1997-98 SESSION COMMITTEE HEARING RECORDS

Committee Name:

Joint Committee for Review of Administrative Rules (JCR-AR)

Sample:

- Record of Comm. Proceedings
- 97hrAC-EdR_RCP_pt01a
- 97hrAC-EdR_RCP_pt01b
- 97hrAC-EdR_RCP_pt02

- *Appointments ... Appt*
-
- *Clearinghouse Rules ... CRule*
- *97hr_JCR-AR_CRule_98-076*
- *Committee Hearings ... CH*
-
- *Committee Reports ... CR*
-
- *Executive Sessions ... ES*
-
- *Hearing Records ... HR*
-
- *Miscellaneous ... Misc*
-
- *Record of Comm. Proceedings ... RCP*
-

98-076 PHAR 15 - STERILE PHARMACEUT. PREPARED BY PHARMACISTS

LCRC FORM 2

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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 **98–076**

AN ORDER to create Phar 15, relating to the preparation of sterile pharmaceuticals by pharmacists.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

05–22–98 RECEIVED BY LEGISLATIVE COUNCIL.

06–18–98 REPORT SENT TO AGENCY.

RNS:AS:kjf;jt

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 ☑

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CLEARINGHOUSE RULE 98–076

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated October 1994.]

2. Form, Style and Placement in Administrative Code

a. Section Phar 1.02 (intro.) should be amended so that the definitions set forth in that section also apply to ch. Phar 15. A similar change should be made in s. Phar 1.01.

b. The rule incorporates various technical standards by reference. For example, s. Phar 15.02 (2) refers to "national sanitation foundations standard 49" and sub. (3) refers to "federal standard 209." The board should review s. 2.08, Manual, regarding incorporation of standards by reference and required consent of the Attorney General and Revisor of Statutes.

c. Section Phar 15.03 refers to a policy and procedure manual and describes the contents of the manual. Presumably, this manual is prepared by a pharmacy. Subsection (1) needs to be written in the active voice to clarify this; i.e., "A pharmacy shall prepare . . . ."

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

Section Phar 15.04 (2) (b) refers to "OSHA regulations." Can these regulations be cited specifically?

Also, s. Phar 15.08 (2) refers to "other protective apparel as determined by OSHA." How does OSHA determine this? Can specific regulations be cited?

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

a. In s. Phar 15.02 (1), "the technique involving" could be deleted.

b. In s. Phar 15.02 (2), a hyphen should be inserted after "low" and after "moderate."

c. In the Note to s. Phar 15.02 (3), it is unclear what "current revision" means. Also, it appears that the comma after "agencies" should be deleted.

d. In s. Phar 15.02 (4) and (5), "by" could be replaced with "due to."

e. In s. Phar 15.04 (1) and in several other provisions of the rule, "A" should replace "The." [For other examples, see s. Phar 15.05 (2) (intro.) and (3).] Also, in the second sentence, should "facility" be replaced with "area"?

f. In s. Phar 15.04 (2) (a), "that are" should be inserted before "capable." Also, it appears that the last sentence could be deleted and "during normal activity" could be inserted after "class 100 conditions" in the first sentence.

g. In s. Phar 15.04 (2) (b), the comma after "used needles" should be replaced with "and" and "as well as" should be replaced with "and." Also, the comma after "compounding" should be moved to follow "and."

h. In s. Phar 15.04 (2) (c), "to include" should be replaced with "including." Also, it appears that "when" should be replaced with "in pharmacies where." Also, that paragraph refers to "class II biological safety cabinet." Although "biological safety cabinetry" is defined, "class II" is not. Also, see s. Phar 15.08 (1).

i. In s. Phar 15.04 (2) (e), "should be" should be deleted.

j. In s. Phar 15.04 (3) (f), it is unclear what "administration devices" are. Could this paragraph be deleted?

k. In s. Phar 15.04 (4), "should" should be replaced with "shall." This change needs to be made in several provisions of the rule.

l. In s. Phar 15.05 (1), "must" should be replaced with "shall" and a hyphen should be inserted between "pharmacy" and "prepared." Throughout the rule, "must" should be replaced with "shall."

m. In s. Phar 15.05 (1) (a), "of personnel" should be inserted at the end of the sentence.

n. In s. Phar 15.05 (2) (intro.), "must" should be replaced with "shall." Also, should "by a single patient" be replaced with "for a single patient"? Also, it appears that "when they" should be replaced with "if the pharmaceuticals." Finally, it appears that "by including it on the label only" should be deleted.

o. In s. Phar 15.05 (2) (a) to (d), "The" should be inserted at the beginning of each sentence.

p. In s. Phar 15.05 (2) (a), it appears that "and" should be replaced with "on."

q. In s. Phar 15.05 (2) (d), the comma after "date" should be moved to follow "requirements."

r. In s. Phar 15.07 (1), "their" should be replaced with "the patient's."

s. In s. Phar 15.07 (2), "associated with" should be replaced with "requirements for."

t. In s. Phar 15.08 (1), "should" in the first sentence should be replaced with "shall" and "should" in the second sentence should be replaced with "may." Also, in the second sentence, "If" should replace "In the event" and the first "other" should be deleted.

u. In s. Phar 15.08 (2), (5) and (6), "must" should be replaced with "shall."

v. In s. Phar 15.09 (intro.), "as part of the labeling" should be replaced with "on the labels."

w. In s. Phar 15.09 (2), "to include" should be replaced with "and" and the comma after "date" should be moved to follow "time."

x. In s. Phar 15.10, "this type" should be replaced with "the type" and "self-" should be deleted.

y. In s. Phar 15.11 (2), the comma after "clean rooms" should be replaced with "and."

z. In s. Phar 15.11 (3), "as well as" should be replaced with "and."

aa. In s. Phar 15.11 (4), in the second sentence, "the" should replace "such." In the last sentence, a hyphen should be inserted between "particulate" and "free."

ab. In s. Phar 15.11 (5), a hyphen should be inserted between "pharmacy" and "prepared."

ac. The excessive use of the passive voice in s. Phar 15.11 makes it difficult for a reader to know who must take the required action. [See s. 1.01, Manual.] In every subsection that begins with "There shall be," these words should be replaced with "A pharmacy shall have . . ." or "A pharmacy shall maintain . . ." or a similar phrase. The second sentence of sub. (1) should begin "_____ shall examine . . . ." The last sentence of sub. (2) should begin "_____ shall maintain . . . ."

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 98-)

PROPOSED ORDER

An order of the Pharmacy Examining Board to create Chapter Phar 15, relating to the preparation of sterile pharmaceuticals by pharmacists.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2) and 450.02 (3), Stats.

Statutes interpreted: s. 450.09 (3) and (4), Stats.

The proposed order of the Pharmacy Examining Board creates standards relating to the compounding of drugs by pharmacists in the areas of (1) pharmaceutical care; (2) the preparation, labeling and distribution of sterile pharmaceutical drugs by pharmacies, either pursuant to or in anticipation of receiving a prescription order; and, (3) product quality and characteristics. The standards would be applied to all sterile pharmaceutical drug products, notwithstanding the location of the patient, whether in a home, hospital, nursing home, hospice or physician's office.

The proposed order recognizes that an important aspect of practice for many pharmacists is the act of compounding. Compounding is defined in sec. 450.01 (3), Stats., to mean to "mix, combine or put together various ingredients or drugs for the purpose of dispensing." Compounding involves the preparation of drugs by a pharmacist for dispensing to patients; as opposed to the dispensing of prefabricated drugs (e.g., tablets, liquids) received from drug manufacturers.

The board currently does not have any rules establishing minimum standards for the preparation of sterile drug products by pharmacists. However, in compounding sterile drug products, the Pharmacy Examining Board believes it is essential to the health, safety and welfare of the public that the pharmaceuticals be prepared in a physical environment that is suitable for the aseptic preparation of drug products. Additionally, appropriate records need to be maintained regarding the preparation of sterile pharmaceuticals (e.g., documentation of refrigerator and freezer temperatures, certification of laminar airflow hoods). Furthermore, pharmacies must maintain a documented, ongoing quality assurance control program to monitor personnel performance,

equipment, and facilities to assure the consistent preparation of quality sterile products for patient use.

Various resources have been reviewed in preparing the proposed rules, including the "Model Rules for Sterile Pharmaceuticals" formulated by the National Association of Boards of Pharmacy, the "Technical Assistance Bulletin on Quality Assurance for Pharmacy-Prepared Sterile Products" issued by the American Society of Hospital Pharmacists, and reference materials regarding the use of sterile products in the United States Pharmacopoeia.

More specifically, s. Phar 15.02 sets forth definitions of several technical terms utilized in the practice of compounding and used throughout the proposed rule. Section Phar 15.03 requires a policy and procedure manual be developed relating to various aspects of the compounding process. Section Phar 15.04 sets forth the physical requirements necessary for the compounding area in order to assure the aseptic preparation of sterile pharmaceuticals. Section Phar 15.05 lists the specific records which must be kept respecting the preparation of sterile pharmaceuticals. Section 15.06 requires the appropriate environment control during the shipping of sterile pharmaceuticals. Section Phar 15.07 specifies that emergency drugs must be available for home care patients receiving sterile pharmaceuticals in the event of an emergency need. Section Phar 15.08 impose additional requirements upon pharmacies compounding "cytotoxic" drugs. Section Phar 15.09 sets forth the labeling requirements for sterile pharmaceuticals. Section Phar 15.10 relates to documenting the training provided a patient who self-administers sterile pharmaceuticals. Section Phar 15.11 requires the establishment of a documented quality assurance control program to monitor personnel performance, equipment and facilities.

TEXT OF RULE

SECTION 1. Chapter Phar 15 is created to read:

CHAPTER PHAR 15

STERILE PHARMACEUTICALS

Phar 15.01 AUTHORITY. The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11 (2) and 450.02 (3), Stats.

Phar 15.02 DEFINITIONS. In this chapter:

(1) "Aseptic preparation" means the technique involving procedures designed to preclude contamination of drugs, packaging equipment or supplies by microorganisms during processing.

(2) "Biological safety cabinet" means a containment unit suitable for preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to national sanitation foundations standard 49.

(3) "Class 100 environment" means an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to federal standard 209.

Note: "Federal Standard 209" current revision is the approved governing standard required for use by all federal agencies, utilizing clean room work station controlled environments.

(4) "Critical activities" means activities that are different from other activities by the increased potential opportunity for contamination to occur.

(5) "Critical objects" means objects that are different from other objects by the increased potential opportunity for contamination to occur.

(6) "Cytotoxic drug" means a pharmaceutical used therapeutically as a toxin to alter biochemical activities of phases of cellular division which uniquely contribute to normal cell growth.

(7) "OSHA" means the federal occupational safety and health administration or its successor.

(8) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of skin.

(9) "Practice of pharmacy" has the meaning given in s. 450.01 (16), Stats.

(10) "Sterile pharmaceutical" means any dosage form devoid of viable microorganisms, including but not limited to parenterals, injectables and ophthalmics.

Phar 15.03 POLICY AND PROCEDURE MANUAL. (1) A policy and procedure manual shall be prepared and maintained for compounding, dispensing, delivery, administration, storage and use of sterile pharmaceuticals.

(2) The policy and procedure manual shall include a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities and guidelines regarding patient education and the provision of pharmaceutical services. In addition it shall include up-to-date information on the preparation of sterile pharmaceuticals.

(3) The policy and procedure manual shall be available to all personnel and updated annually or as needed to reflect current practice.

(4) The policy and procedure manual shall be current and available for inspection by the board or its designee.

Phar 15.04 PHYSICAL REQUIREMENTS. (1) The pharmacy shall have a designated area with entry restricted to designated personnel for preparing sterile pharmaceuticals. This area shall be a room structurally isolated from other areas, with restricted entry and access, and must be designed to avoid unnecessary traffic and airflow disturbances from occurring within the controlled facility. It shall only be used for preparation and documentation of sterile pharmaceuticals. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security. Additional drug inventory and bulk supplies shall be stored in an area separate from the designated area for preparing sterile pharmaceuticals.

(2) The pharmacy shall maintain an environment suitable for aseptic preparation of sterile pharmaceuticals and shall have all of the following:

(a) Appropriate environment control devices capable of maintaining at least class 100 conditions in the workplace where critical objects are exposed and critical activities are performed. Furthermore, these devices are capable of maintaining class 100 conditions during normal activity.

(b) Appropriate disposal containers as required by OSHA regulations for used needles, syringes, as well as for disposal of other items in compounding, and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes. This should be disposed of in a timely manner.

(c) Appropriate environmental controls to include class II biological safety cabinetry when cytotoxic drug products are prepared.

(d) Temperature-controlled delivery containers as necessary.

(e) For hand-washing, a sink with hot and cold running water should be in close proximity.

(f) Administration devices as necessary.

(3) The pharmacy shall have sufficient reference materials related to sterile pharmaceuticals to meet the needs of the pharmacy staff.

(4) The designated area should be closed and disinfected at regular intervals with appropriate agents.

Phar 15.05 RECORDS AND REPORTS. (1) In addition to state required record and reporting requirements, the following additional records and reports must be maintained for pharmacy prepared sterile pharmaceutical documentation:

(a) Training and competency evaluations.

(b) Documentation of refrigerator and freezer temperatures.

(c) Certification of laminar airflow hoods.

(2) The following minimum labeling requirements must be met for sterile pharmaceuticals prepared by a single patient ~~when they~~ are to be completely administered within 28 hours ~~by including it on the label only~~:

(a) Identity of all solutions and ingredients and their corresponding amounts, concentration or volumes ~~and~~ the final preparation container in such a manner as to allow the locating of problematic final products.

(b) Identity of personnel involved in preparation.

(c) Date and time of pharmacy preparation where applicable.

(d) Final sterile pharmaceuticals expiration date and storage requirements where applicable.

Phar 15.06 DELIVERY SERVICE. The pharmacist shall assure the appropriate environmental control of all products shipped.

Phar 15.07 EMERGENCY KITS. (1) When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy must supply the patient or their agent with emergency drugs, when authorized by the physician under protocol, if an emergency situation has been anticipated by either the physician, nurse or pharmacist.

(2) The dispensing pharmacy shall be responsible for providing written instructions on the storage and recordkeeping ~~associated with~~ the emergency kit.

Phar 15.08 CYTOTOXIC DRUGS. In addition to the minimum requirements for a pharmacy established by rule of the board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs:

(1) All cytotoxic drugs ~~should~~ be compounded in a vertical flow, class II, biological safety cabinet. In the event non-exposed surfaces become contaminated with cytotoxic agents, no other products other than cytotoxic agents ~~should~~ be compounded in this cabinet until such time as the cabinet is decontaminated utilizing appropriate techniques to eradicate the contaminant.

(2) Personnel shall be protected by a protective barrier or apparel which ~~must~~ include gloves, gowns and other applicable protective apparel as determined by OSHA.

(3) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile pharmaceuticals.

(4) Pharmacy disposal and patient and caregiver education regarding disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements.

(5) Written procedures for the handling of both major and minor spills of cytotoxic agents ~~must~~ be developed and ~~must~~ be included in the pharmacy policy and procedure manual.

(6) Prepared doses of cytotoxic drugs ~~must~~ be dispensed, labeled with proper precautions on the primary and shipping container and ~~should~~ be shipped in a manner to minimize the risk of accidental rupture of the primary container.

Phar 15.09 LABELING. In addition to the labeling requirements of s. 450.11 (4), Stats., the following must also be included ~~as a part of~~ the labeling of sterile pharmaceuticals:

(1) Control or lot number.

(2) Expiration date, ~~to include~~ time when applicable.

(3) Appropriate auxiliary labeling, including precautions.

(4) Storage requirements.

(5) Identification of the responsible pharmacist.

Phar 15.10 PATIENT TRAINING. A pharmacist is responsible for documenting the patient's training and competency in managing ~~this~~ type of therapy provided by the pharmacist to the patient if ~~self~~ administered by the patient or a caregiver. A pharmacist is responsible for the provision of or supervision of the patient training process in any area that relates to drug compounding, administration, labeling, storage, stability or incompatibility. A pharmacist must be responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

Phar 15.11 QUALITY ASSURANCE. (1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications.

(2) All class 100 clean rooms, horizontal and vertical laminar flow hoods shall be certified by an independent contractor according to federal standard 209 for operational efficiency. All biological safety cabinets shall be certified according to national sanitation

foundations standard 49 or manufacturer's specifications. Certification shall take place before initial use or after relocation and at least annually. Appropriate records shall be maintained.

(3) There shall be written procedures requiring sampling for microbial contamination through a validation procedure, simulation of actual aseptic technique, ~~as well as~~ by using bacterial growth medium to culture environmental samples.

(4) If compounding of parenteral solutions is performed using non-sterile chemicals, extensive end-product sterility testing must be documented. If any parenteral solution fails such testing, procedures shall be in place to quarantine future products for sterility testing to assure end-product sterility prior to release of the products from quarantine. The compounding process must utilize components and techniques which assure a sterile and particulate free product.

(5) There shall be a written justification of the assigned expiration date for pharmacy prepared sterile pharmaceuticals.

(6) There shall be documentation of quality assurance audits, including infection control and sterile technique audits at least annually.

(7) There shall be procedures to assure consistent preparation of sterile pharmaceuticals.

(END OF TEXT OF RULE)

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.

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

FISCAL ESTIMATE

1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is $0.00.

2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: $0.00.

3. The projected net annualized fiscal impact on state funds of the proposed rule is: $0.00.

INITIAL REGULATORY FLEXIBILITY ANALYSIS

These proposed rules will be reviewed by the department through its Small Business Review Advisory Committee to determine whether there will be an economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats.

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5/20/98