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 . . . ."

DEC 1 3 1999

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 98-076)**

TO: Senator Judy Robson, Senate Co-Chairperson
Joint Committee for the Review of Administrative Rules
Room 15 South, State Capitol
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the PHARMACY EXAMINING BOARD is submitting in final draft form rules relating to the preparation of sterile pharmaceuticals by pharmacists.

Please stamp or sign a copy of this letter to acknowledge receipt. If you have any questions concerning the final draft form or desire additional information, please contact Pamela Haack at 266-0495.

State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING

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Administrative Rules in Final Draft Form

Pharmacy Examining Board

Relating to: Sterile Pharmaceuticals

Rule: Chapter Phar 15

Clearinghouse Rule: No. 98-076

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	REPORT TO THE LEGISLATURE ON CLEARINGHOUSE 98-076 (s. 227.19 (3), Stats.)

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS:

No new or revised forms are required by these rules.

III. FISCAL ESTIMATES:

These rules will have no significant impact upon state or local units of government.

IV. STATEMENT EXPLAINING NEED:

This 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. These standards apply to all sterile pharmaceutical drug products, notwithstanding the location of the patient.

The 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 rules establishing minimum standards for the preparation of sterile drug products by pharmacists. However, in compounding sterile drug products, the Pharmacy Examining Board finds it 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 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.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on July 14, 1998. The following individuals appeared:

David Musa, M.B.A., R.Ph., Assistant Director of Pharmacy, University of Wisconsin Hospital and Clinics, Clinical Instructor, University of Wisconsin, School of Pharmacy, Madison, WI (also submitted written comments).
Mark McKibben, R.Ph., East Troy, WI (also submitted written comments).
Ronald Smotana, Madison, WI, representing the University of Wisconsin Hospital and Clinics.
Dave Wegner, Madison, WI, representing the University of Wisconsin Hospital and Clinics.
Carol Petersen, Madison, WI, representing Women's International Pharmacy.
James D. Adler, R.Ph., Marshfield, WI, representing Saint Joseph's Hospital, Marshfield (also submitted written comments).
Cheryl Gain, Madison, WI, representing the Wisconsin Department of Commerce Small Business Ombudsman (also submitted written comments).
Connie Hegerfield, Madison, WI, representing Women's International Pharmacy.

Written comments were also received from:
Richard E. Cook, Director, Pharmacy, Saint Joseph's Hospital, Marshfield, WI.
Tom Thielke, M.S., R.Ph., F.A.S.H.P., Director of Pharmacy, University of Wisconsin Hospital and Clinics, Clinical Professor, University of Wisconsin, School of Pharmacy, Madison, WI.
Dennis G. Maki, M.D., Chairman, Infection Control Committee, Head, Section of Infectious Disease, Professor of Medicine, University of Wisconsin Hospital and Clinics, Madison, WI.
Wayne Loveland, R.Ph., The Prescription Center, La Crosse, WI.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2.f. Section Phar 5.05 (2) (c) authorizes the board to prescribe the examinations or educational requirements, or both, which must be successfully completed by an applicant for reinstatement of a license five years or more after the renewal date. Could these requirements be set forth in the rule? If these rules are not set forth in the rule, how will they be made available to the public?

Response: No, these requirements cannot adequately be set forth in the rule. They are determined on a case-by-case basis. Some may have practiced in other states and some have not. Some have taken continuing education and some have not. Every case is different.

Comment 5.e. If it is found under s. Phar 4.046 that there is an error in an examination which has been administered by the board, should the board be required to take any action, such as reviewing the examination scores of all persons who took that examination to determine if the error in the examination would, if corrected, result in the passing of the examination by an applicant who was considered to have failed?

Response: The board employs this review process as a matter of fairness and due process considerations. The board does not believe it is necessary to state the fundamental proposition in a rule.

Comment 5.f. Should s. Phar 5.01 (2) specify that a person who is practicing under an original license is not required to have a current renewal certificate?

Response: No, the board believes it is sufficiently clear that the receipt of the original license permits a person to practice.

Comment 5.g. Is the address referred to in s. Phar 5.02 (2) the home or business address of the pharmacist?

Response: It could be either. That is left up to the pharmacist.

The remaining recommendations suggested in the Clearinghouse Report were accepted in whole.

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

The rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.

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 98-076)

PROPOSED ORDER

An order of the Pharmacy Examining Board to ***amend*** Phar 1.01 and 1.02 (intro.) and 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.

This 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. These standards apply to all sterile pharmaceutical drug products, notwithstanding the location of the patient.

The 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 rules establishing minimum standards for the preparation of sterile drug products by pharmacists. However, in compounding sterile drug products, the Pharmacy Examining Board finds it 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 these 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 pharmacy to develop and maintain a policy and procedure manual 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 that 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 imposes 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. Phar 1.01 is amended to read:

Phar 1.01 Authority. Rules in chs. Phar 1 to ~~13~~ 15 are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats., and ch. 450, Stats.

SECTION 2. Phar 1.02 (intro.) is amended to read:

Phar 1.02 Definitions. (intro.) As used in chs. Phar 1 to ~~14~~ 15:

SECTION 3. 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 preparation using 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 that contains less than 100 particles 0.5 microns in diameter per cubic foot of air, as described in federal standard 209.

Note: "Federal Standard 209" refers to *Federal standard 209E: airborne particulate cleanliness classes in cleanrooms and clean zones* by the Institute of Environmental Sciences published by the Institute of Environmental Sciences in 1992 and used by the United States General Services Administration as the standard required for use by federal agencies utilizing clean room controlled environments.

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

(5) "Critical objects" means objects that are different from other objects due to 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.

(8) "Parenteral" means a 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 pharmacy shall prepare and maintain a policy and procedure manual 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, and facilities and include guidelines regarding patient education and the provision of pharmaceutical services. In addition, the manual 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) A pharmacy shall have a designated area for preparing sterile pharmaceuticals. This area shall be a room structurally isolated from other areas, with entry and access restricted to designated personnel and shall be designed to avoid unnecessary traffic and airflow disturbances. The designated area shall only be used for preparation and documentation of sterile pharmaceuticals. The designated area 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) A pharmacy shall maintain an environment in the designated area suitable for aseptic preparation of sterile pharmaceuticals and shall have all of the following:

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

(b) Appropriate disposal containers as required by OSHA in 29 CFR PART 1910 for used needles and syringes, and 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 including class II biological safety cabinetry in pharmacies where cytotoxic drug products are prepared.

(d) Temperature-controlled delivery containers as necessary.

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

(f) Administration devices as necessary.

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

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

Phar 15.05 Records and reports. (1) Specific records and reports shall be maintained describing the preparation of sterile pharmaceuticals in the pharmacy. These records and reports shall include:

(a) Training and competency evaluations of personnel.

(b) Documentation of refrigerator and freezer temperatures.

(c) Certification of laminar airflow hoods.

(2) The following minimum labeling requirements shall be met for sterile pharmaceuticals prepared for a single patient if the pharmaceuticals are to be completely administered within 28 hours:

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

(b) The identity of personnel involved in preparation.

(c) The date and time of pharmacy preparation where applicable.

(d) The 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 shall supply the patient or the patient's 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 requirements for 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 shall be compounded in a vertical flow, class II, biological safety cabinet. If non-exposed surfaces become contaminated with cytotoxic agents, no products other than cytotoxic drugs may 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 shall include gloves, gowns and other applicable protective apparel as described in 29 CFR PART 1910 of OSHA regulations.

(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 shall be developed and shall be included in the pharmacy policy and procedure manual.

(6) Prepared doses of cytotoxic drugs shall 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 shall also be included on the labels of sterile pharmaceuticals:

(1) Control or lot number.

(2) Expiration date and 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 the type of therapy provided by the pharmacist to the patient if 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 shall 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) The area designated for preparing sterile pharmaceuticals and all horizontal and vertical laminar flow hoods shall be certified to be operationally efficient and meet the standards of a class 100 environment by an independent contractor. 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. Certification records shall be maintained.

Note: "National Sanitation Foundations Standard 49" refers to *National Sanitation Foundation standard no 49 for class II (laminar flow) biohazard cabinetry / as prepared by the NSF Advisory Committee on Biohazard Cabinetry; and recommended for adoption by the NSF Council of Public Health Consultants* by the National Sanitation Foundation (U.S.) published in 1983 by the National Sanitation Foundation of Ann Arbor, Michigan.

(3) A pharmacy shall have written procedures requiring sampling for microbial contamination through a validation procedure, simulation of actual aseptic preparation, and 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 shall be documented. If any parenteral solution fails the 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 shall utilize components and techniques that assure a sterile and particulate-free product.

(5) A pharmacy shall have written justification of the assigned expiration date for pharmacy prepared sterile pharmaceuticals.

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

(7) A pharmacy shall have 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.

FINAL REGULATORY FLEXIBILITY ANALYSIS

These rules will not have a significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.

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