. Adequacy of References to Related Statutes, Rules and Forms

A number of provisions, including ss. Phar 8.03 (3), 8.06 (2), and 8.08, appear to be reiterations of statutes without additional interpretation or effect. Consider whether those provisions need to be included in the administrative code.

5. Clarity, Grammar, Punctuation and Use of Plain Language

In the "Explanation of Agency Authority" section of the rule analysis, the description of s. 450.02 (3), Stats., should change "[t]" to "[t]he".

October 18, 2021

Pharmacy Examining Board
Department of Safety and Professional Services
PO Box 8366
Madison, WI 53708-8366

Dear PEB Members:

Thank you for the opportunity to comment on the revised Phar 8 regulations related to controlled substances in CR 21-071. I am a pharmacist in Wisconsin and a member of the faculty at the Medical College of Wisconsin School of Pharmacy; the opinions in these comments are my own.

I appreciate the board's efforts in revising the regulations to make them closely aligned with federal regulations as this will reduce confusion in learning and applying these rules. To that end, I have two suggestions that I would ask the board to consider regarding partial fill rules for controlled substances.

I would request that the board consider inclusion in Phar 8 of language explicitly allowing the partial fill of C-II controlled substances on a repeated basis for up to 30 days per patient or prescriber request. Federally, CARA 2016 (21 USC 829(f)) specifically permits this. DEA has proposed rules, published on this in the Federal Register on Dec 2020, which would modify CFR 1306.13 to accommodate this. In addition, the DEA Manual 2020 states on page 58:

> DEA views CARA's partial fill exception to be in addition to the exceptions currently listed under 21 CFR 1306.13. A pharmacist needs to check with their state to determine if its laws or regulations have been changed to parallel CARA. If the state regulations have not changed, and they still only allow the partial filling of a schedule II controlled substance under the conditions outlined in 21 CFR 1306.13(a), then the stricter state law applies until such time as the state makes a change.

Based on this, Wisconsin should adopt specific language allowing repeated partial fill of Schedule II prescriptions for up to 30 days at the discretion of the patient or prescriber, consistent with federal law. Michigan (Mich Comp Laws §333.7333(3)) and Iowa (Iowa Admin Code §657.10.27) have different language in their regulations to accommodate this provision; Minnesota Board of Pharmacy issued a FAQ stating that this practice is consistent with their regulations. As deaths from opioid overdoses nationally and in Wisconsin continue to rise, we should take every opportunity to help people limit the quantity of opioids in circulation. Discretionary partial filling of Schedule II prescriptions is one tool to help do that.

The other consideration I request is regarding clarification of partial fill rules for Schedule III, IV, and V drugs. DEA regulations (§1306.23) allow partial filling of these prescriptions, up to the total number of dosage units prescribed. Wis Stats 961.38 states "The prescription shall not be filled or refilled except as designated on the prescription and in any case not more than 6 months after the date thereof, nor may it be refilled more than 5 times, unless renewed by the practitioner." This language, along with lack of clarity in the regulations, has been a source of confusion among pharmacists over whether leftover quantities from a C-III-V partial fill can be dispensed. It would be helpful to have this clarified in state regulations, so that partial fills up to the total number of dosage units are permitted in Wisconsin. I

don’t believe there is a conflict between 961.38 and this principle; however, clarifying it explicitly for this case would be helpful.

Thank you for your consideration of these comments, and please don’t hesitate to contact me with any questions.

Michael DeBisschop, Pharm.D.
medebisschop@gmail.com
307-262-3738

Pharmacy Society of Wisconsin

DATE: October 20, 2021
TO: John Weitekamp, Chairman
Members, Pharmacy Examining Board (PEB)
FROM: Danielle Womack, Vice President of Public Affairs
Pharmacy Society of Wisconsin
SUBJECT: Phar 8: Controlled Substances

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 Phar 8, relating to controlled substances.

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 updating regulations on pharmacy practice to address contemporary pharmacy practice models.

Upon reviewing the preliminary rule draft, we respectfully suggest some changes based upon feedback from our membership. These changes will bring more clarity to the chapter for pharmacies while ensuring that pharmacy practice is completed safely and effectively for optimum patient safety. Below are the changes that PSW respectfully and specifically requests.

- **Phar 8.05:** Wisconsin statute 961.235(2) requires that pseudoephedrine records are kept for two years; however, this section requires all controlled substance records, including those for pseudoephedrine, to be kept for 5 years. We suggest that the PEB clarify that two years as statutorily required is sufficient for pseudoephedrine recordkeeping.

- **Phar 8.05**: "Perpetual inventory" is not defined, leading to confusion about how inventory shall be tracked. Additionally, questions have arisen about what defines a monthly inspection and what must be contained in each inspection.

- **Phar 8.07(2)**: This section requires that a written prescription be delivered after an emergency fill. We recommend that an electronic prescription also be accepted if received within 7 days of an emergency fill.

- Federal regulations do not discuss controlled substances in kits for long-term care facilities; however current Phar 8.11 discusses this topic. We recommend that this section of the current Phar 8 be kept, as the DEA has stated they expect states to have rules for this issue.

- The rewrite of Phar 8 removes all references to partial dispensing. While federal law allows for partial dispensing, Wis. Stat. 961.38(3) states that "the prescription shall not be filled or refilled except as designated on the prescription," which implies partial fills are not allowed. It would be helpful for clarity for Phar 8 to explicitly endorse the federal allowance for partial fills up to the total dosage units (21 CFR 1306.23). Additionally, CARA 2016 (21 USC 829) allows for partial filling of schedule II drugs per

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patient/prescriber request if allowed under state law; we suggest that the PEB adopt this allowance to parallel CARA.

- Phar 8 does not delineate what a valid signature is for purposes of controlled substance prescribing. With technology constantly changing, pharmacies see electronic, digital, and faxed signatures. It would be helpful for Phar 8 to define what a valid signature is for controlled substance dispensing.

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 rewriting Phar 8. Thank you again for allowing me to testify on behalf of more than 4,000 Pharmacy Society of Wisconsin members.

CVSHealth

John Long
Director Regulatory Affairs, CVS Health

One CVS Drive
Woonsocket, RI 02895

p 614-572-9008
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john.long@cvshealth.com

Via Electronic Mail

October 12, 2021

Nilajah Hardin
Administrative Rules Coordinator
Department of Safety and Professional Services (DSPS)
Division of Policy Development
P.O. Box 8366
Madison, WI 53708-8366
DSPSAdminRules@wisconsin.gov

RE: Chapter Phar 8 Requirements for Controlled Substances

Dear Nilajah Hardin:

I am writing to you in my capacity as Pharmacy Regulatory Affairs Director for CVS Health and its family of pharmacies located across the country. CVS Health would like to thank the Pharmacy Examining Board ("Board") for their constant vigilance to continuously improve regulations that enhance patient care and guide the practice of pharmacy in Wisconsin. Through our integrated offerings across the spectrum of pharmacy care, we are uniquely positioned to provide greater access to care, engage plan members in behaviors that improve their health, and lower overall costs for health plans and their members. CVS Health provides multiple points of care to patients via our retail, mail, infusion, long-term-care, specialty pharmacies and Minute Clinics.

Based on the proposed revisions to Chapter Phar 8 from the Pharmacy Examining Board CVS Health would like to provide the following comments on the amended rules.

Elimination of Phar 8.11 Controlled substances in emergency kits for long term care facilities:

The Pharmacy Examining Board's approach to the review of Chapter Phar 8 was to reduce regulatory burdens on pharmacies, while maintaining public safety. CVS Health fully supports this approach. It appears under these proposed rules, Wisconsin would defer to federal law related to faxed prescriptions, partial dispensing, renewals, and labeling. We do have a concern with removing all rules around e-kits, currently section Phar 8.11. While in general CVS Health supports reducing restrictions related to e-kits in Long Term Care Facilities (LTCFs), The Drug Enforcement Administration's (DEA's) published policy on e-kit allows for them only if the state has laws/regulations around the sourcing, security, accountability, and use applications. Therefore, while CVS Health is in favor of reducing regulatory

language pertaining to the practice of pharmacy, we propose minimal regulatory language making it clear that e-Kits may be placed in LTCFs by provider pharmacies. CVS Health proposes retaining most of the language in current Phar. 8.11.

Phar 8.11 Controlled substances in emergency kits for long term care facilities. Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances: (1) The source of supply must be a DEA registered hospital, pharmacy or practitioner. (2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit. (3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the Phar 8.11 WISCONSIN ADMINISTRATIVE CODE 18 Published under s. 35.93, Wis. Stats., by the Legislative Reference Bureau. Published under s. 35.93, Stats. Updated on the first day of each month. Entire code is always current. The Register date on each page is the date the chapter was last published. Register September 2016 No. 729 emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories. (4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.

WI ADC s Phar 8.01. Federal registration and compliance with federal, state, and local laws and regulations.

(1) Federal registration required. To possess, manufacture, distribute, dispense, or conduct research with controlled substances in this state, pharmacies and pharmacists shall register with the drug enforcement administration as required under federal law.

(2) Controlled substances authorization under federal registration. As provided under s. 961.32 (1m) (a), Stats., pharmacies and pharmacists registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, and conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the provisions of ch. 961, Stats.

(3) Compliance with laws and regulations. Failure to register with the drug enforcement administration or otherwise comply with applicable federal, state, and local laws and regulations relating to possessing, manufacturing, distributing, dispensing, or conducting research with controlled substances constitutes unprofessional conduct for purposes of s. 450.10, Stats.

(4) Nothing in these rules shall prohibit long term care facilities from obtaining an emergency kit, from a DEA registered pharmacy, in compliance with federal law.

Phar 8.05 Recordkeeping.

Phar 8.05 states that the pharmacist-in-charge shall oversee **monthly** inspections, maintenance, and **reconciliation of all controlled substances**, including maintaining a perpetual inventory for all Schedule II controlled substances.

CVS Health supports programs that ensure drug security and eliminates drug diversion. Currently our system of reconciliation and cycle counts allows the pharmacy staff to target drugs with abuse potential and maximize inventory integrity. Currently twenty-eight targeted schedule III – V and all schedule II drugs are cycle counted a minimum of monthly. A pharmacist will review the results and any variances are further researched for reconciliation, root cause analysis and/or correction. CVS Health opposes expanding monthly reconciliation to ALL controlled substances as this has the potential to delay patient care, because drugs are going through a reconciliation process thereby delaying dispensing and is contrary to the Drug Enforcement Administration, which does not require such reconciliations. Alternately, CVS Health supports a change that would limit the application of the reconciliation process to all Schedule II drugs and a targeted subset of higher risk Schedule III – IV controlled substance, requiring a reconciliation on a quarterly cadence.

Therefore, CVS Health proposes the following language.

WI ADC s Phar 8.05. Recordkeeping. Records required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats., shall be maintained for at least 5 years from the date the drug was received, manufactured, distributed, or dispensed or, for a record that is subject to s. 961.385, Stats., until the name of a person to whom a drug is dispensed is delivered to the controlled substances board under s. 961.385, Stats., whichever is sooner. Records shall be readily retrievable, easily readable, and available for inspection by authorized persons for at least 5 years from the date of such record. An electronic recordkeeping system shall have the capability of producing a printout of records as required under this section. The pharmacist-in-charge shall oversee monthly inspections, maintenance, ~~and reconciliation~~ of all controlled substances, as well as quarterly reconciliation of targeted Schedule III-IV controlled substances as identified by the pharmacist-in-charge, including maintaining a perpetual inventory for all Schedule II controlled substances.

Phar 8.06 Identification card requirement under s. 450.11 (1b), Stats.

The proposed language in Phar 8.06 creates a new mandate on a pharmacy to comply with, without any evidence presented by the Board that justifies how the new mandate fosters patient safety and public

protection. Specifically, a pharmacy is now required to obtain an identification card when "delivering" a Schedule II and III controlled substance prescription. The Board should provide clarity by amending the proposed rule and explicitly excluding scenarios where a prescription is delivered. If the ID requirement pertains to delivered prescriptions, it could create a situation where a patient either does not receive their medication or therapy is delayed due to the unavailability of an ID at the time of delivery.

Therefore, CVS Health proposes the following language.

WI ADC s Phar 8.06. Identification card requirement under s. 450.11 (1b), Stats. (1) DEFINITION. In this section and s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community–based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.

(2) IDENTIFICATION CARD REQUIREMENT. As provided under s. 450.11 (1b) (b) and (e), Stats., a controlled substance included in schedule II or III of ch. 961, Stats., may not be dispensed, and may not be delivered to a representative of the ultimate user, without an identification card belonging to the person to whom the drug is being dispensed or delivered. An identification card is not required if any of the following applies:

(a) The drug is administered or dispensed directly to the ultimate user by a practitioner.

(b) The pharmacist or other person dispensing or delivering the drug has personal knowledge of the person to whom the drug is dispensed or delivered, and that the person is the ultimate user or the ultimate user's authorized representative.

(c) The drug is delivered to a health care facility to be administered in the health care facility.

(d) The drug is delivered to the patient's home, or any address as requested by the patient, through mail, common carrier or delivery service.

CVS Health

CVS Health appreciates the opportunity to submit feedback on these Phar 8 rules in Wisconsin. If you have any questions, please contact me directly at 614-572-9008.

Best regards,

John Long RPh, MBA

cc:Executive Director Christine Poleski,
Jameson Whitney, Esq.

From:	Software-Notification@legis.wisconsin.gov
To:	DSPS Admin Rules
Cc:	dwypiszynski@mortonltc.com
Subject:	Public comment on CR 21-071
Date:	Wednesday, October 20, 2021 8:16:43 AM

Name: Dawn Wypiszynski
Address: 201 E. Bell Street, Neenah WI 54956
Email: dwypiszynski@mortonltc.com

Organization: Morton LTC

Comments: Hello Pharmacy Examining Board Members,

Thank you for the opportunity to share comments related to the Phar 8 pending revisions.

1) Phar 8.01 (3) : Clarification requested. Would this note make the entire DEA pharmacist's manual enforceable law?
Note: The United States Department of Justice Drug Enforcement Administration has published a pharmacist's manual, which provides an informational outline of the federal Controlled Substances Act. It can be found online at: https://www.deadiversion.usdoj.gov/pubs/manuals/index.html

2) Phar 8.03 (1): What defines what a pharmacist 'reasonably should know'? This verbiage could put pharmacists in a corner. Consider verbiage change to something like: 'A pharmacist may not dispense controlled substances for a prescription that the pharmacist knows, or has doubt, is not a valid prescription under applicable federal, state, and local laws and regulations.'

3) Phar 8.03 (2): Request clarification: Is this simply separating a prescription for practitioner general dispensing from a medication order for practitioner general dispensing?

4) Phar 8.04: Request clarification on proper method for this to be done. Contact information for the Board is not provided.

5) Phar 8.05: Request clarification for requirements of monthly inspections. How was this interval determined?

6) Phar 8.07(2): Request clarification on proper method for Board notification to be done.

7) It appears that currently, Phar 6.04(3)(a) (4) is missing….. goes from 3 to 5….

***Other comments related to Phar 8 topics that are not currently in draft format:

1) Phar 8.05(1) 'Prescription orders shall be written with ink or indelible pencil or be typewritten and shall be signed by the practitioner.' Request clarification of definition of valid signature for controlled substance orders. With technology options increasing, we receive several types of 'signed orders' each day. However, it's not always clear if the format is legally signed for controlled substances. (Digital, electronically signed but faxed, etc)

3) Phar 8.12(1) and (2)(b)(c). Request clarification of definition of 'practitioner's agent'. In LTC, this verbiage causes confusion when we try to determine if a faxed controlled order can be dispensed. Considering the many staff roles that may be involved in sending controlled prescriptions to LTC pharmacy: medical office nurse/staff faxing from medical office, traveling provider nurse/staff on site at LTC facility or from provider office, LTC nurse/staff (not employed the same as prescriber), hospice nurse/staff at LTC facility or at hospice office. Does the employer have to be the same as the prescriber? Can the fax be received from a 3rd party, like the facility?

4) Phar 8.12(3) Request clarification for requirements of original hard copy prescription. I'm concerned about where the original hard copy will be located if we accept a faxed copy of a written order.

Let me know if you'd like to discuss further.

Thank you,

Dawn Wypiszynski, PharmD
Pharmacy Director

Morton LTC
201 E. Bell Street
Neenah, WI 54956
Office: 920-886-1109

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING 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 ch. Phar 8 relating to requirements for controlled substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.31, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.11 (1b) (a) (1), 450.02 (2), 450.02 (3) (a), (b) (d) and (e), ~~and~~ 961.31, and 961.38 (2) Stats.

Commented [HN-D1]: Clearinghouse Comment #1

Explanation of agency authority:

Commented [HN-D2]: Clearinghouse Comment #1 and 5

Section 15.08 (5) (b) provides that the board "[s]hall 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 450.11 (1b) (a) (1) states ""Health care facility" means a facility, as defined in s. 647.01 (4); any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10; and any other facility identified by the board by rule."

Section 450.02 (2) states that the board "shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05."

Section 450.02 (3) provides that "[t]he board may promulgate rules:

(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

(b) Establishing security standards for pharmacies.

…

(d) Necessary for the administration and enforcement of this chapter and ch. 961.

(e) Establishing minimum standards for the practice of pharmacy."

Section 961.31 gives the Pharmacy Examining Board authority to "promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state."

Section 961.38 (2) states that "In emergency situations, as defined by rule of the pharmacy examining board, schedule II drugs may be dispensed upon an oral prescription of a practitioner, reduced promptly to a written hard copy or electronic record and filed by the pharmacy. Prescriptions shall be retained in conformity with rules of the pharmacy examining board promulgated under s. 961.31. No prescription for a schedule II substance may be refilled."

Related statute or rule: N/A

Plain language analysis:

This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. The rule project simplifies recordkeeping requirements for controlled substances, removes restrictions on receipt of prescriptions via facsimile machine, partial dispensing, renewals, labeling, and emergency kits in long-term care facilities.

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.

Comparison with rules in adjacent states:

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.600 to 68/1330.800 outlines requirements for pharmacy standards and pharmacy operations. Illinois law requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA (IL 68/1330.710). Illinois administrative rule requires that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years (IAC 3100.360). Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available,

and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription (IAC 3100.400).

Iowa: The Iowa Pharmacy Board requires a pharmacy to maintain controlled substance records for at least 2 years and to segregate Schedule I and II drug records from other controlled substance records (Iowa Admin. Code 657-10.36). Iowa also requires that pharmacies keep a perpetual inventory of all Schedule II drugs on hand (Iowa Admin. Code 657-10.18). Iowa only requires a pharmacist to report theft or loss of controlled substances to the Pharmacy Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to merely report to the DEA (Iowa Admin. Code 657-10.21). Iowa also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Iowa Admin. Code 657-10.26).

Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the DEA within 10 days. There does not appear to be a separate requirement to report it to the Pharmacy Board (Mich. R 338.3141). Inventory must be taken of all controlled substances at least annually (Mich. R 338.3151 and 338.3152). Controlled substance records must be retained for at least 5 years, with the first 3 in hard copy form and in the last 2 may be kept electronically. Michigan also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Michigan R 338.3164 and 338.3165).

Minnesota: Minnesota requires a perpetual inventory of Schedule II substances which must be reconciled monthly (Minn. Admin. Code 6800.4600). Pharmacists must report loss or theft of controlled substances to the DEA immediately. There is no requirement that a separate report be made to the state (Minn. Admin. Code 6800.4800). All prescription information must be maintained for at least 2 years (Minn. Admin. Code 6800.3100).

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board completed a comprehensive review of ch. Phar 8, Requirements for Controlled Substances, in order to identify and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices. The board also evaluated ch. Phar 8 for ways to reduce the regulatory impact on pharmacies without negatively impacting public safety.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

A fiscal estimate and economic impact analysis are attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8306; phone (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, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on October 20, 2021 at 9:00 a.m. to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter Phar 8 is repealed and recreated to read:

Chapter Phar 8
REQUIREMENTS FOR CONTROLLED SUBSTANCES

Phar 8.01 Federal registration and compliance with federal, state, and local laws and regulations.
(1) FEDERAL REGISTRATION REQUIRED. To possess, manufacture, distribute, dispense, or conduct research with controlled substances in this state, pharmacies and pharmacists shall register with the drug enforcement administration as required under federal law.
(2) CONTROLLED SUBSTANCES AUTHORIZATION UNDER FEDERAL REGISTRATION. As provided under s. 961.32 (1m) (a), Stats., pharmacies and pharmacists registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, and conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the provisions of ch. 961, Stats.
(3) COMPLIANCE WITH LAWS AND REGULATIONS. Failure to register with the drug enforcement administration or otherwise comply with applicable federal, state, and local laws and regulations relating to possessing, manufacturing, distributing, dispensing, or conducting research with controlled substances constitutes unprofessional conduct for purposes of s. 450.10, Stats.

(4) Nothing in these rules shall prohibit long term care facilities from obtaining an emergency kit, from a DEA registered pharmacy, in compliance with federal law.

Commented [HN-D3]: Public Comment (John Long)

Note: The United States Department of Justice Drug Enforcement Administration has published a pharmacist's manual, which provides an informational outline of the federal Controlled Substances Act. It can be found online at: https://www.deadiversion.usdoj.gov/pubs/manuals/index.html.

Phar 8.02 Purpose of issue of prescription order. Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

Phar 8.03 Valid prescription requirements. (1) A pharmacist may not dispense controlled substances for a prescription the pharmacist knows, or reasonably should know, is not a valid prescription under applicable federal, state, and local laws and regulations.

(2) An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid. A pharmacist knowingly dispensing pursuant to such a purported order, as well as the practitioner issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

~~**(3)** As provided under s. 961.38 (4r), Stats., a pharmacist is immune from any civil or criminal liability and from discipline under s. 450.10, Stats., for any act taken by the pharmacist in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.~~

(4) A valid signature is required for controlled substance dispensing and shall include all of the following:

(a)

(b)

Phar 8.04 Notification of suspicious orders for and theft or loss of controlled substances. A pharmacy or pharmacist shall notify the board of a suspicious order or series of orders for controlled substances or the theft or loss of controlled substances on the same day notification is required to be provided to the drug enforcement administration. Notification to the board shall include all information required to be provided in the notification to the drug enforcement administration.

Phar 8.05 Recordkeeping. (1) Records required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats., shall be maintained for at least ~~5~~ 2 years from the date the drug was received, manufactured, distributed, or dispensed or, for a record that is subject to s. 961.385, Stats., until the name of a person to whom a drug is dispensed is delivered to the controlled substances board under s. 961.385, Stats., whichever is sooner.

(2) Records shall be readily retrievable, easily readable, and available for inspection by authorized persons for at least ~~5~~ 2 years from the date of such record.

(3) An electronic recordkeeping system shall have the capability of producing a printout of records as required under this section.

(4) The pharmacist-in-charge shall oversee monthly inspections, maintenance, ~~and reconciliation~~ of all controlled substances, as well as quarterly reconciliation of targeted schedule III-IV substances as identified by the pharmacist-in-charge, including maintaining a perpetual inventory for all Schedule II controlled substances.

~~**Phar 8.06 Identification card requirement under s. 450.11 (1b), Stats. (1)** DEFINITION. In this section and s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats., any hospital, nursing home, community-based residential facility, county home, county infirmary, county~~

Commented [HN-D4]: Public Comment (Dawn Wypiszynski): "Would this note make the entire DEA pharmacist's manual enforceable law?"

DSPS Admin Rules Comments: Notes are provided for additional information for the reader, they are not intended to introduce outside standards into WI law

Commented [HN-D5]: Public Comment (Dawn Wypiszynski): "What defines what a pharmacist 'reasonably should know?"

Commented [HN-D6]: Public Comment (Dawn Wypiszynski): "Is this simply separating a prescription for practitioner general dispensing from a medication order for practitioner general dispensing"

Commented [HN-D7]: Clearinghouse Comment #4 "A number of provisions, including ss. Phar 8.03 (3), 8.06 (2), and 8.08, appear to be reiterations of statutes without additional interpretation or effect. Consider whether those provisions need to be included in the administrative code."

Commented [HN-D8]: Public Comment (PSW): Define "valid signature"

Public Comment (Dawn Wypiszynski): "Request clarification of definition of valid signature for controlled substance orders"

Commented [HN-D9]: Public Comment (Dawn Wypiszynski): Provide proper method for contacting the Board

Commented [HN-D10]: Clearinghouse Comment #2 (add sections or reorganize)

Commented [HN-D11]: Public Comment (PSW): Should be 2 years not 5 to be consistent with s. 961.325 (2), stats.

Commented [HN-D12]: Public Comment (John Long)

Commented [HN-D13]: Public Comment (PSW): Definition of "perpetual inventory"?

Commented [HN-D14]: Clearinghouse Comment #4 "A number of provisions, including ss. Phar 8.03 (3), 8.06 (2), and 8.08, appear to be reiterations of statutes without additional interpretation or effect. Consider whether those provisions need to be included in the administrative code."

Public Comment (John Long): Add "2d. The drug is delivered to the patient's home, or any address as requested by the patient, through mail, common carrier or delivery service"

~~hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (e), Stats.~~

~~**(2)** IDENTIFICATION CARD REQUIREMENT. As provided under s. 450.11 (1b) (b) and (e), Stats., a controlled substance included in schedule II or III of ch. 961, Stats., may not be dispensed, and may not be delivered to a representative of the ultimate user, without an identification card belonging to the person to whom the drug is being dispensed or delivered. An identification card is not required if any of the following applies:~~

~~**(a)** The drug is administered or dispensed directly to the ultimate user by a practitioner.~~

~~**(b)** The pharmacist or other person dispensing or delivering the drug has personal knowledge of the person to whom the drug is dispensed or delivered, and that the person is the ultimate user or the ultimate user's authorized representative.~~

~~**(c)** The drug is delivered to a health care facility to be administered in the health care facility.~~

Phar 8.07 Dispensing schedule II controlled substances in emergency situations under s. 961.38 (2), Stats. (1) DEFINITION. For purposes of dispensing a schedule II controlled substance under s. 961.38 (2), Stats., "emergency situation" means a situation in which the prescribing practitioner determines all of the following:

(a) Immediate administration of the schedule II controlled substance is necessary for proper treatment of the patient.

(b) No appropriate alternative treatment is available, including the administration of a drug that is not a schedule II controlled substance.

(c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.

(2) REQUIRED NOTIFICATION. A dispensing pharmacist shall notify the board of the failure of a prescribing practitioner to deliver a written or electronic prescription within 7 days after authorizing an emergency oral prescription for a schedule II controlled substance. The notification shall be provided to the board on the same day notification is required to be provided to the drug enforcement administration and shall include all information required to be provided in the notification to the drug enforcement administration.

~~**Phar 8.08 Dispensing and sale of pseudoephedrine products.** The dispensing and sale of pseudoephedrine products shall meet all applicable federal, state, and local laws and regulations relating to schedule V controlled substances, including all the following requirements:~~

~~**(1)** The requirements under ss. 961.23 and 961.38 (4), Stats., for dispensing schedule V controlled substances.~~

~~**(2)** The requirements under s. 961.235, Stats., for records relating to sales of pseudoephedrine products~~.

Phar 8.09 **Controlled substances in emergency kits for long term care facilities.** Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

(1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.

(2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

(3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.

(4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by

Commented [HN-D15]: Public Comment (Michael DeBisschop): Add partial Refills of Schedule II substances consistent with federal Law; Add partial refills for Schedule II, IV, and V

Public Comment (PSW): Endorse federal allowance for partial refills up to the total dosage units; Also allow partial refills of schedule II

DSPS Admin Rules Comment: This would likely require legislation to change s. 961.38 (2) and (3), stats.

Commented [HN-D16]: Public Comment (PSW): Add electronic prescription option

Commented [HN-D17]: Public Comment (Dawn Wypiszynski): Provide proper method for contacting the Board

Commented [HN-D18]: Clearinghouse Comment #4 "A number of provisions, including ss. Phar 8.03 (3), 8.06 (2), and 8.08, appear to be reiterations of statutes without additional interpretation or effect. Consider whether those provisions need to be included in the administrative code."

Commented [HN-D19]: Public Comment (PSW): Add back in Phar 8.11 Controlled Substances in Emergency Kits for Long Term Care Facilities

Public Comment (John Long): Keep most of current Phar 8.11 language.

authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.

(5) Noncompliance with this rule may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

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 [HN-D20]: Other Public Comments from Dawn Wypiszynski:

"It appears that currently, Phar 6.04(3)(a) (4) is missing….. goes from 3 to 5…."

"Phar 8.12(1) and (2)(b)(c). Request clarification of definition of 'practitioner's agent'. In LTC, this verbiage causes confusion when we try to determine if a faxed controlled order can be dispensed. Considering the many staff
roles that may be involved in sending controlled prescriptions to LTC pharmacy: medical office nurse/staff faxing
from medical office, traveling provider nurse/staff on site at LTC facility or from provider office, LTC nurse/staff (not employed the same as prescriber), hospice nurse/staff at LTC facility or at hospice office. Does the employer have to be the same as the prescriber? Can the fax be received from a 3rd party, like the facility?"

"Phar 8.12(3) Request clarification for requirements of original hard copy prescription. I'm concerned about where the original hard copy will be located if we accept a faxed copy of a written order."

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.

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

(13) "Freezer" means a place in which a the temperature is maintained between -13 degrees and 14 degrees Fahrenheit.

(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.

(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.

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.

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. Water containing preparations that are stored for more than six hours before terminal sterilization are also classified as high-risk level compounded sterile preparations.

(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 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. The compounding process is limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing

(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 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.

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 ~~ampuls~~ 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.

~~Phar 15.34 **Urgent use compounded sterile preparations.** (1) The compounding process shall be a continuous process that does not exceed one hour, unless required for the preparation.~~

~~**(2)** Administration shall begin within one hour of the completion of the preparation.~~

~~**(3)** Aseptic technique shall be followed during preparation, and procedures shall be used to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other compounded sterile products.~~

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

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

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 packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package 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 1 hour 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 1-hour BUD and time.

(6) If administration of the compounded sterile preparation has not begun within 1 hour following the start of preparation, it shall be promptly, properly, and safely discarded.

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 sterilization 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 ~~prepared~~ processed Category 2 compounded sterile preparations, one of the following:

1. No sterility testing performed or sterility testing not passed, and ~~Prepared~~ prepared with one or more nonsterile ~~ingredients~~ starting components, ~~which are sterilized with a validated sterilization procedure prior to compounding, no preservative added and no sterility testing performed,~~ one of the following:

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

b. Within ~~7~~ 4 days when the preparation is stored in a refrigerator.

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

2. ~~Prepared only with sterile ingredients, no preservative added and no sterility testing performed~~No sterility testing performed or sterility testing not passed, and prepared with only sterile starting components, one of the following:

a. Within ~~4~~6 days when the preparation is stored at controlled room temperature.

b. Within 10~~9~~ days when the preparation is stored in a refrigerator.

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

3. ~~Prepared only with sterile ingredients, preservative added and no sterility testing performed~~Sterility testing performed and passed, one of the following:

a. Within ~~28~~30 days when the preparation is stored at controlled room temperature.

b. Within ~~42~~45 days when the preparation is stored in a refrigerator.

c. Within ~~45~~60 days when the preparation is stored in a freezer.

~~4. Prepared only with sterile ingredients, no preservative added and sterility testing, one of the following:~~

~~a. Within 28 days when the preparation is stored at controlled room temperature.~~

~~b. Within 42 days when the preparation is stored in a refrigerator.~~

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

~~5. Prepared with only sterile ingredients, preservative added and sterility testing, one of the following:~~

~~a. Within 42 days when the preparation is stored at controlled room temperature.~~

~~b. Within 42 days when the preparation is stored in a refrigerator.~~

~~c. Within 45 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. ~~Prepared with no preservative added and no sterility testing performed~~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. ~~Prepared with no preservative added and sterility testing performed~~Sterility testing performed and passed, one of the following:

a. Within ~~28~~45 days when the preparation is stored at controlled room temperature.

b. Within ~~42~~60 days when the preparation is stored in a refrigerator.

c. Within ~~45~~90 days when the preparation is stored in a freezer.

~~3. Prepared with preservative added and no sterility testing performed, one of the following:~~

~~a. Within 28 days when the preparation is stored at controlled room temperature.~~

~~b. Within 42 days when the preparation is stored in a refrigerator.~~

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

~~4. Prepared with preservative added and sterility testing performed, one of the following:~~

~~a. Within 42 days when the preparation is stored at controlled room temperature.~~

~~b. Within 42 days when the preparation is stored in a refrigerator.~~

~~c. Within 45 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 at cold temperatures between 2 and 8 degrees Celsius.

(c) Within 45 days when the preparation is stored in a solid frozen state at -20 degrees Celsius.

(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 nine days when the preparation is stored at cold temperatures between 2 and 8 degrees Celsius.

(c) within 45 days when the preparation is stored in a solid frozen state at -20 degrees Celsius.

(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 three days when the preparation is stored at cold temperatures.

(c) Within 45 days when the preparation is stored in a solid frozen state.

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

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.

BUD Reference for the 2021 Proposed Revisions to <797>

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Background

This informational document is intended to supplement the proposed *USP* General Chapter <797>. The proposed chapter and additional supplementary materials are posted online here. Proposed <797> is available for public comment until January 31, 2022. This supplemental document is not part of the proposed chapter, is not a comprehensive overview of the proposed chapter, and is not intended to be used in place of the proposed chapter. Rather, it provides a brief explanation of beyond-use date (BUD) assignments and other requirements in the proposed revisions to *USP* <797>.

This does not reflect the Compounding Expert Committee's (CMP EC) opinions on further revisions to the chapter. This document is not intended to be subject to public comment. Stakeholders are encouraged to submit comments on the proposed chapter for the CMP EC to continue to evaluate revisions to the chapter. The CMP EC will consider all comments received on the chapter.

Please note that neither the proposed chapter nor this document are official *United States Pharmacopeia – National Formulary* (*USP-NF*) text and they are not intended to be enforceable by regulatory authorities. Users must refer to the *USP-NF* for official text.

Questions may be sent to CompoundingSL@USP.org.

Introduction

Proposed General Chapter <797> distinguishes three categories of compounded sterile preparations (CSPs): Category 1, Category 2, and Category 3, primarily based on the state of environmental control under which they are compounded, the probability for microbial growth during the time they will be stored, and the time period within which they must be used.

Category 1 CSPs

Category 1 CSPs may be compounded in an ISO Class 5 or better primary engineering control (PEC) placed in an unclassified segregated compounding area (SCA). Category 1 CSPs are assigned a BUD of 12 hours or less at controlled room temperature (CRT) or 24 hours or less if refrigerated, when compounded in accordance with all Category 1 CSP requirements.

2021 Proposed *USP* <797> *Table 10*. BUD Limits for Category 1 CSPs

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

Category 2 CSPs

Category 2 CSPs require more environmental controls and testing than Category 1 CSPs and may be assigned a BUD up to the limits described in *Table 11* of the 2021 proposed *USP* <797>, when compounded in accordance with all Category 2 CSP requirements.

2021 Proposed *USP* <797> *Table 11*. BUD Limits for Category 2 CSPs

Preparation Characteristics		Storage Conditions		
Compounding Method	**Sterility Testing Performed and 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

Category 3 CSPs

Category 3 CSPs may be assigned longer BUDs than the limits set for Category 2 CSPs, up to the limits described in *Table 12* of the 2021 proposed *USP* <797>, when compounded in accordance with all Category 3 CSP requirements. Additional requirements must be met when assigning BUDs for Category 3 CSPs.

2021 Proposed *USP* <797> *Table 12*: BUD Limits for Category 3 CSPs

Preparation Characteristics	Storage Conditions		
Compounding Method	**Controlled Room Temperature (20°–25°)**	**Refrigerator (2°–8°)**	**Freezer (–25° to –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

Summary Comparison of Minimum Requirements for Category 1, Category 2, and Category 3 CSPs in the 2021 Proposed *USP* <797>

Requirements	Category 1 CSPs	Category 2 CSPs	Category 3 CSPs
Personnel Training and Evaluation (See Proposed <797> Section 2)			
Training in sterile compounding principles and practices, and competency evaluation	Initially and at least every 12 months	Initially and at least every 12 months	Initially and at least every 12 months
Garbing competency evaluation	Initial evaluation no fewer than 3 separate times Then at least one time every 6 months	Initial evaluation no fewer than 3 separate times Then at least one time every 6 months	Initial evaluation no fewer than 3 separate times Then at least one time every 3 months for personnel who compound Category 3 CSPs
Aseptic manipulation competency evaluation	Initially and at least every 6 months	Initially and at least every 6 months	Initially and at least every 3 months for personnel who compound Category 3 CSPs
Personal Hygiene and Garbing (See Proposed <797> Section 3)			
Where garb is donned	Within the perimeter of the SCA	Garb should be donned in a classified area before entering the buffer room	Garb should be donned in a classified area before entering the buffer room
Minimum garbing requirements	▸ Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck (e.g., gown); Garment may be reused during a shift if not worn for hazardous drug (HD) compounding and if it is maintained inside the perimeter of an SCA ▸ 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, (i.e., 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	▸ Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck (e.g., gown); Garment may be reused during a shift if not worn for HD compounding and if it is maintained in a classified area ▸ 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, (i.e., 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	If the facility compounds Category 3 CSPs, additional garbing requirements must be continuously met. The following additional garbing requirements must be followed in the cleanroom suite where Category 3 CSPs are prepared for all personnel regardless of whether Category 3 CPs are compounded on a given day: 1. Not allow any exposed skin in the buffer room. (i.e., face and neck must be covered) 2. All low-lint garb must be sterile 3. Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle

Facilities and Engineering Controls (See Proposed <797> Section 4)			
Minimum PEC placement requirements	Unclassified SCA	ISO Class 7 positive-pressure buffer room with an ISO Class 8 positive-pressure anteroom if compounding non-hazardous drugs ISO Class 7 positive-pressure buffer room with an ISO Class 7 positive-pressure anteroom if compounding HDs Pharmaceutical isolator – ISO Class 8 positive-pressure room	ISO Class 7 positive pressure buffer room with an ISO Class 8 positive-pressure anteroom if compounding non-hazardous drugs ISO Class 7 positive pressure buffer room with an ISO Class 7 positive-pressure ante-room if compounding HDs Pharmaceutical isolator – ISO Class 8 positive-pressure room
Certification and Recertification (See Proposed <797> Section 5)			
PEC Recertification	At least every 6 months	At least every 6 months	At least every 6 months
Total airborne particle sampling	At least every 6 months	At least every 6 months	At least every 6 months
Microbiological Air and Surface Monitoring (See Proposed <797> Section 6)			
Viable air sampling	Initially and at least every 6 months	Initially and at least every 6 months	Completed within 30 days prior to commencing Category 3 compounding Then at least monthly
Surface sampling	Initially and at least monthly	Initially and at least monthly	Initially and at least weekly Within the PEC at the end of each batch, before cleaning and disinfection occurs
Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in Compounding Areas (See Proposed <797> Section 7)			
Minimum frequency for cleaning	**PEC(s) and equipment inside the PEC(s)** – On days when compounding occurs and for surface contamination **Removable work tray of the PEC, when applicable** – Work surface of the tray daily on days when compounding occurs. All surfaces and the area underneath the work tray monthly. **Pass-through(s), work surface(s) outside the PEC, and floor(s)** – Daily on days when compounding occurs **Wall(s), door(s), door frame(s), ceiling(s), storage shelving and bins, and equipment outside the PEC(s)** – Monthly	**PEC(s) and equipment inside the PEC(s)** – On days when compounding occurs and for surface contamination **Removable work tray of the PEC, when applicable** – Work surface of the tray daily on days when compounding occurs. All surfaces and the area underneath the work tray monthly. **Pass-through(s), work surface(s) outside the PEC, and floor(s)** – Daily on days when compounding occurs **Wall(s), door(s), door frame(s), ceiling(s), storage shelving and bins, and equipment outside the PEC(s)** – Monthly	**PEC(s) and equipment inside the PEC(s)** – On days when compounding occurs and for surface contamination **Removable work tray of the PEC, when applicable** – Work surface of the tray daily on days when compounding occurs. All surfaces and the area underneath the work tray monthly. **Pass-through(s), work surface(s) outside the PEC, and floor(s)** – Daily on days when compounding occurs **Wall(s), door(s), door frame(s), ceiling(s), storage shelving and bins, and equipment outside the PEC(s)** – Monthly

Minimum frequency for disinfecting	**PEC(s) and equipment inside the PEC(s)** – Before compounding on days when compounding occurs and for surface contamination. Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted and the work surface of the PEC must be disinfected immediately after compounding. **Removable work tray of the PEC, when applicable** – Work surface of the tray before compounding on days when compounding occurs. Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if compounding takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted and the work surface of the PEC must be disinfected immediately after compounding. All surfaces and the area underneath the work tray monthly. **Pass-through(s), work surface(s) outside the PEC, and floor(s)** – Daily on days when compounding occurs **Wall(s), door(s), door frame(s), ceiling(s), storage shelving and bins, and equipment outside the PEC(s)** – Monthly	**PEC(s) and equipment inside the PEC(s)** – Before compounding on days when compounding occurs and for surface contamination. Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted and the work surface of the PEC must be disinfected immediately after compounding. **Removable work tray of the PEC, when applicable** – Work surface of the tray before compounding on days when compounding occurs. Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if compounding takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted and the work surface of the PEC must be disinfected immediately after compounding. All surfaces and the area underneath the work tray monthly. **Pass-through(s), work surface(s) outside the PEC, and floor(s)** – Daily on days when compounding occurs **Wall(s), door(s), door frame(s), ceiling(s), storage shelving and bins, and equipment outside the PEC(s)** – Monthly	**PEC(s) and equipment inside the PEC(s)** – Before compounding on days when compounding occurs and for surface contamination. Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted and the work surface of the PEC must be disinfected immediately after compounding. **Removable work tray of the PEC, when applicable** – Work surface of the tray before compounding on days when compounding occurs. Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if compounding takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted and the work surface of the PEC must be disinfected immediately after compounding. All surfaces and the area underneath the work tray monthly. **Pass-through(s), work surface(s) outside the PEC, and floor(s)** – Daily on days when compounding occurs **Wall(s), door(s), door frame(s), ceiling(s), storage shelving and bins, and equipment outside the PEC(s)** – Monthly
Minimum frequency for applying sporicidal disinfectant	**PEC(s) and equipment inside the PEC(s)** – Monthly **Removable work tray of the PEC, when applicable** – Work surface of the tray, all surfaces, and the area underneath the work tray monthly **Pass-through(s), work surface(s) outside the PEC, and floor(s)** – Monthly **Wall(s), door(s), door frame(s), ceiling(s), and storage shelving and bins** – Monthly **Equipment outside the PEC(s)** – Monthly	**PEC(s) and equipment inside the PEC(s)** – Monthly **Removable work tray of the PEC, when applicable** – Work surface of the tray, all surfaces, and the area underneath the work tray monthly **Pass-through(s), work surface(s) outside the PEC, and floor(s)** – Monthly **Wall(s), door(s), door frame(s), ceiling(s), and storage shelving and bins** – Monthly **Equipment outside the PEC(s)** – Monthly	**PEC(s) and equipment inside the PEC(s)** – Weekly **Removable work tray of the PEC, when applicable** – Work surface of the tray, all surfaces, and the area underneath the work tray monthly **Pass-through(s), work surface(s) outside the PEC, and floor(s)** – Weekly **Wall(s), door(s), door frame(s), ceiling(s), and storage shelving and bins** – Monthly **Equipment outside the PEC(s)** – Weekly

Equipment, Supplies, and Components (See Proposed <797> Section 9)			
Accuracy assessment for automated compounding devices	Initially and again each day the equipment is used to compound	Initially and again each day the equipment is used to compound	Initially and again each day the equipment is used to compound
Release Inspections and Testing (See Proposed <797> Section 12)			
Visual inspection	Before release and dispensing, the CSP must be visually inspected to determine whether the physical appearance is as expected	Before release and dispensing, the CSP must be visually inspected to determine whether the physical appearance is as expected	Before release and dispensing, the CSP must be visually inspected to determine whether the physical appearance is as expected
Sterility testing	Not required	Required for BUDs requiring sterility testing	Required for all Category 3 CSPs
Bacterial endotoxins testing	Not required for Category 1 injectable CSPs	Required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing Category 2 CSPs assigned a BUD that does not require sterility testing, but made from one or more nonsterile components, should be tested	Required for Category 3 injectable CSPs compounded from one or more nonsterile component(s)
Establishing Beyond-Use Dates (See Proposed <797> Section 14)			
BUD Limits	*See Table 10*	*See Table 11*	*See Table 12*
Stability data	The CSP formulation must remain chemically and physically stable, and its packaging must maintain its integrity for the duration of the BUD. A shorter BUD must be assigned when the stability of the CSP or its components is less than the hours or days stated in *Table 10*. Additionally, the BUD must not exceed the shortest remaining expiration date or BUD of any of the starting components.	The CSP formulation must remain chemically and physically stable, and its packaging must maintain its integrity for the duration of the BUD. A shorter BUD must be assigned when the stability of the CSP or its components is less than the hours or days stated in *Table 11*. Additionally, the BUD must not exceed the shortest remaining expiration date or BUD of any of the starting components.	The CSP formulation must remain chemically and physically stable, and its packaging must maintain its integrity for the duration of the BUD. A shorter BUD must be assigned when the stability of the CSP or its components is less than the hours or days stated in *Table 12*. Additionally, the BUD must not exceed the shortest remaining expiration date or BUD of any of the starting components. The BUD assigned to a Category 3 CSP must be supported by stability data obtained using a stability-indicating analytical method that is able to distinguish the active ingredient from its degradants and impurities (e.g., by forced degradation studies) and quantify the amount of the active ingredient. ▸ The Category 3 CSP must be prepared according to the exact formulation (API and other ingredients of identical grade and procedures) from which the stability data are derived

Stability data			• The Category 3 CSP must be packaged and stored in a container closure of the same materials of composition as that used in the study • The analytical method must be validated based on characteristics such as those described in <1225> *Validation of Compendial Procedures* • The compounding facility must have documentation of the stability study, including a description of the methodology (e.g., number of samples taken, storage conditions), validation of the method, the stability-indicating analytical method, and all of the results of the study If the Category 3 CSP is an injection (<788> *Particulate Matter in Injections*) or if it is an ophthalmic solution (<789> *Particulate Matter in Ophthalmic Solutions*), particulate-matter testing is conducted once per formulation with acceptable results. Once for each formulation and for each container closure system in which it will be packaged, the container closure system used is evaluated for and conforms to container closure integrity (see <1207> *Package Integrity Evaluation – Sterile Products*).

Immediate-Use CSPs

CSPs compounded for direct and immediate administration must be administered within 4 hours following the start of preparation and are not subject to the requirements for Category 1, Category 2, or Category 3 CSPs when all requirements for immediate-use CSPs are met.

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 (e.g., 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 for the individual patient 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 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 exact 4-hour time period within which administration must begin.

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 CSP must be used
Multiple-dose CSPs	Whichever is shorter: BUD limits assigned based on *Table 11* or *Table 12* of proposed <797> or Up to 28 days after the multiple-dose container is initially entered or punctured, if supported by antimicrobial effectiveness testing results
Multiple-dose, nonpreserved, aqueous ophthalmic CSPs for use by a single patient	BUD limits assigned based on *Table 11* or *Table 12* of proposed <797> and Discarded 24 hours after first opening if stored at room temperature or 72 hours if refrigerated

Additional Requirements for Multiple-Dose CSPs

An aqueous multiple-dose CSP must additionally pass antimicrobial effectiveness testing in accordance with *USP* <51>. The compounder may rely on antimicrobial effectiveness testing:

1. Conducted (or contracted for) once for each formulation in the particular container closure system in which it will be packaged, or
2. Results from an FDA-registered facility or published in peer-reviewed literature sources, provided that the CSP formulation (including any preservative) and container closure system are exactly the same as those tested, unless a bracketing study is performed. Antimicrobial effectiveness testing may be performed on a low concentration and a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.

For multiple-dose, nonpreserved, aqueous ophthalmic CSPs, the requirement for passing antimicrobial effectiveness testing in accordance with *USP* <51> is not required only if the preparation is:

- Prepared as a Category 2 or Category 3 CSP
- For use by a single patient
- Includes the following statement on the container label: "Discard 24 hours after first opening when stored at controlled room temperature, or after 72 hours when stored under refrigeration."