Notice of Intent to Adopt Rules

A copy of the proposed rules may be obtained at https://rules.wyo.gov

Revised August 2023

1. General Information

a. Agency/Board Name*
Administration & Information, Dpt of/Wyoming State Board of Pharmacy

b. Agency/Board Address	c. City	d. Zip Code
1712 Carey Ave, Ste 200	Cheyenne	82002

e. Name of Agency Liaison	f. Agency Liaison Telephone Number
Matthew R. Martineau	(307)634-9636

g. Agency Liaison Email Address
matt.martineau@wyo.gov

h. Date of Public Notice	i. Comment Period End Date
04/25/2025	06/13/2025

j. Public Comment URL or Email Address:
bop@wyo.gov

k. Program
Pharmacy, Board of

Amended Program Name (*if applicable*):

* ☐ *By checking this box, the agency is indicating it is exempt from certain sections of the Administrative Procedure Act including public comment period requirements. Please contact the agency for details regarding these rules.*

2. Legislative Enactment

For purposes of this Section 2, "new" only applies to regular non-emergency rules promulgated in response to a Wyoming legislative enactment not previously addressed in whole or in part by prior rulemaking and does not include rules adopted in response to a federal mandate.

a. Are these non-emergency regular rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

	Chapter:	Year:
■ **No.** ☐ **Yes.** If the rules are new, please provide the Legislative Chapter Number and Year Enacted:		

3. Rule Type and Information

For purposes of this Section 3, "New" means an emergency or regular rule that has never been previously created.

a. Provide the Chapter Number, Title and Proposed Action for Each Chapter. *Please use the "Additional Rule Information" form to identify additional rule chapters.*

Chapter Number:	Chapter Name:			
8	Wholesale Distributor Regulations	☐ New	■ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
13	Non-Sterile Compounding	☐ New	☐ Amended	■ Repealed
	Amended Chapter Name (*if applicable*):			
17	Sterile Compounding	☐ New	☐ Amended	■ Repealed
	Amended Chapter Name (*if applicable*):			
18	Prescribing by Pharmacists	☐ New	■ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
22	Compounding	■ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
		☐ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			

4. Public Comments and Hearing Information

a. A public hearing on the proposed rules has been scheduled. ■ **No.** ☐ **Yes. Please complete the boxes below.**

Date:	Time:	City:	Location:

b. What is the manner in which interested persons may present their views on the rulemaking action?

■ By submitting written comments to the Agency at the physical and/or email address listed in Section 1 above.

☐ At the following URL: _____

A public hearing will be held if requested by 25 persons, a government subdivision, or by an association having not less than 25 members. Requests for a public hearing may be submitted:

■ To the Agency at the physical and/or email address listed in Section 1 above.

☐ At the following URL: _____

c. Any person may urge the Agency not to adopt the rules and request the Agency to state its reasons for overruling the consideration urged against adoption. Requests for an agency response must be made prior to, or within thirty (30) days after adoption, of the rule, addressed to the Agency and Agency Liaison listed in Section 1 above.

5. Federal Law Requirements

a. These rules are created/amended/repealed to comply with federal law or regulatory requirements. ■ **No.** ☐ **Yes. Please complete the boxes below.**

Applicable Federal Law or Regulation Citation:

Indicate one (1):

☐ The proposed rules meet, but do not exceed, minimum federal requirements.

☐ The proposed rules exceed minimum federal requirements.

Any person wishing to object to the accuracy of any information provided by the Agency under this item should submit their objections prior to final adoption to:

☐ To the Agency at the physical and/or email address listed in Section 1 above.

☐ At the following URL: _____

6. State Statutory Requirements

a. Indicate one (1):

■ The proposed rule change *MEETS* minimum substantive statutory requirements.

☐ The proposed rule change *EXCEEDS* minimum substantive statutory requirements. Please attach a statement explaining the reason that the rules exceed the requirements.

b. ■ The Agency has completed a takings assessment as required by W.S. 9-5-304. A copy of the assessment used to evaluate the proposed rules may be obtained:

■ By contacting the Agency at the physical and/or email address listed in Section 1 above.

☐ At the following URL: _____

7. Additional APA Provisions

a. Complete all that apply in regards to uniform rules:

■ These rules are not impacted by the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j).

☐ The following chapters do not differ from the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j):

_____

(Provide chapter numbers)

☐ These chapters differ from the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j) (see Statement of Principal Reasons).

_____

(Provide chapter numbers)

b. Checklist

■ The Statement of Principal Reasons is attached to this Notice and, in compliance with Tri-State Generation and Transmission Association, Inc. v. Environmental Quality Council, 590 P.2d 1324 (Wyo. 1979), includes a brief statement of the substance or terms of the rule and the basis and purpose of the rule.

☐ If applicable: In consultation with the Attorney General's Office, the Agency's Attorney General representative concurs that strike and underscore is not required as the proposed amendments are pervasive (Chapter 3, *Types of Rules Filings*, Section 1, Proposed Rules, of the Rules on Rules).

8. Authorization

a. I certify that the foregoing information is correct.

Printed Name of Authorized Individual	Matthew R. Martineau
Title of Authorized Individual	Executive Director
Date of Authorization	04/25/2025

WYOMING STATE BOARD OF PHARMACY

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Wyoming Pharmacy Act Rules and Regulations

Statement of Principal Reasons for Revisions

April 25, 2025

The Wyoming State Board of Pharmacy proposes to amend Chapters 8, 13, 17, 18, and 22 of the Wyoming Pharmacy Act Rules and Regulations in order to modernize, reorganize and simplify the Board's Rules and Regulations.

On January 29, 2025, emergency rules were approved. Specifically, Chapter 8 Wholesale Distributor Regulations now clarify that veterinary prescription drug wholesalers may sell or deliver non-controlled substance veterinary medications to a person responsible for the control of a "livestock animal," as that term defined in Wyo. Stat. § 11-29-101(a)(vi), and subject to specified conditions. The Board proposes to permanently revise Chapter 8 to continue to allow this practice.

The Board also proposes to repeal Chapter 13 Non-Sterile Compounding and Chapter 17 Sterile Compounding in order to create a new Chapter 22 Compounding. The new Chapter 22 incorporates United States Pharmacopoeia (USP) chapters 795 Pharmaceutical Compounding – Nonsterile Preparations, 797 Pharmaceutical Compounding – Sterile Preparations, 800 Hazardous Drugs—Handling in Healthcare Settings, and 825 Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging by reference as allowed by Wyo. Stat. § 33-24-127(a). The *Pure Food and Drug Act of 1906* established USP as the standard of purity, strength, and quality for medications in the United States. USP is part of The Joint Commission's survey and is recognized by the Centers for Medicare & Medicaid Services as the minimum threshold for quality that hospitals and Critical Access Hospitals (s) must meet. Additionally, more than forty-five (45) states require compliance with USP, whether through statute or rule.

The Board proposes to remove Chapter 18's requirement that pharmacists must successfully complete a minimum of one hour of an ACPE accredited CE program related to the use of opiate antagonists prior to prescribing. Narcan (naloxone) was first approved by the FDA in 2015 as a prescription drug and is the standard treatment for opioid overdose. Narcan (naloxone) has since been approved for over-the-counter, nonprescription, use. Additionally, Wyo. Stat. Title 35, Ch. 4, Art. 9 Emergency Administration Of Medical Treatment Act does not require pharmacists or other health care practitioners to complete additional CE prior to prescribing epinephrine auto-injectors or opiate antagonists.

As required by Wyoming Statute § 16-3-103(a)(i)(G), these rules meet minimum substantive state statutory requirements.

Chapter 8 Wholesale Distributor Regulations

- Section 9 is revised to clarify that veterinary prescription drug wholesalers may sell or deliver non-controlled substance veterinary medications to a person responsible for the control of a livestock animal, as defined in Wyo. Stat. § 11-29-101(a)(vi) subject to certain conditions:
    - A licensed veterinarian has issued a written a prescription order in the course of an existing, valid veterinarian-client-patient relationship;
    - The prescription order becomes void after two years, unless the veterinarian specifies a shorter expiration date;
    - The veterinary prescription drug wholesale distributor shall not distribute larger quantities than the order authorizes and must sell the non-controlled substance prescription drug(s) in the original, unbroken manufacturer's containers;
    - Records must be retained as specified.
- Sections 13 and 16 are updated to current organization standards.

Chapter 13 Non-Sterile Compounding - ***Repealed***

Chapter 17 Sterile Compounding - ***Repealed***

Chapter 18 Prescribing by Pharmacists

- Section 4(b) is deleted and the section is reorganized accordingly.

Chapter 22 Compounding

- A new chapter is created incorporating USP Chapters 795, 797, 800, and 825 by reference.
- The Board has determined that posting the incorporated material on the Internet would constitute a violation of federal copyright law.
- The copyrighted incorporated material will be available for public inspection and examination, but may not be copied, at the Wyoming Department of Health, 2300 Capitol Avenue, Cheyenne, Wyoming 82002, and at the Wyoming State Board of Pharmacy, 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming 82002.

~~**WHOLESALE DISTRIBUTOR REGULATIONS**~~

~~**CHAPTER 8**~~

CHAPTER 8

WHOLESALE DISTRIBUTOR REGULATIONS

Section 1. Authority.

These rules are promulgated as authorized by the Wyoming Pharmacy Act W.S. § 33-24-101 through -301.

Section 2. Purpose.

The purpose of this rule is to provide for the minimum licensing standards necessary to ensure the safety and efficacy of prescription drugs offered for sale by manufacturers and wholesale distributors.

Section 3. Scope.

This Chapter applies to any person, partnership, corporation or business engaging in the wholesale distribution of human prescription drugs either into, out of, or within this State.

Section 4. Definitions.

(a) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products.

(b) "Common Carrier" means any person or entity who undertakes directly or indirectly to transport property, including prescription drugs, for compensation.

(c) "Designated Representative" means an individual designated by the wholesale distributor and who is actively involved in and aware of the actual daily operation of the wholesale drug distributor at the wholesaler's licensed location.

(d) "Dispenser" means a retail pharmacy, institutional pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliate warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and does not include a person who dispenses only products to be used in animals.

(e) "Distribute" or "Distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription.

(f) "Drug" means a substance recognized as a drug in any official compendium as listed in W.S. § 33-24-127, designated for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals.

(g) "Drug Sample" means a unit of a prescription drug that is not intended to be sold but is intended to promote the sale of the drug.

(h) "Food and Drug Administration" (FDA) means a federal agency within the United States Department of Health.

(i) "Illegitimate product" means a product for which credible evidence shows that the product:

(i) Is counterfeit, diverted or stolen;

(ii) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(iii) Is the subject of a fraudulent transaction; or

(iv) Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

(j) "Manufacturer's Exclusive Distributor" means an individual or entity who purchased the product directly from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

(k) "Misbranded" means a drug whose label is false or misleading or the label does not bear the name and address of the manufacturer, packer or distributor and does not have an accurate statement of the quantities of the active ingredients or:

(i) If the advertising or promotion of a compounded drug is false or misleading in any particular; or

(ii) If it is a drug and it fails to bear the product identifier.

(l) "Outsourcing Facility" means a person who registers with the FDA under section 503B of the federal act to compound sterile drugs for human use under the supervision of a pharmacist but without a prescription from a practitioner for a particular patient.

(m) "Prescription Drug" or "Legend Drug" means a drug which, under federal law, is required to be labeled with one of the following statements:

(i) "Caution: Federal law prohibits dispensing without a prescription";

(ii) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or

(iii) "Rx Only."

(n) "Product Identifier" means a standardized graphic that includes in both human-readable form and on a machine readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

(o) "Product Tracing" means a dispenser shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction, provides:

(i) Transaction Information (TI);

(ii) Transaction History (TH); and

(iii) Transaction Statement (TS).

(p) "Reverse Processor" means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

(q) "Suspect Product" means there is reason to believe that such product:

(i) Is potentially counterfeit, diverted or stolen;

(ii) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(iii) Is potentially the subject of a fraudulent transaction; or

(iv) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(r) "Third Party Logistics Provider" means an entity that provides or coordinates warehousing, distribution, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product but does not take

ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(s) "Transaction" in general means the transfer of product between persons in which a change of ownership occurs. The term transaction does not include:

(i) Intracompany distribution of any product between members of an affiliate or within a manufacturer;

(ii) The distribution of a product among hospitals or other health care entities that are under common control;

(iii) The distribution of a product for emergency medical reasons including a public health emergency, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(iv) The dispensing of a product pursuant to a prescription;

(v) The distribution of product samples by a manufacturer or a licensed wholesale distributor;

(vi) The distribution of blood or blood components intended for transfusion;

(vii) The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

(viii) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization;

(ix) The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors (except that records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors); or

(x) The dispensing of a product approved under section 512(c) of the Federal Food, Drug, and Cosmetic Act regarding a new animal drug application.

(t) "Transaction History" means a statement in paper or electronic form that includes the transaction information of each prior transaction going back to the manufacturer of the product.

(u) "Transaction Information" means:

(i) The proprietary or established name or names of the product;

(ii) The strength and dosage form of the product;

(iii) The national drug code number of the product;

(iv) The container size;

(v) The number of containers;

(vi) The lot number of the product;

(vii) The transaction date;

(viii) The shipment date, if more than twenty-four (24) hours after the transaction date;

(ix) The business name and address of the person from whom ownership is being transferred; and

(x) The business name and address of the person to whom ownership is being transferred.

(v) "Transaction Statement" is a statement in paper or electronic form that the entity transferring ownership in a transaction:

(i) Is authorized under federal law;

(ii) Received the product from a person who is authorized as required under federal law;

(iii) Received transaction information and a transaction statement from the prior owner of the product as required by federal law;

(iv) Did not knowingly ship a suspect or illegitimate product;

(v) Had systems and processes in place to comply with verification requirements outlined in federal law;

(vi) Did not knowingly provide false transaction information; and

(vii) Did not knowingly alter the transaction history.

(w) "Wholesale Distribution" means the distribution of a drug to a person other than a consumer or patient, or receipt of a drug subject by a person other than the consumer or patient, but does not include:

(i) The intracompany distribution of any drug between members of an affiliate or with a manufacturer;

(ii) The distribution of a drug or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(iii) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(iv) The dispensing of a drug pursuant to a prescription;

(v) The distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(vi) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization;

(vii) The purchase or other acquisition by a dispenser, hospital or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(viii) The receipt of a drug by an authorized third party logistics provider who does not take ownership of the drug;

(ix) A common carrier that transports a drug who does not take ownership of the drug;

(x) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(xi) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions; or

(xii) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments.

Section 5. Licensing Requirement.

(a) Every manufacturer, repackager, third party logistics provider, and wholesale distributor of prescription drugs for human use, wherever located, that provides services within this State shall be licensed by the Board and shall annually renew their license using an application provided by the Board. Manufacturers, repackagers, third party logistics providers and wholesale distributors cannot operate from a place of residence. Where wholesale

distribution operations are conducted at more than one location, each such location shall be licensed by the Board.

(b) The Board shall require the following minimum information from each manufacturer, repackager, third party-logistics provider, and wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

(i) All trade or business names used by the licensee (includes "is doing business as" and "formerly known as") which cannot be identical to the name used by another unrelated licensee to purchase/distribute prescription drugs in this State;

(ii) Name(s) of the owner and operator of the licensee (if not the same person), including:

(A) If a person: the name, business address, social security number, and date of birth;

(B) If a partnership: the name, business address, and social security number and date of birth of each partner, and the name of the partnership and federal employer identification number;

(C) If a corporation: the name, business address, social security number, date of birth, and title of each corporate officer and director; the corporate names, state of incorporation, federal employer identification number, and name of the parent company, if any; the name, business address, and social security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC:

(D) If a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;

(E) If a limited liability company: the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and

(F) Any other relevant information the Board requires.

(iii) Name(s), business address(es), and telephone number(s) of the person(s) to serve as the designated representative(s) for each facility of the wholesale distributor that engages in the wholesale distribution of prescription drugs. The Board shall be notified of each change in designated representative within 30 days of the change. Fingerprints and a fifty dollar

($50.00) fee shall be submitted for each designated representative application for a criminal background check and with each application for change in designated representative;

(iv) A list of all state and federal licenses, registrations, or permits, including the license, registration, or permit numbers issued to the wholesale distributor by any other state and federal authority that authorizes the wholesale distributor to purchase, possess, and wholesale distribute prescription drugs;

(v) A list of all disciplinary actions by state and federal agencies against the entity as well as any such actions against principals, owners, directors or officers;

(vi) A full description of each facility and warehouse, including all locations utilized for prescription drug storage or wholesale distribution. The description shall include the following:

(A) Square footage;

(B) A general description of security and alarm systems;

(C) Terms of lease or ownership;

(D) Address; and

(E) Temperature and humidity controls in accordance with this Chapter.

(vii) A copy of the deed for the property on which the entity's establishment is located, if the property is owned by the entity; or a copy of the wholesale distributor's lease for the property on which the establishment is located which has an original term of not less than one (1) calendar year (if the establishment is not owned by the entity);

(viii) Information regarding general and product liability insurance, including copies of relevant policies;

(ix) A description of the entity's drug import and export activities; and

(x) An electronic copy of the entity's written policies and procedures as required by this Chapter.

(c) The information collected pursuant to this Chapter shall be made available only to the Board, a third party recognized by the Board, and to state and federal law enforcement officials. The Board shall make provisions for protecting the confidentiality of the information collected under this section.

(d) All current wholesale distributor licensees and all applicants for licensure as a third party logistics provider or wholesale distributor must submit security in the amount of one hundred thousand dollars ($100,000.00) to the Board. The purpose of these funds will be to secure payment for any administrative penalty assessed by the Board, which remains unpaid thirty (30) days after the liability for the payment is final. A separate bond or other equivalent means of security is not required for each company's separate location or for affiliated companies/groups when such separate location or affiliated companies/groups are required to apply for or renew their wholesale distributor license with the Board. Acceptable forms of security include:

(i) "Surety" bond naming the board as the payee;

(ii) Irrevocable letter of credit naming the board as the payee; or

(iii) Funds deposited in a trust account or financial institution naming the board as the payee.

(e) The Board may waive the security requirement, if the wholesale distributor or third party logistics provider:

(i) Has previously obtained a comparable bond or other comparable security for the purposes of licensure in another state where they possess a valid license in good standing; or

(ii) Is a publicly held company.

(iii) Manufacturers and repackagers shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the Board or a third party recognized by the Board.

(f) Each facility licensed by the Board and all applicants for licensure must provide evidence of Verified-Accredited Wholesale Distributor (VAWD®) accreditation from the National Association of Boards of Pharmacy or from another third party recognized by the Board and must undergo the re-accreditation process periodically after initial accreditation. Manufacturing facilities are exempt from this requirement provided the manufacturing facilities are currently registered with the FDA in accordance with Section 510 of the Federal Act.

(i) Any applicant that is denied accreditation described under this section shall have the right of review of the accreditation body's decision, by:

(A) The accreditation body; and

(B) The Board.

(ii) The recognized accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.

(iii) Individual or third party inspectors must demonstrate to the Board that they have received training or demonstrate familiarity with the inspection standards. A letter for certification from a training program, a notice from the inspector's employing third party organization, or other means recognized by the Board shall be accepted as meeting the requirement.

(g) The Board may license by reciprocity a manufacturer, repackager, third party logistics provider or wholesale distributor that is licensed under laws of another state if:

(i) The requirements of that state are deemed by the Board to be substantially equivalent; or

(ii) The applicant is accredited by a third party recognized by the Board. An applicant that is accredited by a third party recognized and approved by the Board shall not be subject to duplicative requirements set by the Board.

(h) Where operations are conducted at more than one location by a single wholesale distributor, each location shall be licensed by the Board.

(i) Changes in any information required by this section shall be submitted to the Board within thirty (30) days after the change.

(j) All wholesale distributors shall publicly display or have readily available all licenses and the most recent inspection report.

(k) Information submitted by the wholesale distributor to the Board or a third party recognized by the Board that is considered trade secret or proprietary information, as defined under the state privacy and trade secret proprietary statutes, shall be maintained by the Board or a third party recognized by the Board as private or trade secret/proprietary information and be exempt from public disclosure.

(l) Any applicant denied licensure by the Board shall have the right of timely review and appeal as authorized by the Wyoming Administrative Procedure Act.

Section 6. Medical Oxygen Distributors.

(a) Medical oxygen is a prescription drug and distributors or manufacturers or repackagers shall be licensed by the Board and annually renew their licensure in order to provide medical oxygen in or into this State.

(b) Medical oxygen distributors located in this state may be inspected by the Board.

(c) Medical oxygen distributors shall complete all the requirements in this Chapter with the exception that they do not need VAWD® accreditation.

Section 7. Outsourcing Facilities.

(a) Outsourcing facilities shall be licensed by the FDA under section 503(b).

(b) Resident and non-resident outsourcing facilities shall be licensed as such in this State and annually renew their licensure.

(c) Outsourcing facilities located in this State shall be inspected by the Board.

(d) Outsourcing facilities shall complete all the requirements in this Chapter with the exception that they do not need VAWD® accreditation.

(e) Outsourcing facilities shall:

(i) Compound drugs by or under the direct supervision of a licensed pharmacist;

(ii) Compound drugs in accordance with current good manufacturing practice (cGMP) as required by federal law;

(iii) Ensure that pharmacists conducting or supervising compounding shall be proficient in the art of compounding and shall acquire the education, training, or experience to maintain that proficiency and become certified by a compounding certification program approved by the Board;

(iv) Label compounded drugs with:

(A) Required drug and ingredient information;

(B) Facility identification;

(C) The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale;" and

(v) Only compound using bulk drug substances that meet specified FDA criteria. May also compound drugs that appear on an FDA shortage list if the bulk drug substances used comply with the aforementioned specified criteria.

(f) All licensed outsourcing facilities shall report to the Board the biannual reports they are required to provide to the FDA identifying the drugs compounded in the previous six (6) month period, including the drug's active ingredients, strength and dosage form.

Section 8. Third Party Logistics Providers.

(a) Third Party Logistics Providers (3PL) shall be licensed as such in this State and annually renew their licensure.

(b) Third Party Logistics Providers shall complete all the requirements in this Chapter.

Section 9. Wholesale Distributors of Prescription Drugs for Non-Human Use.

(a) Veterinary prescription drug wholesale distributors may be licensed as such in this State and annually renew their license.

(b) Veterinary prescription drug wholesale distributors located in this State may be inspected by the Board.

(c) Veterinary prescription drug wholesale distributors applying for or renewing a license in this State shall complete all the requirements of this Chapter with the exception that they do not need VAWD® accreditation and they are not required to provide a designated representative.

(d) Veterinary prescription drug wholesale distributors may sell or deliver to a person responsible for the control of a livestock animal, as defined in Wyo. Stat. § 11-29-101(a)(vi), a non-controlled substance prescription drug intended for veterinary use provided the following conditions are met:

(i) A licensed veterinarian has issued, prior to such sale or delivery, a written prescription order for the non-controlled substance prescription drug in the course of an existing, valid veterinarian-client-patient relationship;

(ii) The original order must be retained on the premises of the veterinary prescription drug wholesale distributor for two years from the date of the last transaction affecting the order;

(iii) The non-controlled substance prescription drug(s) distributed sold or delivered pursuant to the veterinary drug order issued according to (i) of this subdivision are sold in the original, unbroken manufacturer's containers; and

(iv) The non-controlled substance prescription drug(s), once distributed, may not be returned to the veterinary prescription drug wholesale distributor for resale or redistribution.

(e) The prescription order issued by the veterinarian becomes void after two years, unless the veterinarian specifies a shorter expiration date.

(f) The veterinary prescription drug wholesale distributor shall not distribute larger quantities than the order authorizes.

(g) The original order must be retained on the premises of the veterinary prescription drug wholesale distributor filed by client name. The invoices for each distribution authorized by the order must be attached to the order.

(h) A drug distribution log must be retained on the premises of the veterinary prescription drug wholesale distributor. It shall include the following information:

(i) Date sold/delivered;

(ii) Client name;

(iii) Veterinarian name;

(iv) Non-controlled substance prescription drug sold/delivered;

(v) Quantity of non-controlled substance prescription drug sold/delivered;

(vi) Date of issue of order;

(vii) Expiration of order; and

(viii) Invoice number.

Section 10. Repackagers.

(a) Repackagers of prescription drugs for human use shall be licensed as such in this State and annually renew their licensure.

(b) Repackagers shall complete all the requirements in this Chapter.

Section 11. Minimum Qualifications.

(a) The Board shall consider the following factors in determining eligibility for, and renewal of, licensure:

(i) Any criminal convictions, except minor traffic violations, or civil penalties of the applicant under any federal, state or local laws;

(ii) Any findings by the Board that the applicant has violated, or been disciplined by a regulatory agency in any state for violating any federal, state or local laws;

(iii) The furnishing by the applicant of false or fraudulent material in any application;

(iv) Suspension, sanction, or revocation by federal, state or local government against any license currently or previously held by the applicant or any of its owners for violations of state or federal laws regarding prescription drugs;

(v) Compliance with the requirements to maintain or make available to the Board or to federal, state or local law enforcement officials any required records; and

(vi) Any other factors or qualifications the Board considers relevant to and consistent with public health and safety.

Section 12. Personnel.

(a) Each person that is issued an initial or renewal license as a manufacturer, repackager, third party logistics provider or wholesale distributor of prescription drugs for human use, whether in state or out of state, must designate in writing on a form required by the Board, a person for each facility to serve as the designated representative.

(b) To be certified as a designated representative, a person shall:

(i) Submit an application on a form furnished by the Board and provide information that includes:

(A) Fingerprint cards and fee for a criminal background check;
(B) Date and place of birth;

(C) Occupations, positions of employment, and offices held during the past seven (7) years;

(D) Principal business and address of any business corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;

(E) Whether the person, during the past seven (7) years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction for violating

any federal or state law regulating the possession, control or wholesale distribution of prescription drugs, together with details of such events;

(F) A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven (7) years, which manufactured, administered, prescribed, wholesale distributed, or stored prescription drugs in which such businesses were named as a party in a lawsuit;

(G) A description of any felony criminal offense, or any offense (misdemeanor or felony) involving moral turpitude, or any offense related to the qualifications, functions or duties of that person in connection with the operation of the entity, of which the person, as an adult, was found guilty, regardless of whether adjudication of guilty was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within thirty (30) days after the disposition of the appeal, submit a copy of the final written order of disposition to the Board; and

(H) A passport type and size of photograph of the person taken within the previous year.

(ii) Have a minimum of two (2) years of verifiable full-time managerial or supervisory experience in a pharmacy or entity or another state where the person's responsibilities included but were not limited to recordkeeping, storage, and shipment of prescription drugs;

(iii) Serve as the designated representative for only one location at any one time, except where more than one licensed entity is co-located in the facility and such entities are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code;

(iv) Be actively involved in and aware of the actual daily operations of the entity as follows:

(A) Be employed full-time in a managerial position by the entity;

(B) Be physically present at the location during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and

(C) Be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the entity.

(c) The information collected pursuant to this Chapter shall be made available only to the Board, a third party recognized by the Board, and to state and federal law enforcement officials. The Board and a third party recognized by the Board shall make provisions for protecting the confidentiality of the information collected under this Section.

Section 13. General Minimum Requirements of Facilities Storing and Handling Prescription Drugs.

(a) The following are required for the storage, handling, transport and shipment of prescription drugs and for the establishment and maintenance of records:

~~(a)~~(b) All facilities at which prescription drugs are received, stored, warehoused, handled, held, offered, marketed, transported from or displayed shall:

(i) Be of suitable size and construction to facilitate cleaning, maintenance and proper operations to ensure that all prescription drugs in the facilities are maintained in accordance with the product labeling or in compliance with official compendium standards such as the United State Pharmacopeia-USP-NF;

(ii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

(iii) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution or wholesale distribution, or that are in immediate or sealed secondary containers that have been opened prior to receipt by the entity;

(iv) Be maintained in a clean and orderly condition;

(v) Be free from infestation of any kind;

(vi) Be a commercial location and not a personal dwelling or residence;

(vii) Provide for the secure and confidential storage of all information with restricted access and policies and procedures to protect the integrity and confidentiality of the information; and

(viii) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs.

~~(b)~~(c) All entities involved in the wholesale distribution of controlled substances shall be duly registered with the Drug Enforcement Administration (DEA) and the Board and in compliance with all applicable laws and rules for the storage, handling, transport, shipment and distribution of controlled substances.

Section 14. Security and Anti-Counterfeiting.

(a) All facilities used for drug distribution shall be secure from unauthorized entry as follows:

(i) Access from outside the premises shall be kept to a minimum and be well controlled;

(ii) The outside perimeter of the premises shall be well lighted;

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel;

(iv) All facilities shall be equipped with an alarm system to detect unauthorized entry after hours; and

(v) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(b) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting.

(c) All entities shall be equipped with security measures to protect the integrity of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

Section 15. Examination of Materials.

(a) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain suspect products. This examination shall be adequate to reveal container damage that would suggest possible suspect product or other damage to the contents.

(b) The prescription drugs found to be unacceptable under paragraph "a" above shall be quarantined from the rest of the stock.

(c) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(d) All entities shall comply with reporting requirements and exchange transaction history, transaction information, and transaction statements as outlined in federal law.

Section 16. Policies and Procedures.

(a) All entities shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport,

shipping and wholesale distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Policies and procedures shall include the following:

~~(a)~~(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs due to:

(i) Any action initiated at the request of the FDA or any other federal, state or local law enforcement or other governmental agency, including the board of pharmacy; or

(ii) Any volunteer action by the manufacturer to remove defective or potentially defective prescription drugs from the market.

~~(b)~~(c) A procedure to ensure that all entities prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, natural disaster, or other situations of local, state or national emergency;

~~(c)~~(d) A procedure to ensure that any outdated prescription drugs shall be segregated from other prescription drugs and either returned to the manufacturer or third party return processor or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs;

~~(d)~~(e) A procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of two (2) years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers or containers in accordance with all applicable federal and state requirements;

~~(e)~~(f) A procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving suspect products, in the inventory and reporting of such discrepancies within ten (10) business days to the Board and appropriate federal or state agency upon discovery of such discrepancies;

~~(f)~~(g) A procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drugs to the board, FDA and, if applicable, DEA, within three (3) business days; and

~~(g)~~(h) A procedure for verifying security provisions of common carriers.

CHAPTER 8

WHOLESALE DISTRIBUTOR REGULATIONS

Section 1. Authority.

These rules are promulgated as authorized by the Wyoming Pharmacy Act W.S. § 33-24-101 through -301.

Section 2. Purpose.

The purpose of this rule is to provide for the minimum licensing standards necessary to ensure the safety and efficacy of prescription drugs offered for sale by manufacturers and wholesale distributors.

Section 3. Scope.

This Chapter applies to any person, partnership, corporation or business engaging in the wholesale distribution of human prescription drugs either into, out of, or within this State.

Section 4. Definitions.

(a) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products.

(b) "Common Carrier" means any person or entity who undertakes directly or indirectly to transport property, including prescription drugs, for compensation.

(c) "Designated Representative" means an individual designated by the wholesale distributor and who is actively involved in and aware of the actual daily operation of the wholesale drug distributor at the wholesaler's licensed location.

(d) "Dispenser" means a retail pharmacy, institutional pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliate warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and does not include a person who dispenses only products to be used in animals.

(e) "Distribute" or "Distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription.

(f) "Drug" means a substance recognized as a drug in any official compendium as listed in W.S. § 33-24-127, designated for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals.

(g) "Drug Sample" means a unit of a prescription drug that is not intended to be sold but is intended to promote the sale of the drug.

(h) "Food and Drug Administration" (FDA) means a federal agency within the United States Department of Health.

(i) "Illegitimate product" means a product for which credible evidence shows that the product:

(i) Is counterfeit, diverted or stolen;

(ii) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(iii) Is the subject of a fraudulent transaction; or

(iv) Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

(j) "Manufacturer's Exclusive Distributor" means an individual or entity who purchased the product directly from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

(k) "Misbranded" means a drug whose label is false or misleading or the label does not bear the name and address of the manufacturer, packer or distributor and does not have an accurate statement of the quantities of the active ingredients or:

(i) If the advertising or promotion of a compounded drug is false or misleading in any particular; or

(ii) If it is a drug and it fails to bear the product identifier.

(l) "Outsourcing Facility" means a person who registers with the FDA under section 503B of the federal act to compound sterile drugs for human use under the supervision of a pharmacist but without a prescription from a practitioner for a particular patient.

(m) "Prescription Drug" or "Legend Drug" means a drug which, under federal law, is required to be labeled with one of the following statements:

(i) "Caution: Federal law prohibits dispensing without a prescription";

(ii) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or

(iii) "Rx Only."

(n) "Product Identifier" means a standardized graphic that includes in both human-readable form and on a machine readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

(o) "Product Tracing" means a dispenser shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction, provides:

(i) Transaction Information (TI);

(ii) Transaction History (TH); and

(iii) Transaction Statement (TS).

(p) "Reverse Processor" means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

(q) "Suspect Product" means there is reason to believe that such product:

(i) Is potentially counterfeit, diverted or stolen;

(ii) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(iii) Is potentially the subject of a fraudulent transaction; or

(iv) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(r) "Third Party Logistics Provider" means an entity that provides or coordinates warehousing, distribution, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(s) "Transaction" in general means the transfer of product between persons in which a change of ownership occurs. The term transaction does not include:

(i) Intracompany distribution of any product between members of an affiliate or within a manufacturer;

(ii) The distribution of a product among hospitals or other health care entities that are under common control;

(iii) The distribution of a product for emergency medical reasons including a public health emergency, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(iv) The dispensing of a product pursuant to a prescription;

(v) The distribution of product samples by a manufacturer or a licensed wholesale distributor;

(vi) The distribution of blood or blood components intended for transfusion;

(vii) The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

(viii) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization;

(ix) The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors (except that records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors); or

(x) The dispensing of a product approved under section 512(c) of the Federal Food, Drug, and Cosmetic Act regarding a new animal drug application.

(t) "Transaction History" means a statement in paper or electronic form that includes the transaction information of each prior transaction going back to the manufacturer of the product.

(u) "Transaction Information" means:

(i) The proprietary or established name or names of the product;

(ii) The strength and dosage form of the product;

(iii) The national drug code number of the product;

(iv) The container size;

(v) The number of containers;

(vi) The lot number of the product;

(vii) The transaction date;

(viii) The shipment date, if more than twenty-four (24) hours after the transaction date;

(ix) The business name and address of the person from whom ownership is being transferred; and

(x) The business name and address of the person to whom ownership is being transferred.

(v) "Transaction Statement" is a statement in paper or electronic form that the entity transferring ownership in a transaction:

(i) Is authorized under federal law;

(ii) Received the product from a person who is authorized as required under federal law;

(iii) Received transaction information and a transaction statement from the prior owner of the product as required by federal law;

(iv) Did not knowingly ship a suspect or illegitimate product;

(v) Had systems and processes in place to comply with verification requirements outlined in federal law;

(vi) Did not knowingly provide false transaction information; and

(vii) Did not knowingly alter the transaction history.

(w) "Wholesale Distribution" means the distribution of a drug to a person other than a consumer or patient, or receipt of a drug subject by a person other than the consumer or patient, but does not include:

(i) The intracompany distribution of any drug between members of an affiliate or with a manufacturer;

(ii) The distribution of a drug or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(iii) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(iv) The dispensing of a drug pursuant to a prescription;

(v) The distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(vi) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization;

(vii) The purchase or other acquisition by a dispenser, hospital or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(viii) The receipt of a drug by an authorized third party logistics provider who does not take ownership of the drug;

(ix) A common carrier that transports a drug who does not take ownership of the drug;

(x) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(xi) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions; or

(xii) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments.

Section 5. Licensing Requirement.

(a) Every manufacturer, repackager, third party logistics provider, and wholesale distributor of prescription drugs for human use, wherever located, that provides services within this State shall be licensed by the Board and shall annually renew their license using an application provided by the Board. Manufacturers, repackagers, third party logistics providers and wholesale distributors cannot operate from a place of residence. Where wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the Board.

(b) The Board shall require the following minimum information from each manufacturer, repackager, third party-logistics provider, and wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

(i) All trade or business names used by the licensee (includes "is doing business as" and "formerly known as") which cannot be identical to the name used by another unrelated licensee to purchase/distribute prescription drugs in this State;

(ii) Name(s) of the owner and operator of the licensee (if not the same person), including:

(A) If a person: the name, business address, social security number, and date of birth;

(B) If a partnership: the name, business address, and social security number and date of birth of each partner, and the name of the partnership and federal employer identification number;

(C) If a corporation: the name, business address, social security number, date of birth, and title of each corporate officer and director; the corporate names, state of incorporation, federal employer identification number, and name of the parent company, if any; the name, business address, and social security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC:

(D) If a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;

(E) If a limited liability company: the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and

(F) Any other relevant information the Board requires.

(iii) Name(s), business address(es), and telephone number(s) of the person(s) to serve as the designated representative(s) for each facility of the wholesale distributor that engages in the wholesale distribution of prescription drugs. The Board shall be notified of each change in designated representative within 30 days of the change. Fingerprints and a fifty dollar ($50.00) fee shall be submitted for each designated representative application for a criminal background check and with each application for change in designated representative;

(iv) A list of all state and federal licenses, registrations, or permits, including the license, registration, or permit numbers issued to the wholesale distributor by any other state and federal authority that authorizes the wholesale distributor to purchase, possess, and wholesale distribute prescription drugs;

(v) A list of all disciplinary actions by state and federal agencies against the entity as well as any such actions against principals, owners, directors or officers;

(vi) A full description of each facility and warehouse, including all locations utilized for prescription drug storage or wholesale distribution. The description shall include the following:

(A) Square footage;

(B) A general description of security and alarm systems;

(C) Terms of lease or ownership;

(D) Address; and

(E) Temperature and humidity controls in accordance with this Chapter.

(vii) A copy of the deed for the property on which the entity's establishment is located, if the property is owned by the entity; or a copy of the wholesale distributor's lease for the property on which the establishment is located which has an original term of not less than one (1) calendar year (if the establishment is not owned by the entity);

(viii) Information regarding general and product liability insurance, including copies of relevant policies;

(ix) A description of the entity's drug import and export activities; and

(x) An electronic copy of the entity's written policies and procedures as required by this Chapter.

(c) The information collected pursuant to this Chapter shall be made available only to the Board, a third party recognized by the Board, and to state and federal law enforcement officials. The Board shall make provisions for protecting the confidentiality of the information collected under this section.

(d) All current wholesale distributor licensees and all applicants for licensure as a third party logistics provider or wholesale distributor must submit security in the amount of one hundred thousand dollars ($100,000.00) to the Board. The purpose of these funds will be to secure payment for any administrative penalty assessed by the Board, which remains unpaid

thirty (30) days after the liability for the payment is final. A separate bond or other equivalent means of security is not required for each company's separate location or for affiliated companies/groups when such separate location or affiliated companies/groups are required to apply for or renew their wholesale distributor license with the Board. Acceptable forms of security include:

(i) "Surety" bond naming the board as the payee;

(ii) Irrevocable letter of credit naming the board as the payee; or

(iii) Funds deposited in a trust account or financial institution naming the board as the payee.

(e) The Board may waive the security requirement, if the wholesale distributor or third party logistics provider:

(i) Has previously obtained a comparable bond or other comparable security for the purposes of licensure in another state where they possess a valid license in good standing; or

(ii) Is a publicly held company.

(iii) Manufacturers and repackagers shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the Board or a third party recognized by the Board.

(f) Each facility licensed by the Board and all applicants for licensure must provide evidence of Verified-Accredited Wholesale Distributor (VAWD®) accreditation from the National Association of Boards of Pharmacy or from another third party recognized by the Board and must undergo the re-accreditation process periodically after initial accreditation. Manufacturing facilities are exempt from this requirement provided the manufacturing facilities are currently registered with the FDA in accordance with Section 510 of the Federal Act.

(i) Any applicant that is denied accreditation described under this section shall have the right of review of the accreditation body's decision, by:

(A) The accreditation body; and

(B) The Board.

(ii) The recognized accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.

(iii) Individual or third party inspectors must demonstrate to the Board that they have received training or demonstrate familiarity with the inspection standards. A letter

for certification from a training program, a notice from the inspector's employing third party organization, or other means recognized by the Board shall be accepted as meeting the requirement.

(g) The Board may license by reciprocity a manufacturer, repackager, third party logistics provider or wholesale distributor that is licensed under laws of another state if:

(i) The requirements of that state are deemed by the Board to be substantially equivalent; or

(ii) The applicant is accredited by a third party recognized by the Board. An applicant that is accredited by a third party recognized and approved by the Board shall not be subject to duplicative requirements set by the Board.

(h) Where operations are conducted at more than one location by a single wholesale distributor, each location shall be licensed by the Board.

(i) Changes in any information required by this section shall be submitted to the Board within thirty (30) days after the change.

(j) All wholesale distributors shall publicly display or have readily available all licenses and the most recent inspection report.

(k) Information submitted by the wholesale distributor to the Board or a third party recognized by the Board that is considered trade secret or proprietary information, as defined under the state privacy and trade secret proprietary statutes, shall be maintained by the Board or a third party recognized by the Board as private or trade secret/proprietary information and be exempt from public disclosure.

(l) Any applicant denied licensure by the Board shall have the right of timely review and appeal as authorized by the Wyoming Administrative Procedure Act.

Section 6. Medical Oxygen Distributors.

(a) Medical oxygen is a prescription drug and distributors or manufacturers or repackagers shall be licensed by the Board and annually renew their licensure in order to provide medical oxygen in or into this State.

(b) Medical oxygen distributors located in this state may be inspected by the Board.

(c) Medical oxygen distributors shall complete all the requirements in this Chapter with the exception that they do not need VAWD® accreditation.

Section 7. Outsourcing Facilities.

(a) Outsourcing facilities shall be licensed by the FDA under section 503(b).

(b) Resident and non-resident outsourcing facilities shall be licensed as such in this State and annually renew their licensure.

(c) Outsourcing facilities located in this State shall be inspected by the Board.

(d) Outsourcing facilities shall complete all the requirements in this Chapter with the exception that they do not need VAWD® accreditation.

(e) Outsourcing facilities shall:

(i) Compound drugs by or under the direct supervision of a licensed pharmacist;

(ii) Compound drugs in accordance with current good manufacturing practice (cGMP) as required by federal law;

(iii) Ensure that pharmacists conducting or supervising compounding shall be proficient in the art of compounding and shall acquire the education, training, or experience to maintain that proficiency and become certified by a compounding certification program approved by the Board;

(iv) Label compounded drugs with:

(A) Required drug and ingredient information;

(B) Facility identification;

(C) The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale;" and

(v) Only compound using bulk drug substances that meet specified FDA criteria. May also compound drugs that appear on an FDA shortage list if the bulk drug substances used comply with the aforementioned specified criteria.

(f) All licensed outsourcing facilities shall report to the Board the biannual reports they are required to provide to the FDA identifying the drugs compounded in the previous six (6) month period, including the drug's active ingredients, strength and dosage form.

Section 8. Third Party Logistics Providers.

(a) Third Party Logistics Providers (3PL) shall be licensed as such in this State and annually renew their licensure.

(b) Third Party Logistics Providers shall complete all the requirements in this Chapter.

Section 9. Wholesale Distributors of Prescription Drugs for Non-Human Use.

(a) Veterinary prescription drug wholesale distributors may be licensed as such in this State and annually renew their license.

(b) Veterinary prescription drug wholesale distributors located in this State may be inspected by the Board.

(c) Veterinary prescription drug wholesale distributors applying for or renewing a license in this State shall complete all the requirements of this Chapter with the exception that they do not need VAWD® accreditation and they are not required to provide a designated representative.

(d) Veterinary prescription drug wholesale distributors may sell or deliver to a person responsible for the control of a livestock animal, as defined in Wyo. Stat. § 11-29-101(a)(vi), a non-controlled substance prescription drug intended for veterinary use provided the following conditions are met:

(i) A licensed veterinarian has issued, prior to such sale or delivery, a written prescription order for the non-controlled substance prescription drug in the course of an existing, valid veterinarian-client-patient relationship;

(ii) The original order must be retained on the premises of the veterinary prescription drug wholesale distributor for two years from the date of the last transaction affecting the order;

(iii) The non-controlled substance prescription drug(s) distributed sold or delivered pursuant to the veterinary drug order issued according to (i) of this subdivision are sold in the original, unbroken manufacturer's containers; and

(iv) The non-controlled substance prescription drug(s), once distributed, may not be returned to the veterinary prescription drug wholesale distributor for resale or redistribution.

(e) The prescription order issued by the veterinarian becomes void after two years, unless the veterinarian specifies a shorter expiration date.

(f) The veterinary prescription drug wholesale distributor shall not distribute larger quantities than the order authorizes.

(g) The original order must be retained on the premises of the veterinary prescription drug wholesale distributor filed by client name. The invoices for each distribution authorized by the order must be attached to the order.

(h) A drug distribution log must be retained on the premises of the veterinary prescription drug wholesale distributor. It shall include the following information:

(i) Date sold/delivered;

(ii) Client name;

(iii) Veterinarian name;

(iv) Non-controlled substance prescription drug sold/delivered;

(v) Quantity of non-controlled substance prescription drug sold/delivered;

(vi) Date of issue of order;

(vii) Expiration of order; and

(viii) Invoice number.

Section 10. Repackagers.

(a) Repackagers of prescription drugs for human use shall be licensed as such in this State and annually renew their licensure.

(b) Repackagers shall complete all the requirements in this Chapter.

Section 11. Minimum Qualifications.

(a) The Board shall consider the following factors in determining eligibility for, and renewal of, licensure:

(i) Any criminal convictions, except minor traffic violations, or civil penalties of the applicant under any federal, state or local laws;

(ii) Any findings by the Board that the applicant has violated, or been disciplined by a regulatory agency in any state for violating any federal, state or local laws;

(iii) The furnishing by the applicant of false or fraudulent material in any application;

(iv) Suspension, sanction, or revocation by federal, state or local government against any license currently or previously held by the applicant or any of its owners for violations of state or federal laws regarding prescription drugs;

(v) Compliance with the requirements to maintain or make available to the Board or to federal, state or local law enforcement officials any required records; and

(vi) Any other factors or qualifications the Board considers relevant to and consistent with public health and safety.

Section 12. Personnel.

(a) Each person that is issued an initial or renewal license as a manufacturer, repackager, third party logistics provider or wholesale distributor of prescription drugs for human use, whether in state or out of state, must designate in writing on a form required by the Board, a person for each facility to serve as the designated representative.

(b) To be certified as a designated representative, a person shall:

(i) Submit an application on a form furnished by the Board and provide information that includes:

(A) Fingerprint cards and fee for a criminal background check;
(B) Date and place of birth;

(C) Occupations, positions of employment, and offices held during the past seven (7) years;

(D) Principal business and address of any business corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;

(E) Whether the person, during the past seven (7) years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction for violating any federal or state law regulating the possession, control or wholesale distribution of prescription drugs, together with details of such events;

(F) A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven (7) years, which manufactured, administered, prescribed, wholesale distributed, or stored prescription drugs in which such businesses were named as a party in a lawsuit;

(G) A description of any felony criminal offense, or any offense (misdemeanor or felony) involving moral turpitude, or any offense related to the qualifications, functions or duties of that person in connection with the operation of the entity, of which the person, as an adult, was found guilty, regardless of whether adjudication of guilty was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within thirty (30) days after the disposition of the appeal, submit a copy of the final written order of disposition to the Board; and

(H) A passport type and size of photograph of the person taken within the previous year.

(ii) Have a minimum of two (2) years of verifiable full-time managerial or supervisory experience in a pharmacy or entity or another state where the person's responsibilities included but were not limited to recordkeeping, storage, and shipment of prescription drugs;

(iii) Serve as the designated representative for only one location at any one time, except where more than one licensed entity is co-located in the facility and such entities are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code;

(iv) Be actively involved in and aware of the actual daily operations of the entity as follows:

(A) Be employed full-time in a managerial position by the entity;

(B) Be physically present at the location during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and

(C) Be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the entity.

(c) The information collected pursuant to this Chapter shall be made available only to the Board, a third party recognized by the Board, and to state and federal law enforcement officials. The Board and a third party recognized by the Board shall make provisions for protecting the confidentiality of the information collected under this Section.

Section 13. General Minimum Requirements of Facilities Storing and Handling Prescription Drugs.

(a) The following are required for the storage, handling, transport and shipment of prescription drugs and for the establishment and maintenance of records:

(b) All facilities at which prescription drugs are received, stored, warehoused, handled, held, offered, marketed, transported from or displayed shall:

(i) Be of suitable size and construction to facilitate cleaning, maintenance and proper operations to ensure that all prescription drugs in the facilities are maintained in accordance with the product labeling or in compliance with official compendium standards such as the United State Pharmacopeia-USP-NF;

(ii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

(iii) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution or wholesale distribution, or that are in immediate or sealed secondary containers that have been opened prior to receipt by the entity;

(iv) Be maintained in a clean and orderly condition;

(v) Be free from infestation of any kind;

(vi) Be a commercial location and not a personal dwelling or residence;

(vii) Provide for the secure and confidential storage of all information with restricted access and policies and procedures to protect the integrity and confidentiality of the information; and

(viii) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs.

(c) All entities involved in the wholesale distribution of controlled substances shall be duly registered with the Drug Enforcement Administration (DEA) and the Board and in compliance with all applicable laws and rules for the storage, handling, transport, shipment and distribution of controlled substances.

Section 14. Security and Anti-Counterfeiting.

(a) All facilities used for drug distribution shall be secure from unauthorized entry as follows:

(i) Access from outside the premises shall be kept to a minimum and be well controlled;

(ii) The outside perimeter of the premises shall be well lighted;

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel;

(iv) All facilities shall be equipped with an alarm system to detect unauthorized entry after hours; and

(v) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(b) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting.

(c) All entities shall be equipped with security measures to protect the integrity of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

Section 15. Examination of Materials.

(a) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain suspect products. This examination shall be adequate to reveal container damage that would suggest possible suspect product or other damage to the contents.

(b) The prescription drugs found to be unacceptable under paragraph "a" above shall be quarantined from the rest of the stock.

(c) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(d) All entities shall comply with reporting requirements and exchange transaction history, transaction information, and transaction statements as outlined in federal law.

Section 16. Policies and Procedures.

(a) All entities shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, shipping and wholesale distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Policies and procedures shall include the following:

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs due to:

(i) Any action initiated at the request of the FDA or any other federal, state or local law enforcement or other governmental agency, including the board of pharmacy; or

(ii) Any volunteer action by the manufacturer to remove defective or potentially defective prescription drugs from the market.

(c) A procedure to ensure that all entities prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, natural disaster, or other situations of local, state or national emergency;

(d) A procedure to ensure that any outdated prescription drugs shall be segregated from other prescription drugs and either returned to the manufacturer or third party return processor or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs;

(e) A procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of two (2) years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers or containers in accordance with all applicable federal and state requirements;

(f) A procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving suspect products, in the inventory and reporting of such discrepancies within ten (10) business days to the Board and appropriate federal or state agency upon discovery of such discrepancies;

(g) A procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drugs to the board, FDA and, if applicable, DEA, within three (3) business days; and

(h) A procedure for verifying security provisions of common carriers.

CHAPTER 13

NON-STERILE COMPOUNDING

Section 1. These regulations are promulgated as authorized by the Act.

Section 2. Definitions.

(a) "Active Ingredient" means an ingredient added to a compounded prescription product that provides the therapeutic effect desired from the compounded prescription product. This does not include "inert" ingredients.

(b) "Beyond-use Date (BUD)" means a date after which a compounded product should not be used.

(c) "Component" means any ingredient used in the compounding of a drug product, including those ingredients that may not appear in the labeling of such product.

(d) "Compounding" means and includes the preparation, mixing, or assembling of a drug or device, and the packaging and labeling incident thereto for sale or dispensing:

(i) as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of his/her professional practice.

(ii) for the purpose of research, teaching, or chemical analysis, or

(iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

However, "compounding" does not include mixing or reconstituting of non-sterile products performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(e) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or re-labeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes any

preparation of a drug or device that is sold for resale by pharmacies, practitioners, or other persons.

(f) "Master Compounding Record" means an established record of all compounded products from the time of initial compounding that can be followed each time that compound is prepared in the future.

(g) "Stability" means the extent to which a compounded product retains, within specified limits and throughout its period of both storage and use, the same properties and characteristics it possessed at the time of preparation.

Section 3. General Provisions.

(a) Based on the existence of a pharmacist/patient/practitioner relationship and the presentation of a valid prescription, or in anticipation of prescription medication orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, medications or dosage forms that are not commercially available in the marketplace.

(b) Pharmacists shall, when procuring active ingredients for compounding, obtain a Certificate of Analysis (COA) for each lot number procured, and shall retain each COA for a period of not less than two (2) years from the date the container is emptied. COAs shall be available for review by Board inspectors. Each COA.must be issued by a firm located in the United States. If one is not available from the vendor, the pharmacist shall procure one from a laboratory located in the United States. COAs are not required if the active ingredient utilized is designated USP or NF.

(i) If the product is not designated as USP or NF, then the following minimum information is required on the COA:

(A) Product name;

(B) Lot number;

(C) Expiration date; and

(D) Assay.

(c) Pharmacists may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/practitioner relationship, and provided that they maintain the

prescriptions on file for all such products compounded at the pharmacy as required by the Board, but not under other circumstances.

(d) Pharmacists shall not offer compounded medications to other pharmacies or licensed entities for resale; except pharmacists may offer for sale compounded medications to practitioners or institutional pharmacies for administration to patients in the practitioner's office or in the institutional facility, provided that the pharmacy does not violate Chapter 8. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not solicit business by distributing unsolicited sampling to practitioners (e.g., like a manufacturer).

(e) All compounded products, which include as an ingredient a cytotoxic drug, shall be prepared in a Class II biological safety cabinet.

Section 4. Organization and Personnel.

(a) The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

(b) All pharmacists who engage in drug compounding shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Competency and proficiency in the art of compounding for all pharmacists shall be evaluated, documented, and maintained in the files of the pharmacy by the Pharmacist-in-Charge (PIC). Every pharmacist who engages in drug compounding must be aware of and familiar with all details of the good compounding practices.

(c) Personnel engaged in the compounding shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm covering, or masks shall be worn as necessary to protect personnel from chemical exposure and medication or chemical contamination.

Section 5. Drug Compounding Facilities.

(a) Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. Sterile compounding shall be performed in a separate area in compliance with Chapter 17.

(b) To maintain stability, bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature-controlled area or, if required, under proper refrigeration. The refrigerator shall provide a storage temperature of 36 to 46 degrees Fahrenheit (2 to 8 degrees Centigrade). If a freezer compartment is utilized, it must maintain a temperature of –13 to +14 degrees Fahrenheit (–25 to –10 degrees Centigrade).

(c) Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water for drinking and washing shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single-use towels.

(d) The area(s) used for compounding shall be maintained in a clean and sanitary condition.

(e) If sterile products are being compounded, the pharmacist shall follow Chapter 17 of this regulation.

(f) If drug products with special precautions to prevent contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be utilized in order to prevent cross-contamination.

Section 6. Equipment.

(a) Equipment and utensils used for compounding shall be of appropriate design and capacity, and shall be stored in a manner to protect from contamination. In addition, all equipment and utensils shall be cleaned prior to use to prevent contamination that would alter the safety or quality of the drug product beyond that desired.

(b) Automatic, mechanical, electronic, or other equipment used in compounding shall be routinely inspected, calibrated, or checked according to manufacturer's recommendations to ensure proper performance.

(c) It shall be the responsibility of the PIC to ensure that drug product containers, components, closures, and bagged or boxed components of drug product containers and closures used in compounding shall be handled and stored in a manner to prevent contamination and to permit unhindered inspection and cleaning of the work area.

Section 7. Compounding Controls.

(a) A Master Compounding Record shall be established for each newly compounded item and followed thereafter to monitor the output and to validate the performance of those compounding processes. The Master Compounding Record shall contain:

(i) Official compound name, strength, and dosage form,

(ii) Calculations required to complete the compound,

(iii) Ingredient(s) description and amounts,

(iv) Compatibility and stability information (references when available)

(v) Equipment required to prepare the compound,

(vi) Mixing instructions,

(vii) Any other factors pertinent to the compound preparation,

(viii) A sample label meeting all legal requirements stated in Chapter 2,

(ix) The generic name, quantity and/or concentration of every active ingredient contained within, and

(x) An assigned BUD as applicable.

(b) Components for compounding shall be accurately weighed, measured, or subdivided as appropriate. If a component is transferred from the original container to a new container, the new container shall be labeled with the same information as the original container and the date of transfer.

(c) Written control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

(i) Capsule weight variation;

(ii) Adequacy of mixing to insure uniformity and homogeneity; and

(iii) Clarity, completeness, or pH of solutions.

(d) At the time of dispensing to the patient, the pharmacist shall advise the patient on the proper storage, use, and anticipated shelf life of the compounded prescription product.

Section 8. Labeling Control of Excess or Bulk Compounded Products.

The pharmacist shall label any excess or bulk compounded product to reference it to the formula used and the assigned control number and estimated BUD based on the pharmacist's professional judgment, appropriate testing or published data. The product shall be stored appropriately.

Section 9. Records and Reports.

(a) Records required to be maintained in compliance with this Chapter shall be retained for a minimum period of two (2) years from the date of last activity and be available for inspection by the Board.

(b) For each drug product compounded in excess or bulk quantities, a log book, in addition to those requirements listed in this Chapter, shall be prepared containing the following information:

(i) Name of the product;

(ii) List of ingredients and quantities used, including manufacturer, lot number, and expiration dates;

(iii) Lot number assigned by a pharmacist;

(iv) Beyond use date assigned, as described in this Chapter;

(v) Date of preparation;

(vi) Initials of compounding pharmacist, pharmacy technician or pharmacy technician specialist;

(vii) Initials of supervising pharmacist, if prepared by a pharmacy technician or pharmacy technician specialist; and

(viii) Quantity prepared.

Chapter 17

Sterile Compounding

Section 1. Authority.

These regulations are promulgated pursuant to the Wyoming Pharmacy Act W.S. § 33-24-101 through -301.

Section 2. Definitions.

(a) "Ante-room" means an ISO Class 8 or cleaner room with fixed walls and doors where activities that generate high particulate levels are performed. It is the transition room between the unclassified area of the facility and the buffer room, in which pressure relationships are constantly maintained and large disturbances requiring response from the heating, ventilating, and air-conditioning control system are reduced.

(b) "Aseptic Technique" means processing of pharmaceutical products that involves the separate sterilization of the product and of the package, if not already sterilized, and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.

(c) "Beyond-Use Date" (BUD) means the date, or the time and date, beyond which a preparation shall not be used and shall be discarded. It is determined from the date or time that preparation of the CSP is initiated and is dependent on individual compounding factors.

(d) "Buffer Room" means an ISO Class 7 or cleaner room with fixed walls and doors where the Primary Engineering Control is physically located. The buffer room may only be accessed through the ante-room.

(e) "Cleaning agent" means an agent for the removal of residues from surfaces.

(f) "Cleanroom Suite" means the classified area consisting of both the ante-room and buffer room.

(g) "Closed System Transfer Device" (CSTD) means a drug transfer device that mechanically prohibits entrance of contaminants into the system and escape of hazardous drug or vapor from the system.

(h) "Compounded Sterile Preparation" (CSP) means a preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

(i) "Disinfectant" means a chemical or physical agent used on an inanimate surface and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectant agents are considered a special class of disinfectants that also are effective against bacterial and fungal spores.

(j) "Dynamic operating conditions" means conditions in which operating pharmacy staff are present and simulating or performing compounding. The conditions shall reflect the largest number of pharmacy staff and highest complexity of compounding expected during routine operations as determined by the designated person(s).

(k) "Hazardous Drugs" (HDs) means drugs in which studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs.

(l) "ISO Class" means an air-quality classification from the International Organization for Standardization that limits the number of particles of 0.5 micrometers and larger per cubic meter.

Class Name	Particle Count:
ISO Class 3	35.2/m3
ISO Class 4	352/m3
ISO Class 5	3,520/m3
ISO Class 6	35,200/m3
ISO Class 7	352,000/m3
ISO Class 8	3,520,000/m3

(m) "Media-Fill Test" means a simulation used to qualify processes and pharmacy staff engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.

(n) "One-step disinfectant cleaner" means a product with an EPA-registered or equivalent claim that it can clean and disinfect a non-porous surface in the presence of light to moderate organic soiling without a separate cleaning step.

(o) "Primary Engineering Control" (PEC) means a device that provides an ISO Class 5 or better air quality environment and utilizes unidirectional HEPA filtration for sterile compounding.

(p) "Quality Assurance" (QA) means the system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

(q) "Quality Control" (QC) means the sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.

(r) "Secondary Engineering Control" (SEC) means the area where the PEC is placed.

~~(s) "Segregated Compounding Area" (SCA) means a designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Low-Risk CSPs only.~~

~~(t) "Sporicidal agent" means a chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.~~

~~Section 3. Pharmacy Staff Training and Evaluation.~~

~~(a) Each sterile compounding pharmacy shall develop a written training program that describes the required training, the frequency of training, and the process for evaluating the performance of pharmacy staff involved in preparing CSPs.~~

~~(b) Compounding pharmacy staff shall be initially trained and qualified by demonstrating knowledge of principles and proficiency in core competencies for performing sterile manipulations and achieving and maintaining appropriate environmental conditions. A designated person shall oversee the training of pharmacy staff.~~

~~(c) Training and evaluation of pharmacy staff shall be documented.~~

~~(d) Compounding pharmacy staff shall be able to demonstrate knowledge and competency in the following:~~

~~(i) Using proper aseptic technique~~

~~(A) All compounding pharmacy staff shall perform a media-fill test to assess aseptic technique. The media-fill test shall simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person replacing all the components used in the CSPs with soybean-casein digest media.~~

~~(B) Gloved fingertip and thumb sampling shall be performed inside the PEC following the media-fill test to evaluate aseptic technique.~~

~~(C) If using commercial sterile microbial growth media, a certificate of analysis (COA) shall be obtained from the supplier stating that the lot of the growth media will support the growth of microorganisms.~~

~~(D) If preparing sterile microbial growth media in-house for sterile to sterile media fill testing, the growth promotion capability of the media shall be demonstrated for each batch and documented as described in USP <71>.~~

~~(E) Failure of the media fill test is indicated by visible turbidity or other visual manifestation of growth in the media in one or more container-closure unit(s) on or before the end of the incubation period.~~

~~(F) Results of the evaluation and corrective actions, in the event of failure, shall be documented and include, at a minimum the name of the person evaluated, evaluation date/time, media and components used, including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results.~~

~~(ii) Appropriately and accurately preparing, identifying, purifying, sterilizing, packaging, labeling, storing, dispensing, distributing, documenting and recordkeeping for CSPs.~~

~~(iii) Appropriately cleaning and maintaining the compounding area.~~

~~(iv) How to recognize potential problems, deviations, failures, or errors related to equipment, facilities, materials, or compounding processes that could potentially result in contamination or other adverse impact on CSP quality.~~

~~(v) Hand hygiene and garbing procedures~~

~~(A) All compounding pharmacy staff shall be visually observed while performing hand hygiene and garbing procedures.~~

~~(B) Before being allowed to independently compound, all compounding pharmacy staff shall successfully complete an initial gloved fingertip and thumb sampling on both hands, no fewer than 3 separate times. Each evaluation shall occur after performing a separate and complete hand hygiene and full garbing procedure.~~

~~(C) The initial evaluation shall be performed on donned sterile gloves in a classified area or SCA. Subsequent sampling shall be performed on donned sterile gloves inside of the PEC. If conducting sampling in a compounding aseptic isolator (CAI), compounding aseptic containment isolator (CACI), or a pharmaceutical isolator, samples shall be taken from the sterile gloves placed over the gloves attached to the restricted-access barrier system (RABS).~~

~~(D) Successful completion of initial gloved fingertip and thumb sampling is defined as zero colony-forming units (cfu). Successful completion of subsequent gloved fingertip and thumb sampling after media-fill testing is defined as ≤ 3 cfu (total from both hands).~~

(E) Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or gloved fingertip and thumb sampling results that exceed action levels.

(F) Results of the evaluation and corrective actions, in the event of failure, must be documented. Documentation must include, at a minimum, the name of the person evaluated, evaluation date/time, media and components used, including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results.

(e) Competencies shall be reevaluated every twelve (12) months for low and medium risk level compounding, and every six (6) months for high-risk level compounding.

Section 4. Personal Hygiene and Garbing.

(a) Pharmacy staff shall not handle CSPs if they have open sores, infected wounds, or an upper respiratory infection.

(b) When entering a cleanroom suite or SCA, compounding pharmacy staff shall remove any items that are not easily cleanable or that are not necessary for compounding. At a minimum pharmacy staff shall:

(i) Remove all cosmetics and personal outer garments including, but not limited to bandanas, coats, hats, jackets, sweaters, and vests. If worn, eyeglasses shall be wiped;

(ii) Remove all hand, wrist, and other exposed jewelry including but not limited to piercings that could interfere with the effectiveness of garbing or otherwise increase the risk of contamination of the CSP. Compounding pharmacy staff shall cover any jewelry that cannot be removed;

(iii) Not wear earbuds or headphones;

(iv) Not bring electronic devices that are not necessary for required tasks into the cleanroom suite or SCA; and

(v) Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products, including, but not limited to polish, artificial nails, or extenders shall not be worn.

(c) Handwashing and garbing order shall be outlined in the facility's policies and procedures. Compounding pharmacy staff shall follow established hand hygiene and garbing procedures when entering the cleanroom suite or SCA and prior to handling CSPs.

~~(i) Compounding pharmacy staff shall wash hands and forearms up to the elbows and remove visible debris from underneath the fingernails with soap and water for at least thirty (30) seconds. Low-lint disposable towels or wipes shall be used to dry hands and forearm. Brushes and hand dryers shall not be used for hand hygiene;~~

~~(ii) After handwashing, an alcohol-based hand rub shall be applied to dry hands prior to donning sterile gloves;~~

~~(iii) Garb shall consist of the following minimum requirements:~~

~~(A) Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck;~~

~~(B) Low-lint, disposable shoe covers;~~

~~(C) Low-lint, disposable cover for head that covers the hair and ears, and if applicable, a disposable cover for facial hair;~~

~~(D) Face mask;~~

~~(E) Sterile, powder-free gloves; and~~

~~(F) If using a RABS, disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves shall be worn over the gloves attached to the RABS sleeves.~~

~~(iv) Garb shall be donned or doffed in an order that reduces the risk of contamination. Skin shall not be exposed inside the PEC. Garb shall be replaced immediately if it becomes visibly soiled or if its integrity is compromised;~~

~~(v) Compounding pharmacy staff may re-use gowns within the same shift if the gown is maintained in the classified area or within the perimeter of the SCA and used for non-hazardous drug compounding. All other garb shall be discarded after use;~~

~~(vi) All gloves shall be inspected for holes, punctures, or tears and shall be replaced immediately if such defects are detected. The RABS sleeves and gloves should be changed per the manufacturer's recommendations and as defined in the facility's policies and procedures; and~~

~~(vii) Compounding pharmacy staff shall apply sterile 70% isopropyl alcohol (IPA) to gloves regularly throughout the compounding process and whenever nonsterile surfaces are touched.~~

Section 5. Facilities and Engineering Controls.

(a) The cleanroom suite shall be designed as follows:

(i) The ante-room and buffer rooms shall be separated from areas not directly related to compounding by fixed walls and doors;

(ii) The ante-room shall have a line of demarcation separating the dirty side and the clean side. Alternatively, the facility can have two (2) separate ante-rooms, one dirty and one clean;

(iii) Buffer rooms shall maintain a minimum differential positive pressure of 0.02-inch water column between the buffer and ante-rooms;

(iv) Ante-rooms shall maintain a minimum differential positive pressure of 0.02-inch water column between the ante-room and unclassified areas;

(v) A pressure differential monitoring device shall be used to continuously monitor pressure differentials. Results from the pressure monitoring device shall be reviewed and documented at least daily on the days when compounding is occurring;

(vi) Ante-rooms shall maintain ISO Class 8 or better quality of air and maintain a minimum of 20 to HEPA-filtered air changes per hour (ACPH);

(vii) Buffer rooms shall maintain ISO Class 7 or better air quality and maintain a minimum of 30 total HEPA-filtered ACPH. At least 15 ACPH shall be supplied through the buffer room's heating, ventilation, and air-conditioning (HVAC) system;

(viii) Air supplied to the cleanroom suite shall be introduced through HEPA filters located in the ceiling. Air returns shall be located low in the wall, unless a visual smoke study demonstrates the absence of stagnant flow where particles can accumulate;

(ix) Temperature and humidity shall be controlled through a HVAC system. Free-standing humidifiers/dehumidifiers and air conditioners shall not be used within the classified area;

(A) The cleanroom suite should be maintained at a temperature of 20° C (68° F) or cooler and a relative humidity below 60% to minimize the risk for microbial proliferation and provide comfortable conditions for compounding pharmacy staff;

(B) The designated person shall monitor temperature and humidity of each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device;

(C) The designated person shall verify the accuracy of temperature and humidity monitoring devices at least every twelve (12) months or as required by the manufacturer.

(x) The cleanroom suite shall provide a well-lighted working environment;

(xi) The cleanroom suite shall be designed to allow for easily cleanable conditions:

(A) The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, and non-shedding. These surfaces should be resistant to damage by cleaning agents, disinfectants, sporicidal agents and tools used to clean them;

(B) Overhangs and ledges should be limited, but easily cleanable, if present;

(C) Floors shall include coving to the sidewall, or the juncture between the floor and wall shall be sealed. The junctures between the ceiling and the walls shall be sealed. All penetrations through the ceiling or walls shall be sealed;

(D) If ceilings consist of inlaid panels, the panels shall be caulked around each panel to seal them to the support frame;

(E) The exterior lens surface of all ceiling light fixtures shall be smooth, mounted flush, and sealed;

(F) The walls shall be either constructed of or covered with durable material including but not limited to epoxy painted walls or heavy-gauge polymer. The integrity of the surfaces shall be maintained. Panels shall be joined together and sealed to each other and the support structure;

(G) All furniture, equipment, and other materials necessary for compounding activities should be low-shedding and easily cleaned and disinfected; and

(H) Carts used to transport components or equipment into classified areas shall be constructed from nonporous material with cleanable casters and wheels to allow for cleaning and disinfection. Carts shall not be moved from the dirty side to the clean side of the ante-room unless the entire cart, including casters, is cleaned and disinfected.

(xii) Water supplied to the cleanroom suite shall meet the following requirements:

(A) The sink used for hand hygiene may be placed either inside or outside the ante-room. If placed outside the ante-room, it shall be located in a clean space. If the sink is located inside the ante-room, it may be placed on either the clean side or dirty side of the ante-room;

(B) The sink should allow for hand-free use;

(C) The ante-room shall not contain floor drains;

(D) The buffer room shall not contain plumbed water sources; and

(E) Sprinkler systems shall be recessed, covered, and easily cleanable.

(b) The SCA shall meet the following requirements:

(i) The SCA shall be separated from general pharmacy areas not directly related to compounding by fixed doors and walls;

(ii) The SCA shall be located away from unsealed windows, doors that connect to the outdoors, traffic flow, and other environmental control challenges that could affect the air quality of the PEC within the SCA;

(iii) A visible perimeter shall be established to mark the boundaries of the SCA;

(iv) The SCA shall provide a well-lighted working environment.

(v) Free-standing humidifiers/dehumidifiers and air conditioners shall not be used within the perimeter of the SCA;

(vi) All surfaces shall be clean, uncluttered, and dedicated to compounding;

(vii) All surfaces shall be smooth, impervious, free from cracks and crevices, and non-shedding;

(viii) All surfaces should be resistant to damage by cleaning agents; disinfectants, sporicidal agents, and tools used to clean them;

(ix) Dust-collecting overhangs and ledges should be limited, but shall be easily cleanable if present; and

(x) The sink shall be at least one (1) meter away from the PEC and shall not be placed inside the perimeter of the SCA. The sink should allow for hands free use.

Section 6. Requirements for Certification and Recertification.

(a) Before a classified area or SCA can be used to compound CSPs, it shall be certified using procedures in the current controlled Environmental Testing Association (CETA) certification guideline for sterile compounding facilities or an equivalent guideline. Certifications hall be performed by properly trained individuals.

(b) Certification shall be performed initially, and recertification shall be performed at least every six (6) months. Recertification shall be performed if there are changes to the area including, but not limited to redesign, construction, replacement or relocation if a PEC, or alteration in the configuration of the room that could affect airflow or air quality.

(c) Certification shall include the following:

(i) Airflow testing to determine acceptable pressure differentials in doorways between adjacent rooms and ACPH from the HVAC, ACPH from the PEC and total ACPH;

(ii) HEPA filter integrity testing to include leak testing. HEPA filters shall be tested after installation and as part of recertification;

(iii) Total particle count testing in all classified areas under dynamic conditions;

(iv) Dynamic airflow smoke patter tests for each PED during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSP;

(v) Viable air and surface sampling in each classified area during dynamic operating conditions.

(A) Viable air sampled shall be taken using an impaction device that tests at least 1,000 liters of air from each location sampled;

(B) A general microbial growth media that supports the growth of bacteria and fungi shall be used for surface samples;

(C) Action levels for viable air sampling are > 1CFU for ISO Class 5, > 10 CFU for ISO Class 7, and > 100 CFU for ISO Class 8; and

(D) Action levels for surface sampling are > 3 CFU for ISO Class 5, > 5 CFU for ISO Class 7, and > 50 CFU for ISO Class 8.

~~(d) The certification report shall document the results of all required testing. The certification report shall be readily retrievable.~~

~~(e) A certification report shall document the results of the above required rests.~~

~~(i) The report shall indicate the locations of viable air and surface samples, size of the sample taken, incubation times and temperatures, and growth results; and~~

~~(ii) The number of pharmacy staff present in each PEC and SEC during testing shall be documented.~~

~~(f) All certification and recertification records shall be reviewed by the designated person(s) to ensure that the classified environments meet the above requirements of this chapter.~~

~~(g) In the event of failure, the designated person(s) shall identify the cause and implement a corrective action plan. Data collected in response to corrective actions shall be documented and reviewed by the designated person(s) to confirm the actions taken have been effective.~~

~~Section 7. Cleaning, Disinfecting, and Applying Sporicidal Agents in Compounding Areas.~~

~~(a) All activities in this section shall be performed by trained and appropriately garbed facility staff.~~

~~(b) Facility staff shall clean surfaces prior to being disinfected. Facility staff may use an EPA-registered one-step disinfectant cleaner to accomplish cleaning and disinfection in one step.~~

~~(c) Facility staff shall perform cleaning in the direction of cleanest to dirtiest areas.~~

~~(d) Facility staff shall follow the manufacturer's directions or published data for the minimum contact time of the cleaning, disinfecting, and sporicidal agents.~~

~~(e) Facility staff shall apply sterile 70% isopropyl alcohol (IPA) after cleaning, disinfecting, or applications of a sporicidal agent in the PEC to remove any residue and allow it to dry.~~

~~(f) All cleaning supplies with the exception of tool handles and holders shall be low-lint.~~

~~(g) Wipers, pads, and mop heads should be disposable. Facility staff shall discard disposable cleaning supplies after each cleaning activity.~~

(h) Reusable cleaning tolls shall be made of cleanable materials, cleaned and disinfected before and after each use, dedicated for use in the classified area or SCA, and not removed except for disposal.

(i) Cleaning, disinfecting, and application of sporicidal agents in classified areas and within the perimeter of the SCA shall occur at the following minimum frequencies and include the following surfaces, at a minimum:

(i) Facility staff shall clean and disinfect surfaces of sink(s) at least daily and a sporicidal agent shall be used at least monthly;

(ii) Facility staff shall clean and disinfect all interior surfaces and equipment inside the PEC, pass-through(s), work surfaces outside the PEC, and floors daily. A sporicidal agent shall be used on these surfaces at least monthly;

(iii) Facility staff shall perform cleaning and disinfecting before initiating compounding if compounding is not performed daily; and

(iv) Facility staff shall clean and disinfect walls, doors, door frames, ceilings, storage shelving and bins, and equipment outside the PEC monthly. A sporicidal agent shall be used on these surfaces.

(j) Facility staff shall document all cleaning, disinfecting, and application of sporicidal agents. Records shall be readily retrievable.

Section 8. Introducing Items into the SEC and PEC.

(a) Only furniture, equipment, and other materials necessary for compounding activities shall be permitted in a classified area or SCA. Items shall be placed in a manner that facilitates sterile compounding operations.

(b) Pharmacy staff shall not introduce shipping carton(s) or other corrugated or uncoated cardboard into a classified area or SCA.

(c) Pharmacy staff shall wipe down an item with a sporicidal agent, EPA-registered one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipes prior to introducing the item into the clean side of the ante-room, pass-through, or inside the perimeter of the SCA. Pharmacy staff shall wear gloves when wiping down items.

(i) If a sporicidal agent or EPA-registered one-step disinfectant cleaner is used to wipe an item down, the item shall be allowed to dwell for the minimum contact time specified by the manufacturer before introducing the item into the classified area;

(ii) Pharmacy staff shall allow the item to dry if sterile 70% IPA is used to wipe it down; and

(iii) The wiping procedure shall not render the product label unreadable.

(d) Compounding pharmacy staff shall wipe down any item with sterile 70% IPA using low-lint wipes and allowed to dry prior to introducing the item into the PEC.

(i) Compounding pharmacy staff may remove items from sterile coverings as they are introduced into the PEC without the need to wipe them with sterile 70% IPA;

(ii) The wiping procedure shall not render the product label unreadable; and

(iii) Compounding pharmacy staff shall wipe all critical sites with sterile 70% IPA in the PEC and allowed to dry prior to entering or puncturing vial stoppers, IV bag septums, or ampule necks.

(e) Only equipment necessary for performing compounding activities shall be permitted in the PEC.

(i) Proper placement of equipment in the PEC shall be initially verified by a dynamic airflow smoke pattern test during certification or recertification that demonstrates minimal disruption in airflow. The smoke pattern rest shall be repeated if equipment is moved to a different location in the PEC; and

(ii) Pharmacy staff shall not remove equipment used in the cleanroom suite or within the perimeter of the SCA except for calibration, servicing, cleaning, or other activities associated with maintenance.

Section 9. Equipment, Supplies, and Components.

(a) When using an automated compounding device (ACD), balance, or other automated or electronic equipment to compound a CAP, pharmacy staff shall:

(i) Calibrate all equipment to ensure proper operation;

(ii) Ensure all equipment shall not be reactive or sorptive with compounding components;

(iii) Conduct an accuracy assessment of the ACD before first use and again each day it is used to compound; and

(iv) Maintain records of all equipment calibration, verification, and maintenance.

(b) Pharmacy staff shall ensure that all supplies used in compounding, including, but not limited to beakers, utensils, needles, syringes, filters and tubing sets meet the following requirements:

(i) Supplies shall not be reactive or sorptive with compounding components; and

(ii) Supplies in direct contact with CSPs shall be sterile and depyrogenated.

(c) Pharmacy staff shall ensure all components used in compounding meet the following requirements:

(i) Pharmacy staff shall use conventionally manufactured sterile products when available and appropriate;

(ii) Active pharmaceutical ingredients (APIs) shall comply with criteria in the USP-NF monograph, if one exists, or have a COA that includes the specifications and test results.

(iii) The sterile compounding pharmacy shall obtain APIs from and FDA-registered facility;

(iv) The sterile compounding pharmacy may obtain components other than APIs from an acceptable and reliable source if not available from an FDA-registered facility; and

(v) The sterile compounding pharmacy shall establish the identity, strength, purity, and quality of all components obtained.

Section 10. Master Formulation Records, Compounding Records and Labeling.

(a) Sterile compounding pharmacies shall maintain a master formulation record:

(i) A master formulation record shall be maintained for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredients;

(ii) Any changes or alterations to the master formulation record shall be approved by the designated person(s) and documents; and

(iii) The master formulations record shall include, but is not limited to, the following information:

(A) Name, strength or activity, and dosage form of the CSP;

(B) Identities and amounts of all ingredients;

(C) Type and size of container-closure system(s);

(D) Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions;

(E) Physical description of the final CSP;

(F) BUD and storage requirements;

(G) Reference source to support the stability of the CSP;

(H) Quality control (QC) procedures; and

(I) Other information as needed to describe the compounding process and ensure repeatability.

(b) Pharmacy staff shall create a compounding record for all CSPs:

(i) The prescription, medication order, or label may serve as the compounding record;

(ii) The compounding record may be stored electronically if an ACD workflow management system, or other equipment is used to compound the CSP;

(iii) The compounding record shall be readily retrievable;

(iv) The master formulation record may serve as the basis for preparing the compounding record; and

(v) The compounding record shall include, but is not limited to, the following information:

(A) Name, strength or activity, and dosage form of the CSP;

(B) Date and time of preparation of the CSP;

(C) Assigned internal identification number;

(D) A method to identify the individuals involved in the compounding process and verifying the final CSP;

(E) Name of each component;

(F) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredients(s);

(G) Weight or volume of each component;

(H) Strength or activity of each component;

(I) Total quantity compounded;

(J) Assigned BUD and storage requirements;

(K) Results of QC procedures;

(L) Master formulation record reference for the CSP, if applicable; and

(M) Calculations made to determine and verify quantities and/or concentrations of components, if applicable.

(c) The label on the immediate container of the CSP shall, at a minimum, display the following information:

(i) Assigned internal identification number;

(ii) Active ingredient(s) and their amounts, activities, or concentrations;

(iii) Storage conditions if other than controlled room temperature;

(iv) BUD;

(v) Route of administration;

(vi) Total amount or volume if it is not obvious from the container;

(vii) If it is a single dose container, a statement stating such when space permits; and

(viii) If it is a multiple dose container, a statement stating such.

Section 11. Quality Assurance and Quality Control Programs.

(a) The designated person(s) shall establish a quality assurance (QA) and quality control (QC) program.

~~(b) The program shall be reviewed at least every twelve (12) months. The results of the review shall be documented and appropriate actions shall be taken if needed.~~

~~(c) The QA and QC program shall include systems to establish the following:~~

~~(i) Adherence to procedures;~~

~~(ii) Prevention and detection of errors and quality problems;~~

~~(iii) Evaluation of complaints and adverse events; and~~

~~(iv) Appropriate investigations and corrective actions.~~

~~(d) If a CSP is dispensed or administered before the results of release testing are known, the pharmacy shall have a procedure in place to notify the prescriber of a failure of specifications and determine whether a recall is necessary.~~

~~(e) Recall out of specification dispensed CSPs shall include the following:~~

~~(i) Determination of the severity of the problem and the urgency for implementation and completions of the recall;~~

~~(ii) Determination of the distribution of any affected CSP; including the date and quantity of distribution;~~

~~(iii) Identification of patients who received the CSP; and~~

~~(iv) Disposition and reconciliation of the recalled CSP.~~

~~(f) Complaint handling shall include the following:~~

~~(i) A designated person(s) shall review all complaints to determine whether there is a potential quality problem with the CSP;~~

~~(ii) A thorough investigation shall be initiated and completed for all complaints that involve a quality problem with a CSP;~~

~~(iii) The sterile compounding pharmacy shall maintain a record of each complaint. The record shall contain the following information, at a minimum:~~

~~(A) The name of the complainant or unique identifier;~~

~~(B) The date the complaint was received;~~

(C) The nature of the complaint;

(D) The response to the complaint;

(E) The name and strength of the CSP and its' internal identification number; and

(F) Findings of the investigation and any follow up.

(iv) A CSP that is returned in connection with a complaint shall be quarantined until destroyed after completion of the investigation.

(g) The designated person(s) shall report adverse events potentially associated with a CSP to the Board.

Section 12. Establishing Beyond Use Dates.

(a) Low-risk level CSPs are prepared under the following conditions:

(i) The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices;

(ii) Compounding only involved transferring, measuring and mixing manipulations using not more than three (3) commercially manufactured packages of sterile products, and no more than two (2) entries into any sterile container, product, or administration container/device;

(iii) Manipulations are limited to aseptically opening ampules, penetrating disinfected 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; and

(iv) In the absence of passing a sterility test, the storage periods shall not exceed forty-eight (48) hours at controlled room temperature (20-25°C/68-77°F), fourteen (14) days at a cold temperature (2-8°C/36-46°F), and forty-five (45) days in a solid frozen state (-25 to -10°C/-13 to 14°F).

(b) Medium-risk level CSPs are prepared aseptically under low-risk level conditions and one or more of the following conditions exists:

(i) Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions;

(ii) The compounding process includes complex aseptic manipulations other than a single-volume transfer;

(iii) The compounding process requires unusually long duration; and

(iv) In the absence of passing a sterility test, the storage periods shall not exceed thirty (30) hours at controlled room temperature, nine (9) days at cold temperature and forty-five (45) days in a solid, frozen state.

(c) High-risk level CSPs are prepared under the following conditions:

(i) Nonsterile ingredients, including manufactured products not intended for sterile routes of administration, are incorporated, or a nonsterile device is employed before terminal sterilization;

(ii) Any of the following are exposed to air quality worse than ISO Class 5 for more than one (1) hour:

(A) Sterile contents of commercially manufactured products;

(B) CSPs that lack effective antimicrobial preservatives; and

(C) Sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

(iii) Pharmacy compounding staff are improperly garbed and gloved;

(iv) Nonsterile water-containing preparations are stored for more than six (6) hours before being sterilized; and

(v) In the absence of passing a sterility test, storage periods shall not exceed twenty-four (24) hours at controlled room temperature, three (3) days at a cold temperature, and forty-five (45) days in solid, frozen state.

(d) Pharmacy staff shall meet the following requirements for high-risk level compounding:

(i) Batches of twenty-five (25) or more CSPs shall undergo sterility testing;

(ii) All nonsterile measuring, mixing, and purifying devices shall be rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use;

(iii) All high-risk level CSPs subjected to terminal sterilization shall be pre-filtered by passing through a filter with nominal port size no larger than 1.2 microns preceding or during filling into their final containers, to remove particulate matter; and

(iv) Sterilization by filtration shall be performed with a sterile 0.2 or 0.22 micron nominal pore size filter, entirely within an ISO Class 5 or superior air quality environment.

(e) A sterile compounding pharmacy with a cleanroom suite may compound low, medium, or high-risk level CSPs.

(f) A sterile compounding pharmacy with a SCA may compound low-risk level CSPs and shall not assign a BUD greater than twelve (12) hours at controlled room temperature, or twenty-four (24) hours at refrigerated temperature.

(g) CSPs that have undergone extended sterility and stability testing may be assigned a BUD greater than outlined in this Chapter. CSPs that are assembled according to the manufacturer's instructions may be assigned a BUD in accordance with the manufacturer's recommendations.

Section 13. Immediate Use CSPs.

(a) Compounding of CSPs by pharmacy staff outside of a classified area or SCA for direct and immediate administration to patients is not subject to the requirements of this Chapter, when all of the following conditions are met:

(i) Aseptic processes are followed and written procedures 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;

(ii) Compounding is performed in accordance with the evidence-based information for physical and chemical compatibility of the drugs;

(iii) The preparation involves not more than three (3) different sterile products;

(iv) Any unused starting component from a single-dose container shall be discarded after preparation for the individual patient is complete. Single-dose containers shall not be used for more than one (1) patient;

(v) Administration of the CSP begins within four (4) hours following the start of preparation. If administration has not begun within four (4) hours following the start of preparations, it shall be promptly, appropriately, and safely discarded; and

(vi) Unless the CSP is administered by the person who prepared the CSP or administration is witnessed by the preparer, the CSP shall be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the CSP, and the exact four (4) hour time period within the administration shall begin.

(b) Immediate use CSPs shall not be prepared:

(i) For medium-risk level or high-risk level CSPs;

(ii) In advance for anticipated needs; or

(iii) For batch compounding.

(c) Situations for which the immediate use CSPs can be administered include, but are not limited to:

(i) Cardiopulmonary resuscitation;

(ii) Emergency room treatment;

(iii) Preparation of diagnostic agents, or

(iv) Critical therapy where preparation under conditions for low-risk level CSPs causes delays that subject the patient to additional risk.

Section 14. Sterilization and Depyrogenation.

(a) Pharmacy staff shall sterilize all CSPs that contain nonsterile components or that come into contact with nonsterile devices during any phase of compounding, within six (6) hours after completing the CSP.

(b) Pharmacy staff shall sterilize the CSP in a method without degrading its physical and chemical stability or the packaging integrity.

(c) Pharmacy staff shall document a description of the sterilization process, including temperature, pressure (if applicable), duration, permissible load conditions for each cycle, the use of biological indicators and endotoxin challenge vials, and be readily retrievable.

(d) Pharmacy staff shall document results of terminal sterilization. Documentation shall include, but is not limited to, the temperature, pressure, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials.

~~(e) Equipment used to terminally sterilize CSPs shall be appropriately maintained, calibrated, and cleaned. Maintenance, calibration and cleaning shall be documented by pharmacy staff.~~

~~(f) Depyrogenation processes shall meet the following requirements:~~

~~(i) Depyrogenation shall be used to render glassware, metal, and other thermostable containers and components pyrogen-free;~~

~~(ii) The duration of the exposure period shall include sufficient time for the items to reach the depyrogenation temperature;~~

~~(iii) The items shall remain at the depyrogenation temperature for the durations of the depyrogenation period;~~

~~(iv) The effectiveness of the depyrogenation cycle shall be verified and documented initially and annually thereafter using endotoxin challenge vials to demonstrate the cycle is capable of achieving a 3-log reduction or more in endotoxins;~~

~~(v) The effectiveness of the depyrogenation cycle shall be re-established for any changes to the depyrogenation cycle; and~~

~~(vi) Items that are not thermostable shall be depyrogenated by rinsing with sterile, non-pyrogenic water, and thoroughly drained or dried immediately before use in compounding.~~

~~(g) Sterilization by filtration shall meet the following requirements:~~

~~(i) Sterilizing filters shall be sterile, depyrogenated, have a nominal pore size for 0.22 microns or smaller, and include labeling for pharmaceutical use;~~

~~(ii) Sterilizing filters labeled "for laboratory use only" shall not be used for compounding CSPs;~~

~~(iii) Sterilizing filters shall be certified by the manufacturer to retain at least 10^7 microorganisms of a stain of *Bredundimonas diminuta* per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered;~~

~~(iv) The designated person(s) shall use available published information, supplier documentation, or direct challenge to ensure sterilizing filters:~~

~~(A) Are chemically and physically compatible with all ingredients in the CSP;~~

~~(B) Are chemically stable at the pressure and temperature conditions that will be used; and~~

~~(C) Have enough capacity to filter the required volumes.~~

~~(v) Pharmacy staff shall integrity test filters used to sterilize a CSP according to the manufacturer's recommendations. If multiple filters are required for the compounding process, each filter shall pass a filter integrity test;~~

~~(vi) CSPs prepared using a filter that fails an integrity tests shall be discarded, or, after investigating the cause of the failure and selection of an appropriate filter, re-filtered for sterilization no more than one additional time; and~~

~~(vii) Pharmacy staff shall pre-filter a CSP when it is known to contain excessive particulate matter, performed using a filter of larger nominal pore size to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.~~

~~(h) Sterilization by steam heat shall meet the following requirements:~~

~~(i) 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;~~

~~(ii) The duration of the exposure period shall include sufficient time for the entire contents of the CSP and other items to reach sterilizing temperature;~~

~~(iii) Items shall remain at the sterilizing temperature for the duration of the sterilization period;~~

~~(iv) CSPs shall be placed in the autoclave to allow steam to reach the CSPs without entrapment of air;~~

~~(v) Prior to filling ampules and vials that will be steam sterilized, solutions shall be passed through a filter with a nominal pore size no larger than 1.2 microns for removal of particulate matter;~~

~~(vi) Sealed containers shall be able to generate steam internals. Stoppered and crimped vials shall contain a small amount of sterile water to generate steam;~~

~~(vii) Deep containers shall be inverted or placed on their sides at a downward-sloping angle to minimize air entrapment, and to facilitate condensate drainage, or shall shave a small amount of sterile water placed in them before steam sterilization;~~

(viii) Porous materials and items with occluded pathways shall only be sterilized by steam if the autoclave chamber has suitable cycles for dry goods;

(ix) The effectiveness of steam sterilization shall be verified with each sterilization run or load by using appropriate biological and physiochemical indicators and integrators. Verification shall be documented;

(x) The steam supplied shall be free of contaminants and generated using water per the manufacturer's recommendation.

(xi) A calibrated data recorder or chart shall be used to monitor each cycle and identify cycle irregularities; and

(xii) The date, run, and load numbers of the steam sterilizer used to sterilize a CSP shall be documented.

(i) Sterilization by dry heat shall meet the following requirements:

(i) The duration of the exposure period shall include sufficient time for the entire contents of the CSPs and other items to reach the sterilizing temperature;

(ii) The CSP and other items shall remain at the sterilizing temperature for the duration of the sterilization period;

(iii) The effectiveness of the dry heat method shall be verified and documented with each sterilization run or load, using appropriate biological indicators and confirmation methods;

(iv) The dry heat oven shall be calibrated. Calibration shall be documented;

(v) A calibrated data recorder or chart shall be used to monitor each cycle and identify cycle irregularities; and

(vi) The date, run, and load numbers of the dry heat oven used to sterilize a CSP shall be documented.

Section 15. Release Inspections and Testing.

(a) Pharmacy staff shall visually inspect all CSPs at the completion of compounding, before release and dispensing to:

(i) Determine whether the physical appearance of the CSP is as expected;

(ii) Confirm the CSP and its labeling match the prescription or medication order; and

(iii) Ensure the integrity of the container-closure system.

(b) Pharmacy staff shall visually inspect a CSP immediately before it is released or dispensed; if not released or dispensed on the day of preparation.

(c) CSPs with observed defects shall be discarded or marked and segregated from acceptable CSPs in a manner that prevents them from being released or dispensed.

Section 16. Hazardous Drugs as CSPs.

(a) Hazardous drugs shall be prepared for administration only under conditions that protect personnel in the preparation and storage areas.

(b) Pharmacy staff shall store hazardous drugs separately from other inventory, in a manner to prevent contamination and personnel exposure.

(c) Pharmacy staff shall handle hazardous drugs with caution at all times using appropriate chemotherapy gloves during receiving, distributions, stocking, inventorying, preparation for administration, and disposal.

(d) Hazardous drugs shall be prepared in a BSC or CACI with ISO Class 5 or better air quality.

(e) CSTDs shall be used when the compounding process allows.

(f) A hazardous drug buffer room shall maintain a minimum differential negative pressure of 0.01-inch water column between the buffer room and the ante-room.

(g) The pharmacy shall limit access to areas where hazardous drugs are stored and prepared to protect persons not involved in drug preparation.

(h) Compounding pharmacy staff shall wear PPE when compounding in a BSC or CACI and when using CSTDs.

(i) PPE shall include gowns, face masks, eye protections, hair covers, shoe covers or dedicated shows, and double gloving with sterile chemo-type gloves.

(i) All pharmacy staff who handle or compound hazardous drugs shall be fully trained in the storage, handling, and disposal of hazardous drugs.

(i) Training shall occur prior to preparing or handling hazardous CSPs;

(ii) Training shall be documented for each person, at least annually; and

(iii) Training shall include, but is not limited to the following:

(A) Didactic overview of hazardous drugs in the pharmacy, including mutagenic, teratogenic, and carcinogenic properties;

(B) Ongoing training for each new hazardous drug in the pharmacy;

(C) Pharmacy staff of reproductive capability shall confirm, in writing, that they understand the risks of handling hazardous drugs;

(D) Safe aseptic manipulation practices;

(E) Negative pressure techniques when utilizing a BSC or CACI;

(F) Correct use of CSTDs;

(G) Containment, cleanup, and disposal procedures for breakages and spills; and

(H) Treatment of pharmacy staff in the event of contact and inhalation exposure.

(j) Pharmacy staff shall comply with applicable state and federal regulations when disposing of hazardous drugs.

(k) While preparing hazardous drugs for emergency use, pharmacy staff may compound the hazardous drug outside of a PEC, so long as a CSTD and PPE for hazardous drug compounding are used.

Section 17. Radiopharmaceuticals as CSPs.

(a) Radiopharmaceuticals compounded from sterile components in closed, sterile containers, and with a volume of 100 mL or less for a single-dose injection, or no more than 30 mL taken from a multiple-dose container, are considered low-risk level CSPs and shall comply with the requirements in this Chapter.

(b) Radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes, in a properly functioning and certified PEC, located in an ISO Class 8 or cleaner SEC.

(c) Radiopharmaceuticals vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environments and punctured by needles with no

~~direct contact contamination, may be used up to the time indicated by the manufacturer's recommendations.~~

~~(d) Technetium-99m/molybdenum-99 generator systems shall be stored and operated under conditions recommended by manufacturers, and applicable state and federal regulations.~~

~~(i) Generator systems shall be eluted in an ISO Class 8 or cleaner air environment, to permit special handling, shielding, and air flow requirements.~~

~~(e) Direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity, shall be conducted to limit acute and chronic radiation exposure to a level that is as low as reasonably achievable (ALARA).~~

~~(f) A sterile compounding pharmacy with an SCA may compound radiopharmaceutical CSPs as low-risk level CSPs and shall not assign a BUD greater than twelve (12) hours at controlled room temperature, or twenty-four (24) hours at refrigerated temperature.~~

~~Chapter~~ CHAPTER 18

~~Prescribing by Pharmacists~~ PRESCRIBING BY PHARMACISTS

Section 1. Authority.

These rules are promulgated as authorized by the Wyoming Pharmacy Act W.S. § 33-24-101 et seq.

Section 2. Scope.

This rule applies to any person licensed under Wyoming statutes as a pharmacist and who is practicing within the scope of their license.

Section 3. Immunizations.

Pharmacists may prescribe and administer immunizations in accordance with Board rules and W.S. § 33-24-157.

Section 4. Opiate Antagonists.

~~(a)~~Pharmacists may prescribe and dispense opiate antagonists in accordance with Board rules and W.S. § 35-4-901 et seq.

~~(b) Prior to prescribing an opiate antagonist, a pharmacist shall successfully complete a minimum of one hour of an ACPE accredited continuing education program related to the use of opiate antagonists.~~

Section 5. Epinephrine Auto-Injectors.

Pharmacists may prescribe and dispense epinephrine auto-injectors in accordance with Board rules and W.S. § 35-4-901 et seq.

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CHAPTER 22

COMPOUNDING

Section 1. Authority

These rules are promulgated as authorized by the Wyoming Pharmacy Act W.S. § 33-24-101 through -301.

Section 2. Purpose.

To reference the minimum standards of practice for nonsterile, sterile, hazardous, and radiopharmaceutical compounding in all pharmacy practice settings.

Section 3. Scope.

Applies to all licensees.

Section 4. Incorporation by Reference

(a) All referenced general chapters of the United States Pharmacopeia - National Formulary (USP-NF), in subsection (2), are specifically referring to the USP-NF 2024, Issue 1, which is hereby incorporated and adopted by reference with the effective chapter dates of May 1, 2024. A subscription to all relevant chapters is available for purchase at www.uspnf.com.

(b) The Board has determined that posting the incorporated material on the Internet would constitute a violation of federal copyright law. At the time of adoption, the copyrighted incorporated material will be available for public inspection and examination, but may not be copied, at the Wyoming Department of Health, 2300 Capitol Avenue, Cheyenne, Wyoming 82002, and at the Wyoming State Board of Pharmacy, 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming 82002.

(c) Each standard incorporated by reference in these rules is further identified as follows:

(i) The USP-NF General Chapter 795 Pharmaceutical Compounding – Nonsterile Preparations incorporated by reference in this Chapter of these rules is the USP as existing on March 26, 2025, including amendments adopted by USP as of that date.

(ii) The USP-NF General Chapter 797 Pharmaceutical Compounding – Sterile Preparations incorporated by reference in this Chapter of these rules is the USP as existing on March 26, 2025, including amendments adopted by USP as of that date.

(iii) The USP-NF General Chapter 800 Hazardous Drugs—Handling in Healthcare Settings incorporated by reference in this Chapter of these rules is the USP as existing on March 26, 2025, including amendments adopted by USP as of that date.

(iv) The United States Pharmacopeia (USP) General Chapter 825 Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging incorporated by reference in this Chapter of these rules is the USP as existing on March 26, 2025, including amendments adopted by USP as of that date.

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