



## Certification Page Regular and Emergency Rules

Revised September 2016

**Emergency Rules** (After completing all of Sections 1 through 3, proceed to Section 5 below)

**Regular Rules**

### 1. General Information

a. Agency/Board Name Administration and Information, Dept of/WY State Board of Pharmacy		
b. Agency/Board Address 1712 Carey Avenue, Suite 200	c. City Cheyenne	d. Zip Code 82002
e. Name of Agency Liaison Mary K. Walker		f. Agency Liaison Telephone Number 307-634-9636
g. Agency Liaison Email Address mary.walker@wyo.gov		h. Adoption Date March 29, 2017
i. Program Pharmacy, Board of		

### 2. Legislative Enactment

For purposes of this Section 2, "new" only applies to regular 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 rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

No.  Yes. Please provide the Enrolled Act Numbers and Years Enacted: **Enrolled Acts No. 66 and 49, Senate, 2015**

### 3. Rule Type and Information

a. Provide the Chapter Number, Title, and Proposed Action for Each Chapter.

(Please use the Additional Rule Information form for more than 10 chapters and attach it to this certification)

Chapter Number:	Chapter Name:	<input checked="" type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
1	Rules of Practice and Procedure	<input checked="" type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
15	Long Term Care Pharmacy Services	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
16	Immunization Regulations	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
17	Sterile Compounding	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
		<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed
		<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed
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		<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed
		<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed
		<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed

**3. State Government Notice of Intended Rulemaking**

a. Date on which the Proposed Rule Packet (consisting of the Notice of Intent as per W.S. 16-3-103(a), Statement of Principal Reasons, strike and underscore format and a clean copy of each chapter of rules were: **02/09/2017**

- approved as to form by the **Registrar of Rules**; and
- provided to the **Legislative Service Office and Attorney General:** **02/10/2017**

**4. Public Notice of Intended Rulemaking**

a. Notice was mailed 45 days in advance to all persons who made a timely request for advance notice.  No.  Yes.  N/A

b. A public hearing was held on the proposed rules.  No.  Yes. Please complete the boxes below.

Date: <b>03/29/2017</b>	Time: <b>10:00 am</b>	City: <b>Casper</b>	Location: <b>2211 King Blvd</b>
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c. If applicable, describe the **emergency** which requires promulgation of these rules without providing notice or an opportunity for a public hearing:

**5. Final Filing of Rules**

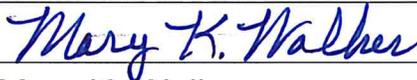
a. Date on which the Certification Page with original signatures and final rules were sent to the **Attorney General's Office for the Governor's signature:** **April 7, 2017**

b. Date on which final rules were approved as to form by the **Secretary of State** and sent to the **Legislative Service Office:** **April 7, 2017**

c.  The Statement of Reasons is attached to this certification.

**6. Agency/Board Certification**

The undersigned certifies that the foregoing information is correct.

Signature of Authorized Individual	
Printed Name of Signatory	Mary K. Walker
Signatory Title	Executive Director, WY State Board of Pharmacy
Date of Signature	April 7, 2017

**7. Governor's Certification**

I have reviewed these rules and determined that they:

1. Are within the scope of the statutory authority delegated to the adopting agency;
2. Appear to be within the scope of the legislative purpose of the statutory authority; and, if emergency rules,
3. Are necessary and that I concur in the finding that they are an emergency.

Therefore, I approve the same.

Governor's Signature	
Date of Signature	



Bessie S. McGirr, RPh, President  
Kerri Kilgore, RPh, Vice President  
John R. McPherson, DDS, Secretary/Treasurer  
Charles W. Smith, Public Member  
Jim Massengill, RPh, Member  
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Jan Shatto, RPT, Member  
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Henry A. (Hank) York, RPh, Inspector/Compliance Officer

Governor: Matthew H. Mead

## WYOMING PHARMACY ACT RULES AND REGULATIONS

### STATEMENT OF PRINCIPAL REASONS FOR REVISIONS

April 2017

The chapters listed in this statement have been reviewed and revisions are proposed to reduce the length and complexity of rules and regulations whenever possible. Each chapter has also been revised to correct spelling, grammar, and format including numbering and pagination. As required by WYO. STAT.ANN. § 16-3-103(a)(i)(G), these proposed rules meet minimum substantive state statutory requirements.

Some of the proposed rules are based on the 2015 General Session of the Wyoming Legislature, specifically Enrolled Act No. 66, Senate, 2015, and Enrolled Act No. 49, Senate, 2015.

#### Chapter 1: Rules of Practice and Procedure of the Wyoming State Board of Pharmacy

Proposed changes to this chapter include updated definitions, procedures for processing applications and complaints, and incorporation by reference to the Uniform Rules for Contested Case Practice and Procedure, adopted by the Office of Administrative Hearings and effective on October 17, 2014.

#### Chapter 15: Long Term Care Pharmacy Services

Clarification of restocking automated dispensing devices has been added.

#### Chapter 16: Immunization Regulations

The description of pneumococcal vaccine has been updated. Vaccines that can be prescribed and administered to minors now includes human papillomavirus (HPV) which is indicated for ages 9 to 26 yr.

#### Chapter 17 Sterile Compounding

Revision to Incorporation by Reference to the United States Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding Sterile Preparations has been made. This reference has become the standard of practice for sterile compounding.



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## SUMMARY OF COMMENTS RECEIVED REGARDING REVISIONS TO THE WYOMING PHARMACY ACT RULES CHAPTERS 1, 2, 8, 15, 16, AND 17

Chapter 1 Rules of Practice and Procedure: No comments were received. The Board voted to go forward with the revisions to this chapter.

Chapter 2 General Practice of Pharmacy: Multiple comments were received regarding Section 4 Definitions, Section 7 Equipment, Section 9 Pharmacist in Charge, Section 10 Prescription Transfer, Section 23 Non-Resident Pharmacy, Section 25 Ancillary Drug Supply, Section 27 Collaborative Pharmacist Care, Section 32 Centralized Prescription Processing, Section 33 Automated Storage and Distribution Systems. Many of these comments were in sections not proposed to be revised at this time. Many comments were also received regarding topics that are not currently in the Wyoming rules. The Board addressed these comments by NOT approving Chapter 2 revisions to go forward at this time. The comments will be considered in future rule-making.

Chapter 8 Manufacturer, Distributor, Wholesaler Prescription Drug Regulations: Multiple comments were received regarding Section 4 Definitions, Section 5 Licensing, Section 14 Security, Section 17 Returned, Damaged and Outdated Prescription Drugs. The Board addressed these comments by NOT approving Chapter 8 revisions to go forward at this time. The comments will be considered in future rule-making.

Chapter 15 Long Term Care Pharmacy Services: Comments were received in favor of the "First Dose Pharmacy" definition in Section 4 plus a request to remove the word "contract" for pharmacies providing first doses. One comment was received regarding Section 8 Automated Dispensing Device requesting the ability to restock by a licensed nurse and electronic verification of restocking. The Board fully considered these comments, then voted to go forward with the revisions to Chapter 15. The comments will be considered in future rule-making.

Chapter 16 Immunization Regulations: One comment was received to incorporate by reference the Centers for Disease Control (CDC) list rather than the "restrictive" list for vaccines which a pharmacist may prescribe and administer to healthy adults and to minors. One comment was received to remove the requirement for registration by pharmacist immunizers. The Board fully considered these comments. It was noted that W.S. § 33-24-157 (c) states: "The board, in cooperation with the Wyoming state board of medicine, shall adopt rules specifying immunizations allowed under this act..."

The board discussed the registration requirement and decided it is the way to determine a pharmacist's training and continuing education, as not all practicing pharmacists were educated on vaccine administration during their academic program. The Board voted to go forward with the revisions to Chapter 16.

Chapter 17 Sterile Compounding: No comments were received. The Board voted to go forward with the revisions to this chapter.

# RULES OF PRACTICE AND PROCEDURE

## CHAPTER 1

### **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 describe procedures for applications and investigations.

### **Section 3.** Scope.

Applies to all applicants and licensees.

### **Section 4.** Definitions.

- (a) "Act" means the Wyoming Pharmacy Act, W.S. § 33-24-101 through -301.
- (b) "Application Review Committee" (ARC) means the Executive Director, at least one Board member, and a Board Compliance Officer.
- (c) "Board" means the Wyoming State Board of Pharmacy.
- (d) "Contestant" means the person, persons, firm or corporations who are licensed under the jurisdiction of the Board against whom a proceeding by petition, verified complaint in writing or formal notice, alleging violation directly or indirectly of any of the terms and provisions of the Act or of the lawful Rules and Regulations of the Board or any related acts and resulting lawful rules and regulations (i.e. Controlled Substances Act, 1971).
- (e) "Contested Case" means any proceeding where legal rights, duties or privileges of a party are required by law to be determined by the Board.
- (f) "Executive Director" means the Executive Director of the Board.
- (g) "License" means the whole or part of any Board permit, certificate, approval, registration or similar form of permission required by law. License does not include a license required solely for revenue purposes.
- (h) "Prosecuting Attorney" means the Assistant Attorney General assigned to the Board to represent the Executive Director in contested cases.
- (i) "Staff" means the personnel of the Board.

**Section 5.** Application Review Process.

(a) Upon receipt of a completed application, the Staff shall review the application and if it is complete and, if there are no grounds for denial, issue the license. If grounds for denial exist, the Staff shall forward the application for review by the Prosecuting Attorney.

(b) The Prosecuting Attorney shall review the application and all other information available and following the review shall:

- (i) Recommend approval of the application; or
- (ii) Recommend the application be forwarded to the ARC for review.

(c) If, after review, the ARC recommends denial of an application:

(i) A preliminary denial letter shall be sent to the applicant. The letter shall:

(A) State the basis for the denial including relevant statutes and rules;  
and

(B) Advise the applicant of the right to request reconsideration.

(ii) If the applicant fails to request reconsideration in writing within thirty (30) days of the preliminary denial letter, the preliminary denial becomes final.

(iii) If the applicant requests reconsideration within thirty (30) days, an informal reconsideration conference shall be held between the ARC, the Prosecuting Attorney, and the applicant.

(iv) Following the informal reconsideration conference, the ARC shall either approve or deny the application.

(v) If denied, the applicant must submit a request in writing for a hearing within thirty (30) days of the date of the denial letter.

(vi) If the applicant fails to request a hearing in writing within thirty (30) days of the date of the denial letter, the denial becomes final.

(d) Application denial hearings.

(i) An application denial hearing is a formal contested case hearing conducted before the Office of Administrative Hearings (OAH) pursuant to the Wyoming Administrative Procedure Act W.S. § 16-3-107 through -113 and Office of Administration Rules.

(ii) The applicant has the burden of proving that he/she meets all requirements for the license requested.

(e) The ARC may attend hearings, but shall not take part in the consideration of any contested case.

**Section 6. Complaints.**

(a) A complaint concerning an alleged violation of the Act must be submitted in writing to the Board. The written complaint shall provide the following information:

- (i) The name and address of the complainant;
- (ii) The name, address, place of employment, and telephone number of the license holder against whom the charges are made, if available and applicable;
- (iii) The specific conduct alleged to constitute the violation;
- (iv) The name and address of any witnesses; and
- (v) The notarized signature of the complainant.

(b) Written complaints shall be referred for investigation to the Board Compliance Officer or to an Investigative Board Member (IBM) selected by Staff from a rotating schedule.

- (i) The IBM shall not take part in the consideration of any contested case.
- (ii) The IBM shall not, by this rule, be barred from attending any disciplinary hearing.

(c) License holders against whom charges are made shall be advised of the investigation and the nature of the complaint.

**Section 7. Investigations and Board Action.**

(a) Upon completion of the investigation, the Board Compliance Officer shall prepare an investigative report which includes:

- (i) The findings of the investigation;
- (ii) A list of statutes and/or Board rules violated; and
- (iii) Any relevant additional information.

(b) The Executive Director shall forward the report and recommendations to the Prosecuting Attorney for review.

(c) Following consultation with the Prosecuting Attorney, the Executive Director shall:

- (i) Send the notice required by Section 6;
  - (ii) Prepare and file a formal petition and notice of hearing setting the matter for a contested case hearing before the Board;
  - (iii) Recommend the Board accept an offer of conditional terms for settlement; or
  - (iv) Recommend the Board dismiss the complaint.
- (d) The Board may resolve a complaint at any time prior to a contested case hearing by:
- (i) Accepting voluntary surrender of a license;
  - (ii) Accepting conditional terms for settlement; or
  - (iii) Dismissing the complaint.

**Section 8.** Service of Notice and Opportunity to Show Compliance.

Prior to commencement of a formal hearing, the Executive Director shall notify the licensee by certified mail of the intent to proceed with disciplinary action. The notice shall give the license holder an opportunity to contest the violations referred to in the Notice or to accept the proposed settlement agreement within twenty (20) days of receipt of the notice

**Section 9.** Incorporation by reference.

(a) For any code, standard, rule or regulation incorporated by reference in this Chapter:

- (i) The Board has determined that incorporation of the full text in these rules would be cumbersome or inefficient given the length or nature of the rules;
- (ii) The incorporation by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (b) of this section; and
- (iii) The incorporated code, standard, rule or regulation is maintained at Board's office and is available for public inspection and copying at cost at the same location.

(b) Each code, standard, rule or regulation incorporated by reference in this Chapter is further identified as follows:

- (i) Chapter 2 – Uniform Rules for Contested Case Practice and Procedure, adopted by the Office of Administrative Hearings and effective on October 17, 2014, found at: <http://soswy.state.wy.us/Rules/RULES/9644.pdf>.

(ii) Chapter 2 – Uniform Procedures, Fees, Costs and Charges for Inspecting, Copying and Producing Public Records adopted by the Department of Administration and Information and effective on September 6, 2016, found at <http://pharmacyboard.state.wy.us>.

## LONG TERM CARE PHARMACY SERVICES

### CHAPTER 15

#### **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 regulate pharmacies who provide services to residents of long term care facilities.

#### **Section 3.** Scope.

Applies to any pharmacy or pharmacist providing services to a long term care facility.

#### **Section 4.** Definitions.

(a) “Long Term Care Facility” (LTCF) means any skilled or intermediate care nursing home, board and care home, or any resident behavioral health facility subject to regulation and licensure by the department of health. For the purpose of this Chapter, long term care facility does not include adult day care facilities, home health agencies, or assisted living facilities.

(b) “Consultant Pharmacist” in a long-term facility means a pharmacist licensed to engage in the practice of pharmacy in this State who is responsible for developing, coordinating, and supervising pharmacy services in a long-term care facility on a regularly scheduled basis.

(c) “Medication Order,” as used in this rule means a written, verbal, facsimile or electronic order from a practitioner or the practitioner’s authorized agent to a licensed nurse in the LTCF for a resident of that facility for administration of a drug or device. For purposes of this Chapter, a “medication order” is considered a prescription, with the exception of controlled substances which require a prescription from the practitioner.

(d) “Provider Pharmacy” means any pharmacy licensed by the Board that provides medications to residents of any long-term care facility pursuant to a medication order or prescription. A provider pharmacy must have a written agreement with the long-term care facility in order to provide services to the residents.

(e) “First Dose Pharmacy” means a pharmacy contracting with a provider pharmacy to ensure that drugs or devices are attainable to meet the immediate needs of the resident or if the provider pharmacy cannot provide services on an ongoing basis.

**Section 5.** Freedom of Choice.

No consultant pharmacist or provider pharmacy shall participate in any agreement or plan that infringes on any resident's right to freedom of choice as to the provider of pharmacy services. A resident in a long-term care facility shall have a choice of a provider pharmacy provided the provider pharmacy complies with this Chapter.

**Section 6.** Pharmacy Responsibilities.

A provider pharmacy shall be responsible for:

(a) Dispensing drugs pursuant to a medication order for an individual resident, properly labeled for that resident, as addressed in Chapter 2 of these rules, including the manufacturer's expiration date. If prepackaged or repackaged by the pharmacy, the expiration date shall be the lesser of the manufacturer's expiration date or twelve (12) months from the date of prepackaging or repackaging;

(b) Dispensing drugs for residents of long-term care facilities in packaging consistent with the drug distribution system required by the facility's policies and procedures;

(c) Developing a drug recall procedure that protects the health and safety of residents including immediate discontinuation of any recalled drug or device and subsequent notification of the prescriber and director of nursing of the facility. The drug recall policy must be readily retrievable at the provider pharmacy and the facility;

(d) Providing service twenty-four (24) hours a day, seven (7) days per week, either directly or by contract with another pharmacy. All "on-call" services shall be verifiable by the board and its inspectors. Ancillary boxes or automated dispensing devices may be used as outlined in Chapter 2 of these rules;-

(e) Performing prospective drug usage reviews for all new and refill medication orders as described in Chapter 9 of these rules;

(f) Providing sufficient and accurate information to facility staff regarding the appropriate administration and use of all dispensed drugs and devices;

(g) Providing intravenous (IV) services or contracting with another pharmacy to provide IV services, if the long term care facility is a skilled unit providing such services;

(h) Communicating with the consultant pharmacist and the facility regarding concerns and resolution thereof, including, but not limited to "on-call" services and IV services; and

(i) Returning non-controlled substance prescriptions dispensed to residents in long term care facilities for re-dispensing under specific conditions listed in Chapter 2. Controlled

substance prescriptions dispensed to residents in long term care facilities cannot be returned to a pharmacy.

**Section 7.** Consultant Pharmacist Responsibilities.

(a) The consultant pharmacist shall assist the long-term care facility in developing policy and procedures for the following:

(i) The manner of issuance of prescription drugs provided by a provider pharmacy to residents of the long-term care facility;

(ii) Storage, administration and record-keeping for all medications administered to residents of the long-term care facility;

(iii) Inspection of drug storage areas;

(iv) Destruction or recycling of unused or discontinued resident medications;  
and

(v) Continuing education for nursing personnel regarding medication administration.

(b) Resident Drug Regimen Review.

(i) The primary duty of the consultant pharmacist is to apply his/her expertise on drugs to the resident's specific situation.

(ii) The consultant pharmacist shall review each resident's medical record at least monthly. State and federal regulations shall be the minimum standards for an adequate drug regimen review.

(iii) The consultant pharmacist shall communicate with provider pharmacies to enhance resident care.

**Section 8.** Automated Dispensing Device.

(a) No drug shall be distributed or issued by the use of any automated dispensing device unless the device and method of operation have been found to ensure the purity, potency and integrity of the drug, and to protect the drug from diversion, and provide that:

(i) The device shall be stocked with drugs only by a pharmacist licensed by the Board or a registered pharmacy technician or pharmacy intern under his supervision;

(ii) The device shall be used only for the furnishing of drugs for administration to residents of that facility; and

(iii) At the time of removal of any drug from the device, it shall automatically make a written or electronic record to be retained by the pharmacist for at least one (1) year, indicating:

- (A) The date of removal of the drug;
- (B) The name, strength, dosage form and quantity of the drug removed;
- (C) The name of the resident for whom the drug was ordered; and
- (D) The name or identification code of the nurse removing the drug from the device.

**Section 9.** First Dose Pharmacy Services.

Provider pharmacy may contract with another pharmacy (first dose pharmacy) for first dose services if in compliance as follows:

(a) Limited Purpose - Services are for the limited purpose of ensuring that drugs or devices are attainable to meet the needs of residents or if the provider pharmacy cannot provide services for the LTCF on an ongoing basis;

(b) Long Term Care Facility Approval - The provider pharmacy obtains approval from the LTCF to obtain first dose services for its residents;

(c) Written Contract - The provider pharmacy has a written contract with the first dose pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and

(d) Medication Orders - The provider pharmacy provides a valid verbal, electronic or paper medication order to the first dose pharmacy. A single medication order may be shared by a provider pharmacy and a first dose pharmacy with no transfer required.

## IMMUNIZATION REGULATIONS

### CHAPTER 16

#### **Section 1.** Authority.

These rules are promulgated as authorized by the Wyoming Pharmacy Act W.S. § 33-24-157.

#### **Section 2.** Purpose.

To describe procedures for pharmacists prescribing and administering immunizations.

#### **Section 3.** Scope.

Applies to pharmacists.

#### **Section 4.** Definitions.

(a) “Healthy Adults” means those individuals who are eighteen (18) years of age or older and have no absolute contraindications to receive immunizations allowed by this Chapter.

(b) “Minor” means those individuals who are seven (7) years of age or older but have not attained the age of eighteen (18) years old and have no absolute contraindications to receive immunizations allowed by this Chapter.

(c) “High Risk Adults” means for the purpose of this Chapter those adults eighteen (18) years of age or older who may have an absolute or relative contraindication to receive immunizations as allowed by this Chapter for whom a physician has issued a prescription authorizing a pharmacist to dispense and administer an immunization. Only those pharmacists that meet the qualifications of this Chapter may administer an immunization to a high risk adult.

(d) “Immunizations” means treatment by vaccination of an organism for the purpose of making it immune to a particular pathogen.

(e) “Private Space” means a physical area separated from the pharmacy that is no less than 48 square feet and has at least a six (6) feet tall partition to ensure patient safety and confidentiality. The partition cannot be a curtain.

(f) “Vaccine” means a preparation of killed microorganisms, toxoids, living attenuated organisms, or living fully virulent organisms, that is administered to produce or artificially increase immunity to a particular disease.

**Section 5. Adults.**

(a) Vaccines which a pharmacist may prescribe and administer to healthy adults or may be administered by a prescription of a physician for high risk adults shall be restricted to:

- (i) Human papillomavirus (HPV);
- (ii) Hepatitis A;
- (iii) Hepatitis B;
- (iv) Influenza;
- (v) Measles, mumps, rubella (MMR);
- (vi) Meningococcal;
- (vii) Pneumococcal;
- (viii) Tetanus, diphtheria, pertussis (Td, Tdap);
- (ix) Varicella; and
- (x) Zoster.

**Section 6. Minors.**

(a) Vaccines which a pharmacist may prescribe and administer to a minor shall be restricted to:

- (i) Influenza; and
- (ii) Human papillomavirus (HPV).

(b) Parental or legal guardian consent shall be required for all minors receiving a vaccination. The parent or legal guardian shall be present during the administration.

**Section 7. Qualifications.**

(a) A pharmacist licensed by the Board may prescribe and administer immunizations to healthy individuals, age 7 years of age and older, or administer immunizations to high risk adults authorized by a physician provided the pharmacist has:

- (i) Registered with the Board to prescribe and administer immunizations;
- (ii) Successfully completed the American Pharmacists Association's (APhA) immunization training certification program entitled "*Pharmacy-Based Immunization Delivery*"

or the Washington State Pharmacy Association's immunization training certification program entitled "*Vaccinating Adults and Adolescents: An Immunization Program Practicum Session*" or other equivalent training certification program approved by the Board;

(iii) Successfully completed training specific to administering vaccines to the pediatric population if they will be administering to minors;

(iv) Current certification in healthcare cardiopulmonary resuscitation (CPR) offered by the American Heart Association or the American Red Cross; and

(v) Completed a minimum of one (1) contact hour (0.1 CEU) of continuing education related to immunizations annually. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (ACPE).

(b) It is unprofessional conduct for a pharmacist to prescribe or administer an immunization, who is not in compliance with this Chapter.

(c) A pharmacy intern who is registered to administer immunizations must do so under the direct supervision of the pharmacist who is registered to administer immunizations.

#### **Section 8.** Registration.

(a) Prior to prescribing or administering immunizations a pharmacist shall submit an application supplied by the Board and a \$10.00 fee. Provided all requirements of this Chapter have been met, the board shall issue a registration. Registrations shall expire on December 31 of each year.

(b) Renewal applications will be mailed by the Board annually on or about November 1.

(c) A pharmacist may not prescribe or administer an immunization unless currently registered with the Board under this Chapter.

#### **Section 9.** Immunizations.

(a) Immunizations authorized by this Chapter shall be prescribed in accordance with the latest notice from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). Specifically, CDC's "*Recommended Adult Immunization Schedule, by Vaccine and Age Group*" and "*Recommended Adult Immunization Schedule by Vaccine and Medical and Other Indications,*" or "*Recommended Immunization Schedule for Persons Aged 0 Through 18 Years,*" including the footnotes provided for each schedule, shall be utilized by the pharmacist when considering the eligibility of a healthy individual to receive an immunization. The latest notice from CDC may be found at CDC's website (<http://www.cdc.gov>).

(b) In addition to the requirements of this Chapter, the pharmacist shall utilize the manufacturer's package insert for indications, contraindications, adverse reactions, dosing,

route of administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this Chapter.

(c) All immunizations shall be administered with the individual receiving the vaccine seated with back support.

(d) A current *Vaccine Information Statement*, as provided by CDC, shall be provided to each person receiving an immunization for each immunization administered. The *Vaccine Information Statement* is available from CDC's website (<http://www.cdc.gov>).

**Section 10.** Record-keeping.

(a) An Immunization Questionnaire and Consent Form shall be completed for each individual receiving an immunization. Two (2) copies shall be provided to the patient. Patients shall be instructed to send one copy to their medical provider. The consent form shall include:

(i) Documentation that the pharmacist has discussed the side effects with the patient; and

(ii) A recommendation that the patient stays in the vicinity for fifteen (15) minutes; and if the patient chooses not to stay, the pharmacist has discussed how to seek treatment for side effects should they occur.

(b) The Immunization Questionnaire and Consent Form shall be filed in a manner that will allow timely retrieval and shall be on file for a time period not less than six (6) years. All records shall be maintained in the pharmacy where the pharmacist who administered the immunization is employed.

**Section 11.** Emergencies.

(a) A pharmacist authorized to prescribe and administer immunizations under this Chapter may administer auto-inject epinephrine in the management of an acute allergic reaction to an immunization following guidelines issued by the American Pharmacists Association's (APhA) or Washington State Pharmacy Association's immunization training certification program.

(b) A pharmacist shall post a protocol as outlined in APhA's or Washington State Pharmacy Association's immunization training certification program and maintain an emergency kit which is readily retrievable to manage an acute allergic reaction to a vaccine administered.

**Section 12.** Immunizations Administered Off-Site.

(a) Vaccines may be administered by a pharmacist at a site away from the pharmacy if proper storage, transportation and disposal of vaccines and supplies are followed, in addition to all other requirements of this Chapter.

(b) The sponsoring organization shall keep the records of administration for a period of not less than six (6) years.

## STERILE COMPOUNDING

### CHAPTER 17

#### **Section 1.** Authority.

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

#### **Section 2.** Incorporation by Reference:

(a) For any code, standard, rule or regulation incorporated by reference in these rules:

(i) The Board has determined that incorporation of the full text in these rules would be cumbersome or inefficient given the length or nature of the rules;

(ii) The incorporation by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (b) of this section;

(iii) The incorporated code, standard, rule or regulation is maintained at 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming, 82002 and is available for public inspection and copying at cost at the same location;

(iv) The incorporated code, standard, rule or regulation is available on the internet at <http://pharmacyboard.state.wy.us/default.aspx>.

(b) Each standard incorporated by reference in these rules is further identified as follows:

(i) The United States Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding – Sterile Preparations incorporated by reference in this Chapter of these rules is the USP as existing on May 1, 2017 – July 31, 2017 including amendments adopted by USP as of that date. Copies of this standard can be obtained from the Board at 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming, 82002.

#### **Section 3.** Purpose.

To reference the minimum standards of practice for sterile compounding.

#### **Section 4.** Scope.

Applies to all licensees.

**RULES OF PRACTICE AND PROCEDURE  
OF THE  
WYOMING STATE BOARD OF PHARMACY**

**CHAPTER 1**

**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 describe procedures for applications and investigations.

**Section 3.** Scope.

Applies to all applicants and licensees.

**Section 4.** Definitions.

~~For the purposes of these regulations, and the Wyoming Pharmacy Act the following definitions shall prevail:~~

(a) ~~“Act” means the Wyoming Pharmacy Act, W.S. § 33-24-101, et. Seq., through -301 and the Wyoming Pharmacy Technician Act, WYO. STAT. ANN. § 33-24-301, et seq.~~

(b) ~~“Application Review Committee” (ARC) means the Executive Director, at least one Board member, and a Board Compliance Officer.~~

(c) “Board” means the Wyoming State Board of Pharmacy.

(d) ~~“Contestantee”~~ means the person, persons, firm or corporations who are license ~~ees by law~~ under the jurisdiction of ~~said the~~ Board against whom a proceeding by petition, verified complaint in writing or formal notice, alleging violation directly or indirectly of any of the terms and provisions of the Act or of the lawful Rules and Regulations of the Board or any related acts and resulting lawful rules and regulations (i.e. Controlled Substances Act, 1971).

(e) “Contested Case” means any proceeding ~~including, but not restricted to, any licensing requirements in which~~ where legal rights, duties or privileges of a party are required by law to be determined by the Board ~~after an opportunity for hearing.~~

~~(f) “Dangerous Substance” means pursuant to § 33-24-127, the Board adopts the most recent edition and its supplements of section 3.1 “Prescription Drug Product List” of the~~

~~FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, (The Orange Book) as the official listing of Dangerous Substances for the State of Wyoming.~~

(g) "Executive Director" means the Executive Director of the Board.

(h) "License" means the whole or part of any Board permit, certificate, approval, registration ~~charter~~ or similar form of permission required by law, ~~but it~~ License does not include a license required solely for revenue purposes.

(i) "Prosecuting Attorney" means the Assistant Attorney General assigned to the Board to represent the Executive Director in contested cases.

~~(j) "Licensing" means the Board process respecting the grant, denial, renewal, revocation, suspension, annulment, withdrawal or amendment of a license.~~

~~(k) "Rule" or "Regulation" means any Board statement of general applicability that implements, interprets and prescribes law or policy.~~

(l) "Staff" means the personnel of the Board ~~or Executive Director~~.

~~(m) "State" means the State of Wyoming.~~

#### **Section 5. Application Review Process.**

(a) Upon receipt of a completed application, the ~~Board Office~~ Staff shall review the application and if it is complete and, if there are no ~~known~~ grounds for denial ~~of the license requested~~, issue the license. If ~~there are known~~ grounds for denial exist, the ~~Board Office~~ Staff shall forward the application for review by ~~to~~ the ~~Application Review Committee (ARC)~~ Prosecuting Attorney.

(b) The ~~ARC~~ Prosecuting Attorney shall review the application and all other information available and following the review ~~may~~ shall:

(i) ~~Approve~~ Recommend approval of the application ~~if the applicant meets all requirements~~; or

(ii) ~~If there are questions as to whether denial is appropriate, forward~~ Recommend the application and an ~~be forwarded to the~~ ARC ~~report to the Assistant Attorney General assigned to the Board for prosecution to for~~ review.

(c) If, after review, the ARC ~~and Assistant Attorney General~~ recommends s denial of an application:

(i) A preliminary denial letter shall be sent to the applicant. The letter shall:

and (A) State the basis for the denial including relevant statutes and rules;

(B) Advise the applicant of the right to request reconsideration.

(ii) If the applicant fails to request reconsideration in writing within thirty (30) days ~~of the date~~ of the preliminary denial letter, the preliminary denial becomes final.

(iii) If the applicant requests reconsideration within thirty (30) days, an informal reconsideration conference shall be held withbetween the ARC, the ~~Assistant Attorney General~~Prosecuting Attorney, and the applicant.

(iv) Following athe informal reconsideration conference, the ARC shall either approve or deny the application.

(v) If denied, the applicant must submit a ~~written~~ request in writing for a hearing within thirty (30) days of the date of the denial letter.

(vi) If the applicant fails to request a hearing in writing within thirty (30) days of the date of the denial letter, the denial becomes final.

(d) Application denial hearings.

(i) An application denial hearing is a formal contested case hearing conducted before the Office of Administrative Hearings (OAH) pursuant to the Wyoming Administrative Procedure Act W.S. § 16-3-107 through -113 and Office of Administration Rules.

(ii) The applicant has the burden of proving that he/she meets all requirements for the license requested.

(e) The ARC may attend hearings, but shall not take part in the consideration of any contested case.

#### **Section 6. Complaints.**

(a) ~~A disciplinary action is initiated against a license holder by submitting a written complaint to the Board office.~~ A complaint concerning an alleged violation of the Act must be submitted in writing to the Board.~~or Board Rules may be submitted by any person or entity, a Board member, or a Board staff member.~~ The written complaint shouldshall provide as much of the following information ~~as may be available and applicable~~:

(i) The name and address of the complainant;

(ii) The name, address, place of employment, and telephone number of the license holder against whom the charges are made, if available and applicable;

- (iii) The specific conduct alleged to constitute the violation;
- (iv) The name and address of any ~~other~~ witnesses; and
- (v) The notarized signature of the complainant.

**Section 7. — Review of Written Complaint.**

(b) Written complaints shall be referred for investigation to the Board ~~staff~~ Compliance Officer/~~Investigator~~ or to an Investigative Board Member (IBM) selected by ~~Board~~ Staff from a rotating schedule.

- (i) The IBM shall not take part in the consideration of any contested case.
- (ii) The IBM shall not, by this rule, be barred from attending any disciplinary hearing.

(c) License holders against whom charges are made ~~will~~ shall be advised of the investigation and the nature of the complaint.

**Section 7. Investigations and Board Action.**

~~Board staff shall investigate those written complaints received which merit further investigation.~~

(a) Upon completion of the investigation, the ~~Executive Director~~ Board Compliance Officer shall prepare an investigative report which includes:

~~(i) — Dismiss the complaint if no evidence of violation of the Act or Board rules is found; or~~

(i) ~~Prepare an investigative report which shall include~~ The findings of the investigation;

~~(A) — The findings;~~

(ii) A list of statutes and/or Board rules ~~believed to have been~~ violated; and

(iii) Any relevant additional information.

(b) The Executive Director shall forward the report and ~~his/her~~ recommendations to the ~~Assistant Attorney General assigned to the Board for prosecution~~ Prosecuting Attorney for review, and consult with the Assistant Attorney General.

(c) Following consultation with the ~~Assistant Attorney General~~ Prosecuting Attorney, the Executive Director ~~shall~~ may:

- (i) Send the notice required by Section 65;
- (ii) Prepare and file a formal petition and notice of hearing setting the matter for a contested case hearing before the Board;
- (iii) Recommend the Board accept an offer of conditional terms for settlement, ~~which may include educational courses; or~~
- (iv) Recommend the Board dismiss the complaint.

(d) The Board may resolve a complaint at any time prior to a contested case hearing by:

- (i) Accepting ~~a~~ voluntary surrender of a license;
- (ii) Accepting conditional terms for settlement; or
- (iii) Dismissing~~a~~ the complaint.

**Section 8.** Service of Notice and Opportunity to Show Compliance.

Prior to commencement of a formal hearing, the Executive Director shall give notice to the licensee by certified mail to the license holder of the facts or conduct which warrant his/her intended intent to proceed with disciplinary action. The notice shall give the license holder an opportunity to show compliance with all lawful requirements for retention contest the violations referred to in the Notice or to accept the proposed settlement agreement of the license within twenty (20) days of the mailing receipt of the notice. Such notice shall be sent to the license holder's last known address by certified mail.

**Section 9.** ~~Formal Hearing Prerequisites Contested Case Hearing.~~ Incorporation by reference.

(a) For any code, standard, rule or regulation incorporated by reference in this Chapter:

- (i) The Board has determined that incorporation of the full text in these rules would be cumbersome or inefficient given the length or nature of the rules;
- (ii) The incorporation by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (b) of this section; and
- (iii) The incorporated code, standard, rule or regulation is maintained at Board's office and is available for public inspection and copying at cost at the same location.

(b) Each code, standard, rule or regulation incorporated by reference in this Chapter is further identified as follows:

(i) Chapter 2 – Uniform Rules for Contested Case Practice and Procedure, adopted by the Office of Administrative Hearings and effective on October 17, 2014, found at: <http://soswy.state.wy.us/Rules/RULES/9644.pdf>.

(ii) Chapter 2 – Uniform Procedures, Fees, Costs and Charges for Inspecting, Copying and Producing Public Records adopted by the Department of Administration and Information and effective on September 6, 2016, found at <http://pharmacyboard.state.wy.us>.

~~(c) — Formal proceedings for a hearing before the Board regarding action against a license holder shall be commenced by petition and notice of hearing, served in person, or by certified mail sent to the address last known by the Board at least thirty (30) days prior to the date set for the hearing. The petition and notice shall contain at least:~~

~~(i) — The name and address of the license holder;~~

~~(ii) — A statement, in ordinary and concise language of the nature of the complaint filed with the Board, the facts upon which the complaint is based, as well as the specific statute(s) or Board rules and regulations alleged to have been violated;~~

~~(iii) — The time, place, and nature of the hearing;~~

~~(iv) — That the hearing is being held pursuant to the authority provided by Wyo. STAT. ANN. § 33-24-101 through 33-24-301.~~

~~(v) — The license holder shall file an Answer or Notice of Appearance, which must be received by the Board at least ten (10) working days prior to the date set for hearing, or the license holder will be in default.~~

**Section 10. Procedures, Fees, Costs and Charges for Inspecting, Copying and Producing Public Records:**

~~(a) — Adoption of Uniform Rules. The Board hereby incorporates by reference the following uniform rules:~~

~~(i) — Chapter 2 – Uniform Procedures, Fees, Costs and Charges for Inspecting, Copying and Producing Public Records adopted by the Department of Administration and Information and effective on September 6, 2016, found at: <http://pharmacyboard.state.wy.us>.~~

~~(ii) — For these rules incorporated by reference:~~

~~(A) — The Board has determined that incorporation of the full text in these rules would be cumbersome or inefficient given the length or nature of the rules;~~

~~(B) — The incorporation by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (b)(i) of this section; and~~

~~(C) — The incorporated rules are maintained at the Board's office and are available for public inspection and copying at the same location.~~

**Section 11. Default.**

~~The Board may enter an order based on the allegations in a petition in any case where the applicant or license holder has not answered or appeared in writing ten (10) working days before the hearing, or in any case in which the applicant or license holder or his/her representative has not appeared at a scheduled hearing for which they had notice.~~

**Section 12. Contested Case Hearing.**

~~(a) — The Office of Administrative Hearings shall act as the hearing officer and shall preside over the formal contested case hearing which shall be conducted pursuant to the Wyoming Administrative Procedure Act and the Office of Administrative Hearings' rules concerning contested case proceedings.~~

~~(b) — At the Board's discretion, contested case hearings shall either be conducted in the presence of a quorum of Board Members or a committee of one (1) or more Board Members.~~

~~(c) — During the formal contested case hearing, Board Members may ask questions of the witnesses and/or the parties including their attorneys.~~

~~(d) — A court reporter shall be present during the hearing and report the entire proceeding.~~

**Section 13. Decisions.**

~~(a) — Proposed Decisions:~~

~~(i) — At the discretion and direction of the hearing officer, the parties may file proposed findings of fact, conclusions of law, and order after the hearing and before the deadline announced in the hearing's closing announcements.~~

~~(ii) — At the discretion and direction of the Board, the hearing officer or the Assistant Attorney General assigned to advise the Board shall prepare proposed findings of fact, conclusions of law, and order following deliberations by the Board or its committee.~~

~~(b) — Final Decisions. Proposed decisions will be given consideration but are not binding upon the Board. All final decisions will be issued by the Board and shall be based exclusively upon the evidence in the record and matters officially noticed. All final decisions~~

~~issued by the Board shall be served to all parties by first class mail sent to their last known address.~~

**Section 14. Appeals.**

~~A Petition for Judicial Review of the Board decision may be filed in the district court in accordance with the Wyoming Rules of Appellate Procedure.~~

**Section 15. Transcripts.**

~~If a Petition for Judicial Review is filed in the district court, the petitioner shall either arrange the preparation and pay for the transcript of the testimony, or reimburse the Board for the cost of the transcript if previously prepared at Board expense.~~

**LONG TERM CARE PHARMACY SERVICES**  
**CHAPTER 15**

**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 regulate pharmacies who provide services to residents of long term care facilities.

**Section 3.** Scope.

Applies to any pharmacy or pharmacist providing services to a long term care facility.

**Section 4.** Definitions.

(a) “Long Term Care Facility” (LTCF) means any skilled or intermediate care nursing home, board and care home, or any ~~patient~~ resident behavioral health facility subject to regulation and licensure by the department of health. For the purpose of this Chapter, long term care facility does not include adult day care facilities, home health agencies, or assisted living facilities.

(b) “Consultant Pharmacist” in a long-term facility means a pharmacist licensed to engage in the practice of pharmacy in this State who is responsible for developing, coordinating, and supervising ~~pharmaceutical~~ pharmacy services in a long-term care facility on a regularly scheduled basis.

(c) “Medication Order,” as used in ~~these rules~~ this rule means a written, ~~oral~~ verbal, facsimile or electronic order from a practitioner or the practitioner’s authorized agent to a licensed nurse in the LTCF for a resident of that facility for administration of a drug or device. For purposes of this Chapter, a “medication order” is considered a prescription, with the exception of controlled substances which require a prescription from the practitioner.

(d) “Provider Pharmacy” means any pharmacy licensed by the Board that provides medications to residents of any long-term care facility pursuant to a medication order or prescription. A provider pharmacy must have a written agreement with the long-term care facility in order to provide services to the residents.

(e) “First Dose Pharmacy” means a pharmacy contracting with a provider pharmacy to ensure that drugs or devices are attainable to meet the immediate needs of the resident or if the provider pharmacy cannot provide services on an ongoing basis.

**Section 5.** Freedom of Choice.

No consultant pharmacist or provider pharmacy shall participate in any agreement or plan that infringes on any resident's right to freedom of choice as to the provider of pharmacy services. A resident in a long-term care facility shall have a choice of a provider pharmacy provided the provider pharmacy complies with this Chapter.

**Section 6.** Pharmacy Responsibilities.

A provider pharmacy shall be responsible for:

(a) Dispensing drugs pursuant to a medication order for an individual resident, properly labeled for that resident, as addressed in Chapter 2 of these rules, including the manufacturer's expiration date. If prepackaged or repackaged by the pharmacy, the expiration date shall be the lesser of the manufacturer's expiration date or twelve (12) months from the date of prepackaging or repackaging;

(b) Dispensing drugs for residents of long-term care facilities in packaging consistent with the drug distribution system required by the facility's policies and procedures;

(c) Developing a drug recall procedure that protects the health and safety of residents including immediate discontinuation of any recalled drug or device and subsequent notification of the prescriber and director of nursing of the facility. The drug recall policy must be readily retrievable at the provider pharmacy and the facility;

(d) Providing service twenty-four (24) hours a day, seven (7) days a per week, either directly or by contract with another pharmacy. All "on-call" services shall be verifiable by the board and its inspectors. Emergency Ancillary boxes or automated dispensing devices may be used as outlined in Chapter 2 of these rules;

(e) Performing prospective drug usage reviews for all new and refill medication orders as described in Chapter 9 of these rules;

(f) Providing sufficient and accurate information to facility staff regarding the appropriate administration and use of all dispensed drugs and devices;

(g) Providing intravenous (IV) services or contracting with another pharmacy to provide IV services, if the long term care facility is a skilled unit providing such services;

(h) Communicating with the consultant pharmacist and the facility regarding concerns and resolution thereof, including, but not limited to "on-call" services and IV services; and

(i) Returning non-controlled substance prescriptions dispensed to patients residents in long term care facilities for re-dispensing under specific conditions listed in Chapter 2. Controlled substance prescriptions dispensed to patients residents in long term care facilities cannot be returned to a pharmacy.

**Section 7.** Consultant Pharmacist Responsibilities.

(a) The consultant pharmacist shall assist the long-term care facility in developing policy and procedures for the following:

(i) The manner of issuance of prescription drugs provided by a provider pharmacy to residents of the long-term care facility;

(ii) Storage, administration and record-keeping for all medications administered to residents of the long-term care facility;

(iii) Inspection of drug storage areas;

(iv) Destruction or recycling of unused or discontinued ~~patient~~ resident medications; and

(v) Continuing education for nursing personnel regarding medication administration.

(b) ~~Patient~~ Resident Drug Regimen Review.

(i) The primary duty of the consultant pharmacist is to apply his/her expertise on drugs to the ~~patient's~~ resident's specific situation.

(ii) The consultant pharmacist shall review each ~~patient's~~ resident's medical record at least monthly. State and federal regulations shall be the minimum standards for an adequate drug regimen review.

(iii) The consultant pharmacist shall communicate with provider pharmacies to enhance ~~patient~~ resident care.

**Section 8.** Automated Dispensing Device.

(a) No drug shall be distributed or issued by the use of any automated dispensing device unless the device and method of operation have been found to ensure the purity, potency and integrity of the drug, and to protect the drug from diversion, and provide that:

(i) The device shall be stocked with drugs only by a pharmacist licensed by the Board or a registered pharmacy technician or pharmacy intern ~~or~~ under ~~the~~ his supervision; ~~of a pharmacist.~~

(ii) The device shall be used only for the furnishing of drugs for administration to ~~patients~~ residents of that facility; and

(iii) At the time of removal of any drug from the device, it shall automatically make a written or electronic record to be retained by the pharmacist for at least one (1) year, indicating:

- (A) The date of removal of the drug;
- (B) The name, strength, dosage form and quantity of the drug removed;
- (C) The name of the ~~patient~~ resident for whom the drug was ordered; and
- (D) The name or identification code of the nurse removing the drug from the device.

**Section 9. First Dose Pharmacy Services.**

Provider pharmacy may contract with another pharmacy (first dose pharmacy) for first dose services if in compliance as follows:

(a) Limited Purpose - Services are for the limited purpose of ensuring that drugs or devices are attainable to meet the needs of residents or if the provider pharmacy cannot provide services for the LTCF on an ongoing basis;

(b) Long Term Care Facility Approval - The provider pharmacy obtains approval from the LTCF to obtain first dose services for its residents;

(c) Written Contract - The provider pharmacy has a written contract with the first dose pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and

(d) Medication Orders - The provider pharmacy provides a valid verbal, electronic or paper medication order to the first dose pharmacy. A single medication order may be shared by a provider pharmacy and a first dose pharmacy with no transfer required.

**IMMUNIZATION REGULATIONS  
CHAPTER 16**

**Section 1.** Authority.

These rules are promulgated as authorized by the Wyoming Pharmacy Act W.S. § 33-24-157.

**Section 2.** Purpose.

To describe procedures for pharmacists prescribing and administering immunizations.

**Section 3.** Scope.

Applies to pharmacists.

**Section 4.** Definitions.

(a) "Healthy Adults" means those individuals who are eighteen (18) years of age or older and have no absolute contraindications to receive immunizations allowed ~~in~~ by this Chapter.

(b) "Minor" means those individuals who are seven (7) years of age or older but have not attained the age of eighteen (18) years old and have no absolute contraindications to receive immunizations allowed ~~in~~ by this Chapter.

(c) "High Risk Adults" means for the purpose of this Chapter those adults eighteen (18) years of age or older who may have an absolute or relative contraindication to receive immunizations as allowed by this Chapter for whom a physician has issued a prescription authorizing a pharmacist to dispense and administer an immunization. Only those pharmacists that meet the qualifications of this Chapter may administer an immunization to a high risk adult.

(d) "Immunizations" means treatment by vaccination of an organism for the purpose of making it immune to a particular pathogen.

(e) "Private Space" means a physical area separated from the pharmacy that is no less than 48 square feet and has at least a six (6) feet tall partition to ensure patient safety and confidentiality. The partition cannot be a curtain. ~~The requirement for private space will be in effect on July 20, 2014.~~

(f) "Vaccine" means a preparation of killed microorganisms, toxoids, living attenuated organisms, or living fully virulent organisms, that is administered to produce or artificially increase immunity to a particular disease.

**Section 5.** Adults. ~~(age 18 and older).~~

(a) Vaccines which a pharmacist may prescribe and administer to healthy adults or may be administered by a prescription of a physician for high risk adults shall be restricted to:

- (i) Human papillomavirus (HPV);
- (ii) Hepatitis A;
- (iii) Hepatitis B;
- (iv) Influenza;
- (v) Measles, mumps, rubella (MMR);
- (vi) Meningococcal;
- (vii) Pneumococcal ~~(Polysaccharide)~~;
- (viii) Tetanus, diphtheria, pertussis (Td, Tdap);
- (ix) Varicella; and
- (x) Zoster.

**Section 6.** Minors ~~(age 7 through 17).~~

(a) Vaccines which a pharmacist may prescribe and administer to a minor shall be restricted to:

- (i) Influenza; and
- (ii) Human papillomavirus (HPV).

(b) Parental or legal guardian consent shall be required for all minors receiving a vaccination. The parent or legal guardian shall be present during the administration.

**Section 7.** Qualifications.

(a) A pharmacist licensed by the Board may prescribe and administer immunizations to healthy individuals, age 7 years of age and older, or administer immunizations to high risk adults authorized by a physician provided the pharmacist has:

- (i) Registered with the Board to prescribe and administer immunizations;
- (ii) Successfully completed the American Pharmacists Association's (APhA) immunization training certification program entitled "*Pharmacy-Based Immunization Delivery*"

or the Washington State Pharmacy Association's immunization training certification program entitled "*Vaccinating Adults and Adolescents: An Immunization Program Practicum Session*" or other equivalent training certification program approved by the Board;

(iii) Successfully completed training specific to administering vaccines to the pediatric population if they will be administering to minors;

(iv) Current certification in healthcare cardiopulmonary resuscitation (CPR) offered by the American Heart Association or the American Red Cross; and

(v) Completed a minimum of one (1) contact hour (0.1 CEU) of continuing education related to immunizations annually. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (ACPE).

(b) It is unprofessional conduct for a pharmacist to prescribe or administer an immunization, who is not in compliance with this Chapter.

(c) A pharmacy intern who is registered to administer immunizations must do so under the direct supervision of the pharmacist who is registered to administer immunizations.

#### **Section 8.** Registration.

(a) Prior to prescribing or administering immunizations a pharmacist shall submit an application supplied by the Board and a \$10.00 fee. Provided all requirements of this Chapter have been met, the board shall issue a registration. Registrations shall expire on December 31 of each year.

(b) Renewal applications will be mailed by the Board annually on or about November 1.

(c) A pharmacist may not prescribe or administer an immunization unless currently registered with the Board under this Chapter.

#### **Section 9.** Immunizations.

(a) Immunizations authorized by this Chapter shall be prescribed in accordance with the latest notice from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). Specifically, CDC's "*Recommended Adult Immunization Schedule, by Vaccine and Age Group*" and "*Recommended Adult Immunization Schedule by Vaccine and Medical and Other Indications,*" or "*Recommended Immunization Schedule for Persons Aged 0 Through 18 Years,*" including the footnotes provided for each schedule, shall be utilized by the pharmacist when considering the eligibility of a healthy individual to receive an immunization. The latest notice from CDC may be found at CDC's website (<http://www.cdc.gov>).

(b) In addition to the requirements of this Chapter, the pharmacist shall utilize the manufacturer's package insert for indications, contraindications, adverse reactions, dosing,

route of administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this Chapter.

(c) All immunizations shall be administered with the individual receiving the vaccine seated with back support.

(d) ~~Vaccine Information Statement~~— A current *Vaccine Information Statement*, as provided by CDC, shall be provided to each person receiving an immunization for each immunization administered. The *Vaccine Information Statement* is available from CDC's website (<http://www.cdc.gov>).

**Section 10.** Record-keeping.

(a) An Immunization Questionnaire and Consent Form shall be completed for each individual receiving an immunization. Two (2) copies shall be provided to the patient. Patients shall be instructed to send one copy to their medical provider. The consent form shall include:

(i) Documentation that the pharmacist has discussed the side effects with the patient; and

(ii) A recommendation that the patient stays in the vicinity for fifteen (15) minutes; and if the patient chooses not to stay, the pharmacist has discussed how to seek treatment for side effects should they occur.

(b) The Immunization Questionnaire and Consent Form shall be filed in a manner that will allow timely retrieval and shall be on file for a time period not less than six (6) years. All records shall be maintained in the pharmacy where the pharmacist who administered the immunization is employed.

**Section 11.** Emergencies.

(a) A pharmacist authorized to prescribe and administer immunizations under this Chapter may administer auto-inject epinephrine in the management of an acute allergic reaction to an immunization following guidelines issued by the American Pharmacists Association's (APhA) or Washington State Pharmacy Association's immunization training certification program.

(b) A pharmacist shall post a protocol as outlined in APhA's or Washington State Pharmacy Association's immunization training certification program and maintain an emergency kit which is readily retrievable to manage an acute allergic reaction to a vaccine administered.

**Section 12.** Immunizations Administered Off-Site.

(a) Vaccines may be administered by a pharmacist at a site away from the pharmacy if proper storage, transportation and disposal of vaccines and supplies are followed, in addition to all other requirements of this Chapter.

(b) The sponsoring organization shall keep the records of administration for a period of not less than six (6) years.

STERILE COMPOUNDING  
CHAPTER 17

**Section 1.** Authority.

(a) These rules are promulgated as authorized by the Wyoming Pharmacy Act W.S. § 33-24-101 through -301. ~~and pursuant to the Wyoming Administrative Procedure Act, W.S. § 16-3-101, et seq. The effective date of this Chapter is January 1, 2012.~~

**Section 2.** Incorporation by Reference:

(a) For any code, standard, rule or regulation incorporated by reference in these rules:

(i) The Board has determined that incorporation of the full text in these rules would be cumbersome or inefficient given the length or nature of the rules;

(ii) The incorporation by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (b) of this section;

(iii) The incorporated code, standard, rule or regulation is maintained at 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming, 82002 and is available for public inspection and copying at cost at the same location;

(iv) The incorporated code, standard, rule or regulation is available on the internet at <http://pharmacyboard.state.wy.us/default.aspx>.

(b) Each standard incorporated by reference in these rules is further identified as follows:

(i) The United States Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding – Sterile Preparations incorporated by reference in this Chapter of these rules is the USP as existing on May 1, 2017 – July 31, 2017 including amendments adopted by USP as of that date. Copies of this standard can be obtained from the Board at 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming, 82002.

**Section 3.** Purpose.

To reference the minimum standards of practice for sterile compounding.

**Section 4.** Scope.

Applies to all licensees.

~~Section 5. Definitions.~~

~~(a) "Ante-Area" means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, compounded sterile preparation labeling, and other high particulate generating activities are performed. It is also a transition area where pressure relationships are constantly maintained so that air flows from clean to dirty areas.~~

~~(b) "Aseptic Processing" means processing of pharmaceutical products that involves the separate sterilization of the product and of the package, 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 a date after which a compounded sterile preparation shall not be used, stored, or transported. BUD is determined from the date or time the preparation is compounded.~~

~~(d) "Biological Safety Cabinet" means a ventilated cabinet for compounded sterile preparations, personnel, product, and environmental protection having:~~

~~(i) an open front with inward airflow for personnel protection;~~

~~(ii) downward High-Efficiency Particulate Air (HEPA) filtered laminar airflow for product protection; and~~

~~(iii) HEPA-filtered exhausted air for environmental protection.~~

~~(e) "Buffer Area" means a Clean Room or area in which the Primary Engineering Control is physically located. In this area, activities include the preparation and staging of components and supplies used to compound sterile products.~~

~~(f) "Clean Room" means a room with a minimum of an ISO Class 7 environment (ISO Class 8 environment for compounding radiopharmaceuticals):~~

~~(i) in which the concentration of airborne particles is controlled;~~

~~(ii) that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room;~~

~~(iii) in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary; and~~

~~(iv) in which microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear is not exceeded for a specified cleanliness class.~~

~~(g) "Closed System Transfer Device (CSTD)" is a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of Hazardous Drug or vapor concentrations outside the system.~~

~~(h) —“Compounding Aseptic Containment Isolator” (CACI) means a closed system designed to provide personnel protection from exposure to undesirable levels of airborne drug throughout the compounding and transfer processes, and designed to provide an aseptic environment for compounding sterile preparations. Air is first passed through a microbial retentive filter (HEPA minimum) system. If volatile Hazardous Drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.~~

~~(i) —“Compounding Aseptic Isolator” (CAI) means a closed system specifically designed to maintain an aseptic compounding environment within the isolator. Air is first passed through a microbially retentive filter (HEPA minimum). Transfers are designed to minimize the entry of contamination and are accomplished through air locks, glove rings, or ports.~~

~~(j) —“Critical Area” means any area in the Buffer Area where products or containers are exposed to the environment. It should be an ISO Class 5 environment.~~

~~(k) —“CSP” means compounded sterile product.~~

~~(l) —“Critical Site” means a location that includes any component or fluid pathway surfaces (such as injection ports) or openings (such as opened ampules or needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination.~~

~~(m) —“Cytotoxic Drug” means a pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system, and the alteration of a host’s inflammatory response system.~~

~~(n) —“Disinfectant” means an agent applied to inanimate objects that frees from infection and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores.~~

~~(o) —“FDA” means the United States Food and Drug Administration, Department of Health and Human Services.~~

~~(p) —“Hazardous Drugs” means studies in animals or humans indicate that exposures to them have a potential for causing cancer, developmental or reproductive toxicity, or harm to organs.~~

~~(q) —“HEPA Filter” means a filter where air is forced through in a uniform flow and 99.97% of all particles three-tenths (0.3) microns or larger are removed.~~

~~(r) —“Immediate-Use” compounded sterile preparations means those products used in situations where there is a need for emergency or immediate patient administration. — Examples are cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where delays caused by using conditions described for Low-Risk Level subjects the patient to additional risk. Batch compounding or storage is not appropriate for Immediate-Use compounded sterile preparations.~~

~~(i) —The compounding process involves simple transfer of not more than three (3) commercially manufactured packages of sterile nonhazardous products from the manufacturers’ original containers and not more than two (2) entries into any one container.~~

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

~~(iii) —During preparation, aseptic technique is followed. — If not immediately administered, the finished compounded sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter, or biological fluids, mix-ups with other products, and direct contact of outside surfaces.~~

~~(iv) —Administration begins not later than one (1) hour following the START of the preparation of the compounded sterile preparation.~~

~~(v) —Unless immediately and completely administered by the person who prepared it, or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one (1) hour BUD and time.~~

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

~~(s) —(s) —“ISO (International Organization for Standardization) Classification of Particulate Matter in Room Air” means limits in particles of 0.5 micrometer and larger per cubic meter. — Class Name and Particle Count:~~

<del>(I)</del>	<del>ISO Class 3</del>	<del>35.2 m<sup>3</sup></del>
<del>(II)</del>	<del>ISO Class 4</del>	<del>352 m<sup>3</sup></del>
<del>(III)</del>	<del>ISO Class 5</del>	<del>3,520 m<sup>3</sup></del>
<del>(IV)</del>	<del>ISO Class 6</del>	<del>35,200 m<sup>3</sup></del>
<del>(V)</del>	<del>ISO Class 7</del>	<del>352,000 m<sup>3</sup></del>
<del>(VI)</del>	<del>ISO Class 8</del>	<del>3,520,000 m<sup>3</sup></del>

~~(t) “Media-Fill Test” means using a microbiological growth medium to substitute for the actual drug product to simulate admixture compounding in determining the quality of a person’s technique.~~

~~(u) “Multiple Dose Container” means more than one (1) dose is in the vial and it usually contains antimicrobial preservatives. The BUD for an opened or entered Multiple Dose Container with antimicrobial preservatives is twenty-eight (28) days, unless otherwise specified by the manufacturer.~~

~~(v) “Negative Pressure Room” means a room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is *into* the room.~~

~~(w) “Parenteral” means a sterile preparation of drugs for injection through one (1) or more layers of skin.~~

~~(x) “Positive Pressure Room” means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out of* the room.~~

~~(y) “Primary Engineering Control” (PEC) means a device or room that provides an ISO Class 5 environment for the exposure of Critical Sites when compounding sterile products. Such devices include, but may not be limited to, Laminar Airflow Workbenches (LAFWs), Biological Safety Cabinets (BSCs), Compounding Aseptic Isolators (CAIs), and Compounding Aseptic Containment Isolators (CACIs).~~

~~(z) “Quality Assurance” means, for purposes of these regulations, the set of activities used to ensure that the processes used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.~~

~~(aa) “Quality Control” means, for the purposes of these regulations, the set of testing activities used to determine that the ingredients, components, and final sterile products meet predetermined requirements with respect to identity, purity, nonpyrogenicity, and sterility.~~

~~(bb) “Risk Levels” means, for the purposes of these regulations, the categories assigned according to the potential for microbial contaminations of compounded sterile preparations:~~

~~(i) Low-Risk Level means compounded sterile preparations under the following conditions:~~

~~(A) Compounded with aseptic manipulations entirely with ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices;~~

~~(B) The compounding involves only transfer, measuring, and mixing using not more than three (3) commercially manufactured packages of sterile~~

~~products and not more than two (2) entries into any one sterile container (not applicable to compounding Low-Risk Level CSP radiopharmaceuticals);~~

~~(C) Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers with sterile needles and syringes, and transferring sterile liquids into sterile administration devices or containers for storage;~~

~~(D) In the absence of passing a sterility test, the storage periods cannot exceed forty-eight (48) hours at controlled room temperature, for not more than fourteen (14) days at a refrigerated temperature, and for forty-five (45) days in solid frozen state, minus twenty-five degrees Centigrade (-25°C) or colder; minus ten degrees Fahrenheit (-10°F) or colder.~~

~~(E) Examples of Low-Risk Level compounding include single-volume transfers of sterile dosage forms from ampules, bottles, bags, and vials with sterile needles OR simple aseptic measuring and transferring with not more than three (3) packages of manufactured sterile products including an infusion or diluents solution. The solution content of ampules should be passed through a sterile filter to remove any particles.~~

~~(ii) Low-Risk Level with twelve (12) hour or less BUD means:~~

~~(A) PEC shall be certified and maintain ISO Class 5 for exposure of Critical Sites and shall be in a Segregated Compounding Area restricted to sterile compounding activities that minimize the risk of contamination;~~

~~(B) The location shall not have unsealed windows or doors that connect to the outdoors or in a location with high traffic flow, nor be adjacent to construction site, warehouse, or food preparation areas;~~

~~(C) Personnel shall follow the procedures in Sections 3 and 7 for personnel cleansing and garbing and additional requirements prior to compounding. Sinks shall not be located adjacent to the ISO Class 5;~~

~~(D) Specifications in Sections 3, 4, and 7 through 9 for cleaning and disinfecting, personnel training and competency evaluation, and environmental sampling shall be followed;~~

~~(E) Quality Assurance includes routine disinfection, air quality testing, visual confirmation that compounding personnel are properly gowned and garbed, review of all orders and packages of ingredients, and visual inspection of the compounded sterile preparation to ensure the absence of particulate matter or leakage, and thoroughness of labeling. Visual inspection of Low-Risk Level CSP radiopharmaceuticals will be limited, in accordance with radiation safety practices;~~

~~(F) Media-Fill Test procedure is performed annually by each person authorized to compound.~~

~~(iii) — Medium Risk Level means compounded sterile preparations are prepared aseptically under Low Risk Level conditions and one or more the following conditions exists:~~

~~(A) — Multiple small doses of sterile products are combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions;~~

~~(B) — The compounding process includes complex aseptic manipulations other than the single volume transfer;~~

~~(C) — The compounding process requires unusually long duration such as that required to complete dissolution;~~

~~(D) — In the absence of passing a sterility test, the storage periods cannot exceed thirty (30) hours at controlled room temperature, for not more than nine (9) days at refrigerated temperature, and for forty five (45) days in solid frozen state, minus twenty five degrees Centigrade (-25°C) or colder; minus ten degrees Fahrenheit (-10°F) or colder.~~

~~(E) — Examples of Medium Risk Level compounded sterile preparations include total parenteral nutrient fluids using manual or automated devices, filling of reservoirs of injection and infusion devices with more than three sterile drug products, transfer of volumes from multiple ampules or vials into one or more final sterile containers.~~

~~(F) — Quality Assurance procedures include all elements of Low Risk Level compounded sterile preparations as well as a more challenging Media-Fill Test passed annually or more frequently.~~

~~(G) — Media-Fill Tests are performed at least annually under stressful conditions encountered during compounding Medium Risk Level CSPs.~~

~~(H) — If the pharmacy performs sterility testing, the pharmacy will document results of tests, as described in their policies and procedures. If sterility is documented, the compounded product may be retained and used up to the limits established by authoritative sources for potency and stability.~~

~~(iv) — “High Risk Level” compounded sterile preparations means the end product is either contaminated or at a high risk to become contaminated, for example:~~

~~(A) — Nonsterile ingredients are incorporated or a nonsterile device is employed before terminal sterilization;~~

~~(B) — Exposure to air quality worse than ISO Class 5 for more than one (1) hour by the sterile contents, a lack of effective antimicrobial preservatives, or sterile surfaces of devices and containers;~~

~~(C) — Personnel are improperly garbed and gloved;~~

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

~~(E) It is assumed, not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendia specifications in unopened or in opened packages of bulk ingredients.~~

~~(F) The storage periods cannot exceed twenty-four (24) hours at controlled room temperature; cannot exceed three (3) days at refrigerated temperature; and cannot exceed forty-five (45) days in solid frozen state, minus twenty-five degrees Centigrade (-25°C) or colder; minus ten degrees Fahrenheit (-10°F) or colder.~~

~~(G) All nonsterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile pyrogen free water, then thoroughly drained or dried immediately before use for High-Risk Level compounding. All High-Risk Level solutions subjected to terminal sterilization are prefiltered by passing through a filter not larger than 1.2 microns. Sterilization of High-Risk Level solutions by filtration shall be performed with a sterile 0.2 micron or 0.22 micron nominal pore size filter entirely within an ISO-Class 5 or superior air quality environment.~~

~~(H) Examples of High-Risk Level Conditions include: dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized; exposing the ingredients or components to air quality worse than ISO-Class 5 for more than one (1) hour; measuring and mixing in nonsterile devices; assuming, without appropriate evidence, that packages contain at least ninety-five percent (95%) by weight of their active chemical and have not been contaminated between uses.~~

~~(I) Quality Assurance procedures include all those for Low-Risk Level compounded sterile preparations and, in addition, a Media-Fill Test that represents High-Risk Level compounding semiannually by each person authorized to compound High-Risk Level compounded sterile preparations.~~

~~(cc) "Segregated Compounding Area" means a designated space, either a demarcated area or room, which is restricted to preparing Low-Risk Level compounded sterile preparations with twelve (12) hour or less BUD. The area must contain a device that provides Unidirectional Flow of ISO-Class 5 air quality and shall be void of activities and materials that are extraneous to sterile compounding.~~

~~(dd) "Single-Dose Container" means a vial intended for a single parenteral use and is labeled as such. Opened or needle-punctured Single-Dose Containers such as bags, bottles, syringes, and vials shall be used within one (1) hour, if opened in worse than ISO-Class 5 air quality, and any remaining contents must be discarded. Opened single-dose ampules shall not be stored for any time period. Single-dose vials exposed to ISO-Class 5 or cleaner air may be used up to six (6) hours after initial needle puncture.~~

~~(ee) “Temperature” means, for the purposes of these regulations:~~

~~(i) “Frozen” means temperatures of minus twenty five degrees Centigrade (-25°C to -10°C) or colder, minus 13 to plus 14 degrees Fahrenheit (-13 F to 14 F);~~

~~(ii) “Refrigerated” means temperatures of two to eight degrees Centigrade (2°C to 8°C), thirty six to forty six degrees Fahrenheit (36°F to 46°F).~~

~~(iii) “Room Temperature” means temperatures of twenty to twenty five degrees Centigrade (20°C to 25°C), sixty eight to seventy seven degrees Fahrenheit (68°F to 77°F).~~

~~(ff) “Unidirectional Flow” means airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.~~

~~(gg) “USP” means the United States Pharmacopeia, an official public standards setting authority for all prescription and over the counter medicines and other health care products manufactured or sold in the United States. USP sets standards for the quality, purity, strength, and consistency of these products. USP is a non-governmental, not for profit public health organization.~~

~~(hh) “USP 797” means Chapter 797 in the United States Pharmacopeia-National Formulary book of public pharmacopeial standards specifically for pharmaceutical compounding of sterile preparations.~~

~~**Section 6.** Physical Layout and Environment.~~

~~(a) Compounding environment description.~~

~~(i) The compounding environment shall be contained in an area that is segregated from other pharmacy activities and limits access and activities to personnel, materials, and processes that are directly related to production of sterile compounded products, therefore, minimizing risk of particulate or microbial contamination. The compounding area shall be of sufficient size, lighting, and physical conditions (such as maintenance of temperature of 70 degrees Fahrenheit (70°F) or lower) to maximize the compounding accuracy and potential of compounding personnel.~~

~~(ii) The compounding area shall be constructed of smooth, impervious, non-particulate shedding materials that optimize the ability to routinely clean and disinfect surfaces. Ventilation should occur in a manner that allows the maintenance of appropriate ISO Class designations of each separate working area and should avoid disruption and cross room currents.~~

~~(iii) — The compounding area shall have walls, floors, and ceilings, along with fixtures, counters, shelves, and cabinets, that are smooth, impervious, free of cracks or crevices, non-shedding, and resistant to damage that could occur from routine disinfection with cleaning agents. Junctions between surfaces should be caulked or formed in a manner to avoid deep corners that cannot be reached and disinfected. Additional equipment/features, such as pass-throughs, refrigerators, lights, and vents shall be constructed to not become a vector for contamination of the work area.~~

~~(iv) — The compounding area will not contain supplies other than those that are necessary for compounding and will not be considered a bulk storage area. All particle-shedding packing will be removed and products cleaned before being brought into the compounding area.~~

~~(b) — Low-Risk Level and Medium-Risk Level compounding areas.~~

~~(i) — Ante-Area.~~

~~(A) — The compounding work room shall contain an Ante-Area that conforms to ISO Class 8 conditions.~~

~~(B) — The Ante-Area may contain a hands-free sink and closed soap system that allows use and movement to the next compounding area without recontamination of hands on extrinsic surfaces.~~

~~(C) — The Ante-Area shall have area to support the gowning of compounding personnel.~~

~~(ii) — Buffer Area.~~

~~(A) — The compounding work room shall contain a Buffer Area that conforms to ISO Class 7 conditions. When compounding Low-Risk Level radiopharmaceutical CSPs, the compounding work room shall contain a Buffer Area that conforms to ISO Class 8 conditions.~~

~~(B) — The Buffer Area shall be physically separated or have designated boundaries that separate it from the Ante-Area. The Buffer Area shall not be in a location with high traffic. The Buffer Area shall not be in a location with unsealed windows or doors that connect to the outdoors.~~

~~(C) — Ventilation shall assure that contamination from the Ante-Area does not enter the Buffer Area through utilization of filtered Unidirectional Flow and principles of air displacement.~~

~~(D) The Buffer Area shall not contain sinks or drains and shall be void of all materials, equipment, and fixtures that are not directly involved in the current processing of compounded sterile preparations.~~

~~(E) The construction, arrangement, and ventilation of the Buffer Area shall not allow conditions that could adversely affect compounding, such as aberrant heating, cooling, door drafts, and personnel traffic air currents.~~

~~(iii) Primary Engineering Control (PEC).~~

~~(A) The Buffer Area shall contain a Primary Engineering Control that conforms to ISO Class 5 conditions. This may be accomplished through utilization of a laminar flow hood, Compounding Aseptic Isolator, Compounding Aseptic Containment Isolator, or an entire clean room that is filtered, ventilated, and constructed to maintain ISO Class 5 conditions during dynamic operating conditions.~~

~~(iv) Compounding Aseptic Isolators (CAIs).~~

~~(A) Compounding Aseptic Isolators shall be contained inside of an ISO Class 7 Buffer Area, unless the manufacturer of the unit can certify that its engineering controls will maintain ISO Class 5 conditions during dynamic operating conditions, such as personnel and product entry or transfer and throughout typical compounding duties.~~

~~(B) The compounding pharmacy that employs a Compounding Aseptic Isolator as a Buffer Area and Primary Engineering Control shall maintain documentation from the manufacturer.~~

~~(c) High-Risk Level additions.~~

~~(i) All conditions of Low-Risk Level and Medium-Risk Level compounding shall be maintained, and shall include the additional requirement that the Buffer Area shall have physical separation from the Ante-Area.~~

~~(d) Immediate Use and twelve (12) hour Beyond-Use Date (BUD).~~

~~(i) Compounding pharmacies may utilize a Primary Engineering Control in conditions that are less than ISO Class 7 quality, as long as the Primary Engineering Control is appropriately maintained, is segregated from other activities, personnel comply with all gowning and garbing procedures, and the compounded sterile preparation will be used immediately or within twelve (12) hours of compounding.~~

~~(ii) Personnel utilizing this form of compounding must be appropriately trained, with documentation in:~~

- ~~(A) — Personnel;~~
- ~~(B) — Equipment;~~
- ~~(C) — Product cleansing;~~
- ~~(D) — Gowning and garbing;~~
- ~~(E) — Utilization of the Primary Engineering Control;~~
- ~~(F) — Aseptic practices;~~

~~**Section 7.** — and be subject to all quality requirements of normal sterile compounding staff.~~

~~**Section 8.** — Responsibility of Compounding Personnel.~~

~~(a) — Professional compounding personnel are responsible for ensuring that, at a minimum:~~

~~(i) — Proper aseptic technique is practiced at all times during sterile product compounding;~~

~~(ii) — Compounded sterile preparations are appropriately and accurately prepared, identified, purified, sterilized, packaged, labeled, stored, dispensed, and distributed;~~

~~(iii) — The compounding area is appropriately cleaned and maintained.~~

~~(b) — Compounding supervisors (persons who supervise the compounding and dispensing of compounded sterile preparations) are responsible for ensuring that:~~

~~(i) — Compounding personnel are appropriately educated to correctly perform compounding duties and ensure that correct compounding procedures and processes are used;~~

~~(ii) — Compounding equipment is clean, accurate, appropriate and properly inspected and the compounding environment is properly maintained, isolated and inspected;~~

~~(iii) — Ingredients have their correct identity, quality, and purity and opened or partially used containers are properly stored and inspected;~~

~~(iv) — Proper and adequate sterilization methods are used;~~

~~(v) — Completed compounded sterile preparations are appropriately packaged, labeled, and assigned an appropriate BUD, and evaluated for safety;~~

~~(vi) — Deficiencies in compounding can be rapidly identified and corrected;~~

~~(vii) A written Quality Assurance program is established for monitoring, evaluating, correcting, and improving the activities, systems, and processes that support the preparation of compounded sterile preparations;~~

~~(viii) Policies and procedures are prepared and updated for the compounding, dispensing, delivery, administration, storage, and use of sterile pharmaceutical products appropriate for their facility.~~

**~~Section 9. Personnel Training and Evaluation in Aseptic Manipulation Skills.~~**

~~(a) Personnel who prepare compounded sterile preparations shall be trained in the theoretical principals and practical skills of Aseptic Processing and in achieving and maintaining ISO Class 5 environmental conditions before they begin to prepare compounded sterile preparations.~~

~~(i) This can be through any combination of written, audio, or video sources.~~

~~(ii) Personnel shall also pass written and Media-Fill Testing of aseptic technique before they begin to prepare compounded sterile preparations.~~

~~(iii) Results of all testing shall be recorded.~~

~~(b) Personnel shall also perform a didactic review and pass written and Media-Fill Testing of aseptic technique:~~

~~(i) annually for Low and Medium Risk Level compounding;~~

~~(ii) semiannually for High Risk Level compounding.~~

~~(c) There shall be a process to retest and evaluate for personnel who fail testing processes.~~

~~(d) Results of all testing shall be recorded.~~

**~~Section 10. Hazardous Drugs as CSPs.~~**

~~(a) Physical Requirements.~~

~~(i) If the pharmacy practice site is engaged in the compounding of hazardous sterile products, they must ensure the safety of the personnel during the compounding and storage of the Hazardous Drugs.~~

~~(ii) Appropriate garbing must be used during receiving, distribution, stocking, inventorying, preparation for administration, and disposal of Hazardous Drugs.~~

~~(iii) Personnel shall be appropriately trained prior to initial handling and annually thereafter in the storage, handling, preparing, and disposing of Hazardous Drugs.~~

~~(iv) — Such pharmacy will be designed and equipped for appropriate storage.~~

~~(A) — Hazardous Drugs must be stored separately from other inventory and storage areas so identified.~~

~~(B) — Access should be limited to appropriate personnel.~~

~~(v) Such pharmacy will have an appropriate area to prepare sterile Hazardous Drugs.~~

~~(A) — All Hazardous Drugs shall be prepared in a CACI or in a BSC that is located in a negative pressure room. — If a compounding facility prepares hazardous drugs in a sufficiently low volume (five [5] or less products per week), the use of two tiers of containment (e.g., a Closed System Transfer Device within a BSC) is acceptable.~~

~~(vi) — Such pharmacy will have a procedure for disposal of materials containing hazardous residues in accordance with state and federal laws.~~

#### ~~Section 11. — Radiopharmaceuticals as CSPs.~~

~~(a) — (a). — Standards for the production of Positron Emission Tomography (PET) drugs are addressed in USP Chapter <823> *Radiopharmaceuticals for Positron Emission Tomography Compounding*, while USP Chapter <797> applies to the further handling, manipulation, or use of the product once it is released as a finished drug product from a production facility.~~

~~(i) — For the purpose of this Section, the following shall be designated low-risk level radiopharmaceutical CSPs:~~

~~(A) — Radiopharmaceuticals — compounded — from — sterile components in closed sterile containers, using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment.~~

~~(B) — Compounded Radiopharmaceuticals with a volume of 100 mL or less for a single dose injection or not more than 30 mL taken from a multiple dose container.~~

~~(ii) — Radiopharmaceuticals prepared as Low-Risk Level CSPs with 12-Hour or Less BUD shall be prepared in a properly designated and segregated compounding area.~~

~~(iii) Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturer recommendations or as established by stability testing.~~

~~(iv) Technetium-99m/molybdenum-99 generator systems shall be stored and operated under conditions recommended by the manufacturer and applicable state and federal regulations in an ISO Class 8 or cleaner air environment.~~

~~**Section 12. Gowning and Garbing.**~~

~~(a) Personal cleansing and gowning/garbing shall be as follows:~~

~~(i) Personnel shall not compound if they have open sores or infected wounds;~~

~~(ii) Personnel shall not compound if they have an upper respiratory infection;~~

~~(iii) Upon entering a compounding area, personnel must remove outer garments (such as coats, hats, sweaters, bandanas, vests, and scarves), hand and other exposed jewelry, and any other unnecessary and potentially contaminated or particle shedding articles. If hand jewelry cannot be removed, then it must be thoroughly cleaned and covered with a sterile glove;~~

~~(iv) Hand cleansing and donning of personal protective equipment should proceed in a manner that goes from the dirtiest to the cleanest area: shoe covers, hair covers, facial hair covers, and face mask or eye shields (if working with caustic or irritant agents). Cleansing should be done in a no-touch sink using appropriate antibacterial detergent, starting at the hands and nails and progressing to the elbows. The process should take at least thirty (30) seconds. Hand and forearm drying should be done with non-shedding paper towels.~~

~~(A) At this point, personnel should don a non-shedding gown with sleeves that fit snugly around wrists. Lastly, sterile gloves should be donned. The gloves should form a continuous surface with the gown sleeves. Care should be exercised when progressing through the Ante-Area and Clean Room to not re-contaminate the gloves.~~

~~(B) Re-sanitizing of the gloves with sterile 70% IPA should occur routinely throughout the compounding process, or at any point that the gloves may have touched a non-sterile surface.~~

~~(v) If it is necessary to leave the compounding area, hand cleansing and replacement of all personal protective equipment except for the non-shedding gown shall occur. The gown must be left in the Ante-Area if it is to be reused during a shift (not to exceed twenty four (24) hours).~~

~~(vi) If a Compounding Aseptic Isolator is used, gowning and garbing should occur in a manner consistent with the manufacturer's documented procedures. If no studies have been done and the manufacturer cannot assure maintenance of sterility and ISO Class 5 conditions outside of an ISO Class 7 space, the compounder must follow gowning and garbing procedures discussed above.~~

**~~Section 13.~~** Policy and Procedure.

~~(a) Pharmacies that engage in the practice of sterile compounding shall have a Policies and Procedures (P&P) manual that describes the common practices of the pharmacy. The P&P manual will be reviewed and updated as necessary, at least annually. The Pharmacist in Charge (PIC) is responsible for the completeness, accuracy, and enforcement of compliance with the procedures by all pharmacy personnel. This P&P manual will be available at all times to staff and at the request of a Board of Pharmacy Inspector. All staff will review the P&P manual before engaging in sterile compounding and annually thereafter. If the PIC changes, the new PIC must review, date, and initial the P&P manual within thirty (30) days.~~

~~(b) The Policies and Procedures manual will contain procedures detailing at least the following:~~

- ~~(i) Responsibilities of compounding personnel;~~
- ~~(ii) Personnel training and testing;~~
- ~~(iii) Competency practices and assessment of compounding personnel;~~
- ~~(iv) Quality Assessment and Quality Improvement activities;~~
- ~~(v) Proper use and deployment of environmental controls;~~
- ~~(vi) Gowning and garbing practices;~~
- ~~(vii) Inspection of finished products, labeling, storage, and transfer to final use areas for storage or use;~~
- ~~(viii) Introduction of supplies and products into the compounding area;~~
- ~~(ix) The formulation, process for compounding, BUD, and storage requirements of each routinely compounded CSP.~~

**~~Section 14.~~** Elements of Quality Control.

~~(a) — Compounding facility.~~

~~(i) All pharmacies engaging in sterile compounding shall have a Quality Assurance Program that is in written format with documentation that illustrates that the Program is being followed. Documentation of compliance with the Quality Assurance Program will be available for evaluation by Inspectors of the Wyoming Board of Pharmacy and other pertinent regulatory agencies. The Quality Assurance Program shall include, though not be limited to:~~

~~(A) — Adequacy of training and evaluation of personnel;~~

~~(B) — Verification, monitoring, and review of the adequacy of the compounding process;~~

~~(C) — Maintenance of an appropriate environment for compounding sterile preparations;~~

~~(D) — Review of the final product for accuracy of preparation, quality, and purity and, where appropriate, sterility and bacterial endotoxin content;~~

~~(E) — Monitoring for adverse or negative patient outcomes due to utilization of a compounded sterile preparation or other quality related issue, and that identified issues are included in the facility's overall Quality Assurance Program.~~

~~(F) — Addressing problems or issues identified by the Quality Assurance Program, including follow-up and assurance of correction.~~

~~(b) — Personnel.~~

~~(i) All personnel engaged in preparation of sterile products will be adequately trained before they begin compounding.~~

~~(ii) Training shall include didactic learning and experiential components with results validated by testing of aseptic skills and knowledge including, but not limited to:~~

~~(A) — Gowning and garbing assessment;~~

~~(B) — Media-Fill Testing that is representative of compounding performed;~~

~~(C) — Gloved fingertip testing done three (3) times prior to initial compounding and annually thereafter;~~

~~(D) — Knowledge of sterile compounding processes; facility policies, procedures and quality programs; and legal requirements of state, federal, and pertinent regulating agencies.~~

~~(iii) — All documentation of results will be available for review by pertinent individuals or agencies.~~

~~(c) — Compounding Risk Levels.~~

~~(i) The Quality Assurance Program will correspond to the level of compounding risk that is undertaken at the individual facility. The facility's Quality Assurance Program shall include the following for each level:~~

~~(A) — Low-Risk Level Compounding.~~

~~(I) Routine disinfection and air quality testing conducted to minimize microbial surface contamination and maintenance of ISO Class 5 conditions;~~

~~(II) Visual confirmation of personnel practices and garbing;~~

~~(III) Review of all orders and materials to ensure that the correct identity and quantity of ingredients were compounded;~~

~~(IV) Visual inspection of the sterile product to ensure the absence of particulate matter in the solution; appropriateness of color, clarity, and volume; the adequacy and competence of the container; and appropriateness of labeling. Visual inspection of Low-Risk Level radiopharmaceutical CSPs will be limited, in accordance with radiation safety practices.~~

~~(V) Annual basic Media-Fill Testing that is conducted in conditions of equal stress to the actual compounding process.~~

~~(B) — Medium-Risk Level Compounding.~~

~~(I) All elements of the Low-Risk Level compounding quality requirements plus a more challenging Media-Fill Test performed at least annually.~~

~~(C) — High-Risk Level Compounding.~~

~~(I) All elements of the Low-Risk Level compounding quality requirements plus a Media-Fill Test that represents High-Risk Level compounding completed semiannually by all compounding personnel.~~

~~(d) — Verification of accuracy and sterility in High-Risk Level compounding.~~

~~(i) The compounding facility will have policies and procedures detailing standard practices that assure compounded sterile products are accurately produced and that the quality procedures in place achieve and maintain sterility.~~

~~(ii) High-Risk Level compounding shall have additional procedures and quality assurance to ensure accurate and sterile products.~~

~~(iii) Sterility and depyrogenation shall be achieved when necessary by the appropriate application of dry heat, steam heat, or filtration. Appropriate resources~~

~~shall be used to determine the appropriate method for sterilization while maintaining strength, purity, quality, and package integrity.~~

~~(iv) Sterility and Bacterial Endotoxin testing shall be done when there are batches of more than twenty five (25) identical individual single dose packages; when in multiple dose vials for administration to multiple patients; or when exposed longer than twelve (12) hours at two to eight degrees Centigrade (2°C to 8°C), or longer than six (6) hours at above eight degrees Centigrade (8°C).~~

~~(v) If dispensed before results are obtained, daily monitoring of the testing will occur and, if positive results come back, the product will be immediately recalled and notification of results will be forwarded to the end patient and physician.~~

~~(e) Environmental quality and control.~~

~~(i) The facility producing compounded sterile preparations will have policies and procedures sufficient to ensure preparation of products that are sterile and of accurate strength, purity, quality, and package integrity. A Quality Assurance Program will be present that illustrates the adequacy of the processes used. The Quality Assurance Program will include, but not be limited to:~~

~~(A) Viable and nonviable environmental air sampling performed:~~

~~(I) As part of commissioning and certification of facilities or equipment;~~

~~(II) Following servicing of facilities or equipment;~~

~~(III) As part of re-certification (every six (6) months);~~

~~(IV) In response to identified problems with end products, staff technique or work practices, or patient-related infections that could be due to the compounded sterile preparation.~~

~~(B) Primary Engineering Controls and equipment will be monitored as part of the comprehensive Quality Assurance Program that assures maintenance of appropriate air quality and the ability to produce sterile and stable compounded products.~~

~~(f) Patient monitoring.~~

~~(i) The compounding facility will have policies and procedures detailing its Quality Assurance Program that monitor for adverse effects, negative outcomes, and medication errors.~~

~~(ii) The compounding facility will have a process that allows patients and other recipients to address their questions and to report any concerns they may have with the compounded sterile preparation or administrative device.~~

~~(iii) Reports of adverse events will be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences.~~

~~(iv) Compounding personnel are encouraged to participate in the adverse event reporting and product defects programs of the FDA and USP.~~

~~**Section 15.** Verification of Automated Compounding Devices for Parenteral Nutrition Compounding.~~

~~(a) Wherever possible, Parenteral nutritional solutions should be compounded using an automated compounder or repeater pump to ensure accuracy and sterility of these compounded products.~~

~~(b) Written procedures outlining use of equipment, calibration, appropriate maintenance, monitoring for proper function, and specified time frames for these activities shall be established and followed. Results and logs of calibration and maintenance reports shall be kept on file at the pharmacy for at least two (2) years and shall be available for inspection.~~

~~(c) Manufacturer recommendations regarding calibration and maintenance shall be made part of each facility's policies and procedures.~~

~~(d) The automated compounder shall be cleaned prior to each set-up and as necessary according to the manufacturer's guidelines.~~

~~(e) Accuracy assessments of automated compounding devices shall be conducted and daily or on each day used. At routine intervals, the pharmacist in charge or his/her designee will review these assessments to avoid potentially clinically significant cumulative errors over time.~~