Notice of Intent to Adopt Rules

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

Revised September 2016

1. General Information

a. Agency/Board Name
Administration & Information, Dept of/WY State Board of Pharmacy

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

e. Name of Agency Liaison	f. Agency Liaison Telephone Number
Mary K. Walker	307-634-9636

g. Agency Liaison Email Address
mary.walker@wyo.gov

h. Date of Public Notice	i. Comment Period End Date
February 6, 2017	March 28, 2017

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

k. 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 & 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Chapter Number:	Chapter Name:	New	Amended	Repealed
1	Rules of Practice and Procedure	■	■	☐
2	General Practice of Pharmacy	■	■	☐
8	Wholesale Distributor Regulations	☐	■	☐
15	Long Term Care Regulations	☐	■	☐
16	Immunization Regulations	☐	■	☐
17	Sterile Compounding	☐	■	☐
		☐	☐	☐
		☐	☐	☐
		☐	☐	☐
		☐	☐	☐

4. Public Comments and Hearing Information

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

Date:	Time:	City:	Location:
March 29, 2017	10:00 a.m.	Casper	2211 King Blvd, Hearing Room of the Oil & Gas Commission

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

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

☐ At the following URL: _____

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

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

☐ At the following URL: _____

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

5. Federal Law Requirements

a. These rules are created/amended/repealed to comply with federal law or regulatory requirements.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

Applicable Federal Law or Regulation Citation: Drug Quality & Security Act Title 1 and Title 2, November 27, 2013

Indicate one (1):

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

☐ The proposed rules exceed minimum federal requirements.

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

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

☐ At the following URL: _____

6. State Statutory Requirements

a. Indicate one (1):

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

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

b. Indicate one (1):

■ The Agency has complied with the requirements of W.S. 9-5-304. A copy of the assessment used to evaluate the proposed rules may be obtained:

■ By contacting the Agency at the physical and/or email address listed in Section 1 above.
☐ At the following URL: _____

☐ Not Applicable.

7. Additional APA Provisions

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

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

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

Chapters 1, 2, 8, 15, 16, 17

(Provide chapter numbers)

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

(Provide chapter numbers)

b. Checklist

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

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

8. Authorization

a. I certify that the foregoing information is correct.

Printed Name of Authorized Individual	Mary K. Walker
Title of Authorized Individual	Executive Director
Date of Authorization	December 16, 2016

Additional Rule Information

Revised September 2016

1. General Information

a. Agency/Board Name Administration & 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. Na Name of Agency Liaison	f. Agency Liaison Telephone Number 307-634-9636		
g. Agency Liaison Email Address mary.walker@wyo.gov	h. Adoption Date		
i. Program			

2. Rule Type and Information, Cont.

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

Chapter Number:	Chapter Name:	☐ New ☐ Amended ☐ Repealed
Chapter Number:	Chapter Name:	☐ New ☐ Amended ☐ Repealed
Chapter Number:	Chapter Name:	☐ New ☐ Amended ☐ Repealed
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Chapter Number:	Chapter Name:	☐ New ☐ Amended ☐ Repealed
Chapter Number:	Chapter Name:	☐ New ☐ Amended ☐ Repealed

BOARD OF PHARMACY WYOMING

Bessie S. McGirr, RPh, President
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Jan Shatto, RPT, Member
Ronnie LeBlanc, RPh Board Member
Brenda Upton, RPh, Board Member

1712 Carey Avenue, Suite 200, Cheyenne, WY 82002
307-634-9636 Telephone
307-634-6335 Fax
bop@wyo.gov electronic mailbox
Mary K. Walker, RPh, Executive Director

Lisa V. Hunt, RPh, Inspector/Compliance Officer
Henry A. (Hank) York, RPh, Inspector/Compliance Officer

Governor: Matthew H. Mead

WYOMING PHARMACY ACT RULES AND REGULATIONS

STATEMENT OF PRINCIPAL REASONS FOR REVISIONS
JANUARY 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 2: General Practice of Pharmacy
Proposed changes to this chapter include further developing regulations for electronic records for dispensed prescriptions. Rules regarding disposal of medications are based on changes in federal rules. Regulations describing the process to transfer a prescription are clarified. The return of prescription drugs to a pharmacy after dispensing is updated. Fees and late fees for new types of distributors are listed based on changes to federal regulations. Ancillary drug supplies for nursing homes and other facilities are revised. Procedures to follow when a pharmacy closes are changed based on information from the Drug Enforcement Administration.

Chapter 8: Manufacturer, Distributor, Wholesaler Prescription Drug Regulations
Definitions have been updated based on the federal Drug Quality and Security Act of 2013 (DQSA). Descriptions of several additional licenses under this chapter include medical oxygen distributors, outsourcing facilities, third party logistics providers and wholesale distributors of prescription drugs for non-human use. The section describing “pedigrees” and electronic track and trace requirements are deleted as required by the DQSA.

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.

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.

(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.

RULES OF PRACTICE AND PROCEDURE
OF THE
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CHAPTER 1

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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 licensedees ~~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 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 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 ~~with~~between the ARC, the ~~Assistant Attorney General~~Prosecuting Attorney, and the applicant.

(iv) Following ~~a~~the 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 ~~should~~shall 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 6~~5~~;

(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~~al~~ 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~~notify 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 apaplicable 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.~~

GENERAL PRACTICE OF PHARMACY REGULATIONS

CHAPTER 2

Section 1. Authority.

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

Section 2. Purpose.

The purpose of this regulation is to coordinate the requirements for pharmacy services by providing minimum standards, conditions, and physical guidelines for facilities and pharmacists in professional settings.

Section 3. Scope.

This Chapter applies to any person, partnership, corporation, limited liability company, or other entity engaging in the practice of pharmacy within the state.

Section 4. Definitions.

(a) "Active pharmacy practice" means a pharmacist who engages in the practice of pharmacy, as defined in W.S. § 33-24-124, a minimum of four hundred (400) hours per calendar year.

(b) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(i) A practitioner (or by his or her authorized agent); or

(ii) The patient or research subject at the direction of the practitioner.

(c) "Ancillary kit" means a tamper-evident sealed and secured container or secured automated dispensing device containing drugs.

(d) "Audit trail" means a record showing who has accessed an information technology application and what operations the user performed during a given period.

(e) "Authentication" means verifying the identity of the user prior to allowing access to the information application.

(f) "Automated Dispensing Device" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage,

packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

(g) "Board of Pharmacy" or "Board" means the Wyoming State Board of Pharmacy.

(h) "Collaborative pharmacy practice" is that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol and in collaboration to provide patient care services to achieve optimal medication use and desired patient outcomes.

(i) "Collaborative practice agreement" means a written voluntary agreement, between a pharmacist and a prescribing practitioner that defines a collaborative practice.

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

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

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

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

However, "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with the labeling.

(k) "Confidential information" means information maintained by the pharmacist in the patient's records, or communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or, as the patient directs, to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being, and to such other persons or governmental agencies authorized by law to investigate controlled substance law violations.

(l) "Consultant pharmacist" means a pharmacist who establishes policies and procedures for the distribution and storage of drugs, visits the facility on a regularly scheduled basis, but is not physically present at the facility for a set number of hours on a daily basis, and conducts prospective and retrospective drug utilization reviews, including the identification of problems and recommendations for resolution of identified problems for residents of the facility.

(m) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(n) “Device” means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part of accessory, which is required under federal law to bear the label, “Caution: Federal law restricts this device to sale by or on the order of a physician.”

(o) “Digital signature” means an electronic identifier that:

(i) Is intended by the party using it to have the same force and effect as a manual signature;

(ii) Is unique to the authorized signer;

(iii) Is capable of verification;

(iv) Is under the sole control of the authorized signer;

(v) Is linked to the prescription in such a manner, that, if the prescription information is changed, the signature is invalidated; and

(vi) Conforms to Wyoming State Statute and Board Rules and Regulations.

(p) “Dispense” means the interpretation, evaluation and implementation of a prescription drug or nonprescription drug under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient, research subject or an animal.

(q) “Distribute” means the delivery of a drug or device other than by administering or dispensing.

(r) “Dosage form” means the physical formulation or medium in which the product is manufactured and made available for use including, but not limited to, tablets, capsules, oral solutions, aerosols, inhalers, gels, lotions, creams, ointments, transdermals and suppositories.

(s) “Drug” means an article recognized as a drug in any official compendium, or supplement thereto, designated for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals.

(t) “Drug therapy management” means the same as medication therapy management as defined in this Chapter.

(u) “Electronic prescription” means a prescription that is generated on an electronic application and transmitted as an electronic data file.

(v) “Electronic signature” means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person’s approval of the information contained in the message.

(w) “Electronic transmission” means:

(i) Transmission of the digital representation of information from one computer or other similar electronic device to another computer, which is authenticated by a digital signature; or

(ii) Transmission of the electronic representation of information from one computer or other similar electronic device to a facsimile (fax) machine, which is authenticated by an electronic signature.

(x) “Foreign pharmacy graduate” means a pharmacist whose undergraduate pharmacy degree was conferred by a recognized school of pharmacy outside of the United States, the District of Columbia and Puerto Rico. United States citizens who have completed their pharmacy education outside the United States are foreign pharmacy graduates. Foreign nationals who have graduated from schools in the United States are not foreign pharmacy graduates.

(y) “Labeling” means the process of preparing and affixing a label to any drug container, exclusive of the labeling by a manufacturer, packager or distributor.

(z) “Medication therapy management” (also known as “drug therapy management”) is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medical therapy management (MTM) services are independent of, but can occur in conjunction with, the provision of a medication or a medical device MTM encompasses a broad range of professional activities and responsibilities within the licensed pharmacist’s scope of practice. MTM services may be performed without a collaborative practice agreement. These services may include, but are not limited to, the following, according to the individual needs of the patient:

(i) Performing or obtaining necessary assessments of the patient’s health status;

(ii) Formulating a medication treatment plan;

(iii) Selecting, initiating, modifying or administering medication therapy;

(iv) Monitoring and evaluating the patient’s response to therapy, including safety and effectiveness;

(v) Performing a comprehensive medication review to identify, resolve and prevent medication-related problems, including adverse drug events;

(vi) Documenting the care delivered and communicating essential information to the patient’s other primary care providers;

(vii) Providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;

(viii) Providing information, support services and resources designed to enhance patient adherence with his or her therapeutic regimens;

(ix) Coordinating and integrating MTM services within the broader health care management services being provided to the patient;

(x) Such other patient care services as may be allowed by law; or

(xi) Ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, as it directly relates to MTM, provided:

(A) The pharmacy or service is certified by the US Department of Health and Human Services, as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA); or

(B) The tests do not otherwise require a physician's order and the pharmacy or service has obtained a CLIA Certificate of Waiver from the US Department of Health and Human Services; and

(C) The pharmacist is qualified to direct the laboratory.

(aa) "Non-resident pharmacy" means a licensed pharmacy located outside this State where drugs are dispensed and/or pharmaceutical care is provided to residents within this state.

(bb) "Paper prescription" means a prescription created on paper or computer generated to be printed or transmitted via fax that includes a manual signature.

(cc) "Patient confidences" as used in WYO. STAT. ANN. § 33-24-101(b)(4)(C), means information transmitted by the prescribing practitioner or agent to the pharmacist or agent for the purpose of treating the patient and information transmitted by the patient or agent to the pharmacist or agent for the purpose of treatment, and includes the patient's name, address, medical condition and drugs lawfully prescribed for the patient. The pharmacist may release otherwise confidential information pertaining to the patient's treatment to a minor's parent or guardian, the patient's third-party payor or the patient's agent.

(dd) "Patient counseling" means the verbal communication by the pharmacist of information, to the patient or caregiver, in order to improve therapy by ensuring proper use of drugs and devices. Patient counseling may be supplemented with printed materials.

(ee) "Pharmacist care" (also known as pharmaceutical care) is patient care activities provided by a pharmacist, with or without the dispensing of drugs or devices, intended to achieve positive clinical outcomes and to optimize the patient's health-related quality of life.

(ff) "Pharmacist's collaborative scope of practice" means those duties and limitations of duties agreed upon by a pharmacist and the collaborating practitioner (subject to Board approval and applicable law), and includes the limitations implied by the specialty practiced by the collaborating practitioner.

(gg) "Pharmacist-in-Charge" ("PIC") means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws, rules pertinent to the practice of pharmacy and the distribution of drugs.

(hh) "Pharmacy" means an area(s) where drugs are dispensed and/or pharmacist care is provided.

(ii) "Pharmacy intern" is described in Chapter 3 of these rules.

(jj) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which he/she practices to prescribe drugs in the course of professional practice.

(kk) "Prepackage" means to prepare a drug in a container in advance of actual, immediate need for dispensing, prior to the receipt of an order. Such packaging may be in a unit dose or unit of issue package for use in a unit dose dispensing system or in a container suitable for a traditional dispensing system.

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

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

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

(iii) "Rx Only."

(mm) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient.

(nn) "Readily retrievable" means records kept in such a manner that they can be separated out from all other records and produced for review within forty-eight (48) hours.

(oo) "Registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy.

(pp) "Remodeled pharmacy" means an existing retail pharmacy that is relocated to a different address, or a pharmacy that undergoes remodeling at a cost equal to or greater than twenty-five thousand dollars ($25,000.00).

(qq) "Repackage" means to prepare a unit dose or unit of issue package or traditional dispensing system package for dispensing pursuant to an existing order.

(rr) "State Board," as used in W.S. § 33-24-136(b), shall mean the boards of medicine, dental examiners, nursing, podiatry, optometry and veterinary medicine of the State of Wyoming and their similar counterpart boards of any of the states in the United States of America.

(ss) "Traditional dispensing system" means a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages.

(tt) "Unit dose dispensing system" means a drug distribution system that is in a pharmacy and uses unit dose packages or unit of issue packages that enable distribution of packaged doses in a manner that preserves the identity and the integrity of the drug.

(uu) "Unit dose package" means a package that contains one unit of medication.

(vv) "Unit of issue package" means a package that provides multiple units of doses separated in a medication card or other similarly designed container.

(ww) "Wholesale distributor" is defined in Chapter 8 of these rules.

Section 5. Pharmacist Licensure by Examination.

(a) The Board shall utilize those standardized examinations as prepared and administered by the National Association of Boards of Pharmacy (NABP). These standardized examinations shall include the following:

(i) North American Pharmacist Licensing Examination (NAPLEX®); and

(ii) Multistate Pharmacy Jurisprudence Examination (MPJE®).

(b) Applicants for licensure by examination will be licensed, provided they:

(i) Submit a properly completed "Pharmacist License by Examination" application, as provided by the Board, with the proper fee and fee/fingerprints for a criminal background check. However, any applicant who has on file at the Board office a criminal background history dated within twelve (12) months of the date of application need not resubmit fee/fingerprints for a criminal background history;

(ii) Pass the NAPLEX® with a minimum score of 75;

(A) Candidates who do not receive a passing grade on the NAPLEX® shall be allowed two (2) retakes, for a total of three (3) examinations.

(B) All retakes require payment of fees plus a forty-five (45) day waiting period, as required by NABP.

(iii) Pass the MPJE® for Wyoming with a minimum score of 75;

(A) Candidates who do not receive a passing grade on the MPJE® for Wyoming may retake the examination for a maximum of five (5) attempts.

(B) All retakes require payment of fees, plus a thirty (30) day waiting period, as required by NABP.

(iv) Meet the required practical experience requirement of 1,200 internship hours as specified in Chapter 3 of these rules;

(v) Complete all requirements within two (2) years of the date of application to the Board office;

(vi) Meet the requirements of W.S. § 33-24-116; and

(vii) Ensure the Board receives the results of a criminal background history report from the Wyoming Division of Criminal Investigation (DCI).

(c) Applicants who have applied for score transfer of their NAPLEX® examination to Wyoming will be licensed by examination provided they meet the following requirements:

(i) The NAPLEX® score transferred is 75 or more;

(ii) A properly completed "Pharmacist Licensure by Examination" application, as provided by the Board, with the proper fee, has been submitted to the Board office;

(iii) Pass the MPJE® for Wyoming with a minimum score of 75;

(A) Candidates who do not receive a passing grade on the MPJE® for Wyoming may retake the examination for a maximum of five (5) attempts.

(B) All retakes require payment of fees, plus a thirty (30) day waiting period, as required by the NABP.

(iv) The required practical experience requirement of 1,200 internship hours is met, as specified in Chapter 3 of these rules;

(v) All requirements completed within one (1) year of the date of the NAPLEX® examination, which was utilized for the score which was transferred to Wyoming;

(vi) Board receipt of a criminal background history report from the DCI; and

(vii) Meet the requirements of W.S. § 33-24-116.

(d) No candidate will be licensed until the required practical experience, as specified in Chapter 3 of these rules has been met.

(e) Candidates failing to meet all requirements within the time period allowed in this chapter must file a new application, including payment of the fees or, if applicable, seek licensure by license transfer, as outlined in this chapter.

(f) The Board reserves the right to require an interview with any applicant seeking licensure by examination to practice pharmacy in Wyoming.

(g) The Board shall charge fees to cover administrative costs, which shall include one (1) wall certificate and a renewal certificate for the current license year.

(h) Foreign pharmacy graduates, holding a FPGEC® Certificate issued by the Foreign Pharmacy Graduate Examination Committee ®, may apply for licensure as a pharmacist under this section. To be eligible for FPGEC® certification, applicants must satisfy the following requirements established by the FPGEC®:

(i) Provide verification of educational equivalency of an applicant's foreign pharmacy education and the applicant's licensure or registration as a pharmacist outside the United States;

(ii) Pass the Foreign Pharmacy Graduate Equivalency Examination (FPGEE®); and

(iii) Obtain an acceptable score on the Test of English as a Foreign Language Internet-based Test (TOEFL® iBT), with minimal scores of 21 for listening, 22 for reading, 26 for speaking and 24 for writing.

Section 6. Pharmacist Licensure by Reciprocal License Transfer.

Any pharmacist, who is licensed by examination and is in good standing in any state which is a member of the NABP and who desires to be licensed by reciprocity into this state, shall proceed in the manner outlined by the NABP after first submitting the "Preliminary Application for Transfer of Pharmacist Licensure" obtained from the NABP.

(a) All candidates for license transfer shall be required to:

(i) File all appropriate applications with the Board;

(ii) Pay the required application fee;

(iii) Complete the two (2) fingerprint cards provided by the Board for the criminal background check;

(iv) Pay the required criminal background check fee;

(v) Pass the MPJE® for Wyoming;

(vi) Prove good moral character;

(vii) Prove they have been in active pharmacy practice, as defined in this chapter, for the year preceding the date of their application for license transfer. Applicants failing to show proof must complete an internship in Wyoming approved by the Board of no less than four hundred (400) hours;

(viii) Meet all requirements under the Wyoming Pharmacy Act and these rules; and

(ix) If applying as a foreign pharmacy graduate, possess a FPGEC® Certificate.

(b) The Board must receive the applicant's criminal background history report from the DCI before a pharmacist license by transfer will be issued.

(c) The Board shall not issue a pharmacist license by license transfer until all conditions under this chapter have been met.

(d) All applications for licensure by reciprocity shall expire one (1) year from date of issue by the NABP.

(e) The Board reserves the right to require an interview with any applicant seeking licensure by reciprocity to practice pharmacy in Wyoming.

(f) In the event of rejecting an application, the fees paid to the Board will not be refunded.

(g) The Board will accept licensure by reciprocity for pharmacists licensed in California after January 1, 2004.

Section 7. Minimum Structural and Equipment Requirements to Operate a Retail Pharmacy.

(a) All retail pharmacies operating in this State must meet the following requirements:

(i) The pharmacy shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with adequate sewage disposal;

(ii) The pharmacy shall be properly lighted and ventilated. The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of pharmaceuticals;

(iii) The pharmacy shall have adequate shelving; there shall be adequate counter space; the working surface shall be kept clear and uncluttered at all times for the preparation or compounding of prescriptions to meet the requirements of the pharmacy. Any pharmacy where compounding prescriptions occurs must meet the structural and equipment requirements identified in Chapter 13 of these rules;

(iv) A fax machine or similar electronic equipment capable of producing an identical document shall be located in the pharmacy;

(v) A separate refrigerator located in the pharmacy, with sufficient capacity to serve the needs of the pharmacy, equipped with a thermometer which provides a storage temperature of 36-46 degrees Fahrenheit (2-8 degrees Centigrade). The use of such refrigerator shall be limited to the storage of drugs. If a freezer compartment is utilized, it must maintain a temperature of -13 to 14 degrees Fahrenheit (-20 to -10 degrees Centigrade);

(vi) Class A prescription balance or electronic scale with 10 mg sensitivity;

(vii) A professional reference library (text or electronic format) that shall include the following:

(A) Current Wyoming pharmacy laws;

(B) Current edition of *Facts and Comparisons* or a comparable reference accepted by the Board;

(C) Current drug interaction text that provides, at a minimum, quarterly updates;

(D) Wyoming State Board of Pharmacy quarterly newsletter by access to the Board website; and

(E) The current edition (as incorporated by reference in this Chapter), with supplements, of the U.S. Food and Drug Administration (FDA) "Orange Book" or an alternate reference that provides the same information as the FDA "Orange Book." Proven access to the Board website link to the Orange Book meets this requirement.

(viii) Pharmacies must maintain adequate security to deter theft of drugs by personnel or public. Security requirements for new or remodeled pharmacies must meet the requirements of this chapter. No person other than the pharmacist, intern or technician employed by the pharmacy shall be permitted in the pharmacy without the express consent of the PIC. If the pharmacy is located in a facility in which the public has access and the pharmacy's hours of operation are different from the rest of the facility, the pharmacy must be designed so that it can be securely locked and made inaccessible when the pharmacy is not open;

(ix) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition;

(x) If automated counting devices are utilized, the pharmacy shall have a method to calibrate and verify the accuracy of the automated counting device and shall verify the accuracy and document doing so on a quarterly basis;

(xi) Consecutive numbering of all prescriptions must be maintained, along with appropriate printing equipment to product prescription drug labels; and

(xii) In addition to the requirements identified in this chapter, all pharmacies involved in the preparation of sterile compounded products must meet the requirements of Chapter 17 of these rules.

(b) In addition to the requirements of this chapter, except for a change of ownership of an existing pharmacy, an individual or business who opens a new pharmacy or remodels an existing retail pharmacy shall provide to the Board staff no later than thirty (30) calendar days prior to commencing construction or remodeling the pharmacy, a set of blueprints or other acceptable documents, which indicate the physical layout of the planned or remodeled pharmacy.

(c) The proposed new pharmacy or pharmacy to be remodeled shall meet the following minimum standards:

(i) The pharmacy shall consist of no less than 500 square feet;

(ii) The pharmacy shall include an identified counseling area, which is apart from the cash register, apart from the prescription “pick up” area, and offers sufficient privacy for counseling. A separation of three (3) feet is the minimum space between patients to allow for privacy during counseling. Pharmacies that do not provide prescription services to “Walk-in” customers are not required to have a counseling area;

(iii) Located within the pharmacy, but not counted in the square footage requirements of the pharmacy, shall be restroom facilities, access to which shall be limited to pharmacy staff;

(iv) Access to the pharmacy shall be secured as follows:

(A) If the pharmacy is located within another business, which does not have identical hours of operation, the pharmacy shall be secured with solid core or metal doors with a deadbolt and a locking doorknob. If glassed areas are utilized, then adequate intrusion detectors must be in place. Pharmacy walls must extend to the roof or provide security acceptable to the Board. The pharmacy shall meet all other applicable federal or state regulations concerning security access.

(B) Those pharmacies not included in (A) shall be secured with solid core, metal or safety glass exterior doors secured with a deadbolt, and must utilize an adequate intrusion detector. If the pharmacy shares a common wall with another business, this wall must extend to the roof. The pharmacy shall meet all other applicable federal or state regulations concerning security access.

(v) A separate refrigerator, sufficient in capacity to serve the needs of the pharmacy staff, shall be available for storage of employees' food or beverage. This refrigerator shall be identified for "Employee Use Only;" and

(vi) All prescription data shall be processed utilizing electronic data processing equipment and shall be sequentially numbered. There shall be adequate computer terminals and printers available to process anticipated prescription volume for the new or remodeled pharmacy.

(d) Upon written request, and for good cause, the Board may waive any of the requirements of this chapter. A waiver that is granted under this section shall only be effective when issued by the Board in writing.

(e) For a change in ownership of a retail or institutional pharmacy, the Board shall be notified at least twenty-one (21) days before the change.

Section 8. Licensing of Facilities.

(a) Prior to the issuing of the registration to operate a pharmacy or prescription department in Wyoming, the Board will inspect the pharmacy for minimum standards including space, fixtures, sanitation, reference library, technical equipment and security. The application will include the number of hours the pharmacy will be in operation per week.

(b) The facility application shall list the names of all licensed pharmacists employed, specifically identifying the Pharmacist-in-Charge (PIC). The PIC determines which employees shall have access to the pharmacy.

(c) The Board shall be notified within seven (7) days of every change in PIC. A controlled substance inventory is required when there is a change in PIC, at the time of the change. This inventory shall include the signatures of both the outgoing and incoming PIC, and the date and time the inventory was taken. If the inventory cannot be conducted with both pharmacists, then the incoming PIC shall conduct an inventory. A copy of the controlled substance inventory and signed Certification of Responsibilities as Pharmacist-in-Charge (PIC) shall be forwarded to the Board office within fifteen (15) days of conducting the inventory.

(d) When a pharmacy changes ownership, the original license becomes void and a new license must be secured by the new owner or owners. A new license is required even if there is no change in the name of the pharmacy or in the registered PIC of the pharmacy.

In the case of a corporation, limited liability company or partnership holding a pharmacy license, the Board shall be notified and a new license applied for any time the majority of stock in the corporation is sold or a majority of the partners of the partnership or members of the limited liability company change. This shall constitute new ownership. Requirements for the change of ownership are the same as outlined in this section.

(e) A pharmacy license registers the pharmacy to which it is issued only at the location specified on the application and is not transferable.

(f) The Board shall be notified in writing at least thirty (30) days before a pharmacy change of address. The new location shall be inspected by the Board prior to issuance of an amended pharmacy license for the new location. The new location must meet all requirements for a new or remodeled pharmacy, as noted in this chapter.

(g) All licenses and certificates issued by the Board shall be displayed in a prominent place in the facility and always in view of the public.

(h) Resident Pharmacy Licenses shall indicate “Institutional” or “Retail.”

Section 9. Pharmacist-in-Charge (PIC).

Every licensed pharmacy must be in the continuous daily charge of a pharmacist. A pharmacist shall be designated as the PIC and shall have direct control of the pharmacy services of said pharmacy.

(a) A pharmacist may not serve as the PIC unless said pharmacist is physically present in the pharmacy a minimum of thirty-two (32) hours per week, except for time periods of less than thirty (30) days when absent due to illness, family illness or death, scheduled vacation or other authorized absence, every week, or eighty percent (80%) of the time the pharmacy is open, if opened less than forty (40) hours per week.

(b) A pharmacist may not serve as PIC for more than one pharmacy at a time. The name of the PIC shall be designated on the application of the pharmacy for the license and in each renewal period. A pharmacist may seek a waiver from the Board to serve as PIC for more than one pharmacy, provided those requirements for number of hours physically present in the pharmacy are met.

(c) It shall be the responsibility of the person, partnership, firm, or corporation holding a pharmacy license to notify the Board immediately of the disability of the PIC for a period exceeding thirty (30).

(d) A corporation or other non-pharmacist owner must comply strictly with the above provisions and provide a PIC who will have complete control of the pharmacy services of the pharmacy.

(e) Responsibilities of the PIC include requiring compliance with all federal and state pharmacy laws and regulations. It shall be the duty of the PIC to report all pharmacy violations within their facility to the Board, with the single exception that, whenever a PIC or staff pharmacist reports a pharmacist or pharmacy technician to the Wyoming Professional Assistance Program (WPAP) for suspected substance abuse, no further reporting to the Board regarding the name of the suspected substance abuse impaired pharmacist or pharmacy technician needs to be done. Any pharmacy technician-in-training or pharmacy intern suspected of substance abuse and reported to WPAP shall be reported to the Board.

(f) Additional responsibilities of the PIC shall be to:

(i) Establish policies and procedures for the procurement, storage, compounding and dispensing of pharmaceuticals;

(ii) Supervise the professional employees of the pharmacy;

(iii) Supervise the non-professional employees of the pharmacy;

(iv) Establish and supervise the recordkeeping for the security of all pharmaceuticals;

(v) Report any significant loss or theft of drugs to the Board and other authorities;

(vi) Ensure that all professional staff, including registered pharmacists, interns, pharmacy technicians-in-training and registered pharmacy technicians, have valid licenses or registrations in good standing and that all certificates are on display. Pharmacists must report any change of address or place of employment to the Board within fifteen (15) days of the change;

(vii) Ensure that all pharmacy licenses, including state and federal controlled substances registration, are valid and posted;

(viii) Develop and implement a procedure for drug recall, including a quarantine area designated separately from other drugs awaiting return; and

(A) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit or damaged prescription drugs or prescription drugs that are otherwise unfit for dispensing.

(B) The prescription drugs found to be unacceptable shall be quarantined from the rest of the stock until examination and determination that the prescribed drugs are not outdated, damaged, deteriorated, misbranded, counterfeit, contraband or adulterated.

(ix) Assure that all expired drug products are removed from active stock and placed in an area designated for return.

(g) Every pharmacy shall have at least one registered pharmacist on duty and physically present in the building at all times that the pharmacy is open for the transaction of business. If the pharmacist is absent from the building where there is a licensed retail pharmacy, the prescription department must be locked and kept so until that pharmacist's return. A sign stating "Prescription Department Closed – No Registered Pharmacist on Duty" shall be conspicuously posted.

(h) No pharmacy shall be permitted to operate without a PIC.

Section 10. Transfer of Prescription Orders Between Prescription Drug Outlets.

A prescription label or a written copy of a prescription order from another pharmacy may be issued for informational purposes only and shall not be considered to be a valid prescription order. A pharmacist who receives such a label or prescription order copy shall either contact the prescribing practitioner for authorization to dispense the prescription or, alternatively, shall comply with this section.

(a) A pharmacist, pharmacy technician or pharmacy intern shall transfer prescription order information for non-controlled substances upon the request of a patient. Transfer of prescription order information for the purpose of refilling a prescription is subject to the following requirements:

(i) The information is communicated verbally by one pharmacist or pharmacy intern to another pharmacist;

(ii) The information is sent to the receiving pharmacy via fax by a pharmacist, pharmacy intern, or pharmacy technician with the consent of the supervising pharmacist;

(iii) The information is electronically transferred between pharmacies by a pharmacist, pharmacy intern or pharmacy technician with the consent of the supervising pharmacist;

(iv) A pharmacy intern may receive a transferred prescription for non-controlled substances if the transfer is initiated by a pharmacist, not another pharmacy intern or pharmacy technician; or

(v) Pharmacies electronically transferring information must satisfy all information requirements of a transferred prescription including those requirements in W.S. § 33-24-136.

(b) The transferring pharmacist, pharmacy technician or pharmacy intern shall:

(i) Write the word “void” across the face of the original prescription order to make the order invalid or electronically document that the prescription has been voided; and

(ii) Record on the reverse side of the invalidated prescription order or electronic document:

(A) His/her name;

(B) The name of the receiving pharmacist;

(C) The name of the receiving pharmacy;

(D) The telephone number of the receiving pharmacy; and

(E) The date of the transfer.

(c) The pharmacist or pharmacy intern receiving the transferred prescription order information shall create a written or electronic record of the prescription, write the word “transfer” or a word of similar import on the face of the transferred prescription order or electronically document that the prescription has been transferred, and provide all information required by law or regulation to be on the prescription order, including:

(i) The name of the patient, including the date of birth, if available;

(ii) The name of the prescribing practitioner and DEA number, if a controlled substance;

(iii) The date of issue of the original prescription order;

(iv) The date of the initial compounding and dispensing of the original prescription order;

(v) The number of refills authorized;

(vi) The number of valid refills remaining;

(vii) The date of the last refill of the original prescription order;

(viii) The prescription order number from which the prescription order information was transferred;

(ix) The name of the transferring pharmacist or pharmacy intern; and

(x) The name and telephone number of the transferring pharmacy.

(d) The transferring pharmacy shall retain the original prescription order.

(e) The receiving pharmacy shall retain the transferred prescription order.

(f) The pharmacist or pharmacy intern at the receiving pharmacy at the time of the dispensing of the transferred prescription shall inform the patient that the prescription order is now invalid at the pharmacy from which it was transferred.

(g) A transferring pharmacy shall comply with all requirements of this regulation, including invalidation of the prescription order and deactivation of the order in the computer.

(h) Nothing in this rule shall be deemed to permit the transfer of a prescription order for a Schedule II controlled substance.

(i) A prescription order for a controlled substance in Schedule III through V may be transferred only one time, that transfer being from the pharmacy where the prescription was originally filled. It shall not be further transferred by, or to, any other pharmacy. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the practitioner's authorization.

(j) The transfers of Schedules III, IV and V controlled substances are subject to the following requirements:

(i) The transfer must be communicated directly between two licensed pharmacists;

(ii) The transferring pharmacist must do the following:

(A) Write the word "VOID" on the face of the invalidated prescription; or for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record;

(B) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record; and

(C) Record the date of the transfer and the name of the pharmacist transferring the information.

(iii) For paper prescriptions and prescriptions received verbally, and reduced to writing or an electronic record by a pharmacist, the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing or an electronic record all information require including:

(A) Date of issuance of original prescription;

(B) Original number of refills authorized on original prescription;

(C) Date of original dispensing;

(D) Number of valid refills remaining and date(s) and locations of previous refills;

(E) Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;

(F) Name of pharmacist who transferred the prescription; and

(G) Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled.

(iv) For an electronic prescription being transferred electronically, the transferring pharmacist shall provide the receiving pharmacist with the following information in addition to the original electronic prescription data:

(A) The date of the original dispensing;

(B) The number of refills remaining and the date(s) and locations of previous refill(s);

(C) The transferring pharmacy's name, address, DEA registration number and prescription number for each dispensing;

(D) The name of the pharmacist transferring the prescription; and

(E) The name, address, DEA registration number and prescription number from the pharmacy that originally filled the prescription, if different.

(v) The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription under this chapter.

(k) The original and transferred prescription(s) of controlled substances in Schedules III, IV and V must be maintained for a period of two (2) years from the date of last dispensing.

(l) Pharmacies electronically accessing the same prescription record for controlled substances in Schedules III, IV and V must satisfy all information requirements of a manual mode for prescription transfer.

(m) When a pharmacist receives a paper or verbal prescription indicating that the prescription was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription has not dispensed the prescription, that pharmacy must mark the electronic version as void or canceled. If the

pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.

(n) A prescription order for a non-controlled prescription drug may be transferred from one pharmacy to another pharmacy only so long as there are refills remaining and each pharmacy can establish that a valid refill existed at the time of dispensing.

(o) The original and transferred prescription(s) must be maintained for a period of two (2) years from the date of last dispensing.

Section 11. Labeling Prescription Drug Containers.

(a) All original or refill prescription drug containers utilized in a traditional dispensing system shall be labeled as follows:

(i) name of the patient;

(ii) brand or generic name of the drug product dispensed, unless otherwise specified;

(iii) drug strength and quantity;

(iv) the name, address, and telephone number of the pharmacy;

(v) the practitioner's name;

(vi) the serialized number of the prescription;

(vii) the date the prescription was filled or refilled;

(viii) purpose for use where appropriate;

(ix) directions for use; including accessory cautionary information as required for patient safety;

(x) the identifying initials of the dispensing pharmacist; and

(xi) any other information required by federal or state law.

(b) All original or refill prescription drug containers utilized in a traditional dispensing system shall be labeled with the product's physical description, including any identification code that may appear on the tablets and capsules. A waiver will be granted for new drugs for the first one hundred-twenty (120) days on the market and ninety (90) days for drugs which the national reference file has no description on file.

(c) All unit does or unit of issue packaging shall be labeled as follows:

(i) Brand name and/or generic name of the prescription drug;

(ii) Strength;

(iii) Manufacturer's lot number;

(iv) Manufacturer's expiration date. If prepackaged or repackaged by the pharmacy, the expiration date shall be the lesser of the manufacturer's expiration date of twelve (12) months from the date of prepackaging or repackaging;

(v) All unit of issue packaging dispensed shall include the following information on the label, in addition to that required by this chapter;

(A) Name, address and telephone number of the pharmacy;

(B) Prescription number;

(C) Name of the patient;

(D) Name of the practitioner;

(E) Directions for use;

(F) Date dispensed;

(G) Initials of dispensing pharmacist;

(H) Accessory cautionary labels for patient safety; and

(I) Quantity of medication.

(vi) All unit of issue packaging dispensed by a retail pharmacy to residents of long-term care facilities, as defined in Chapter 15 of these rules, as well as prescription drugs dispensed from hospital emergency room departments, as described in Chapter 12 of these rules, shall be labeled with the product's physical description, including any identification code that may appear on the tablets and capsules.

Section 12. Child-Resistant Packaging.

(a) The Consumer Product Safety Commission enforces the Poison Prevention Packaging Act (PPPA), which requires that all prescription medication shall be dispensed in child-resistant packaging.

(b) Unless the prescription drug is expressly exempted from the federal regulations, the drug must be dispensed in a child-resistant package. Exceptions to this requirement do exist as follows:

(i) The purchaser may request either a one-time or a blanket waiver from the requirement. A one-time request shall be documented on the prescription or patient profile records by the pharmacist; or

(ii) The practitioner, at the request of the patient, may request a one-time waiver. However, the practitioner cannot request a blanket waiver.

(c) Child-resistant prescription containers cannot be reused for refills of prescriptions. However, glass containers may be reused, provided that a new safety closure is used.

Section 13. Record of Refills.

The following information shall be recorded in a readily retrievable manner when a prescription is filled: date refilled, quantity, and pharmacist's initials. If a refill was not authorized on the original prescription or, if no refills remain, the pharmacist may contact the prescriber to obtain a new prescription. If authorization is obtained, the name of the practitioner authorizing the prescription and, if applicable, the name of the agent transmitting the prescription, must be recorded, as well as the number of refills authorized.

Both the supervising pharmacist and the intern must initial any prescription or prescription refilled by the intern.

Section 14. Practitioner/Patient Relationship as Affecting Prescriptions.

(a) Upon learning that a practitioner/patient relationship has been terminated for reasons other than discharge of the patient by the practitioner, a pharmacist utilizing his/her professional judgment may honor a patient's request for remaining medication refills, for a period of not exceeding twelve (12) months.

(b) It shall be unprofessional conduct for a resident or non-resident pharmacy, or pharmacist, to dispense, sell or offer to sell prescription drugs to persons located within this State, or any other state, on the basis of a prescription generated solely through an internet practitioner consultation questionnaire. All pharmacies or pharmacists included in this section are prohibited from linking an internet site with or relating a site to any other site, business or practitioner that provides prescriptions for medications solely on the basis on an internet practitioner consultation questionnaire.

Section 15. Return or Exchange of Prescription Drugs.

(a) Pharmacies (institutional or retail) are prohibited from accepting from patients or their agents any dispensed prescription drug for re-dispensing, unless the following are met:

(i) If previously dispensed drugs are returned from locations that employ persons who are licensed to administer drugs, and the prescription drugs were maintained under the control of those persons licensed to administer drugs;

(ii) The prescription drugs shall be returned to the pharmacy from which they were originally dispensed;

(iii) The PIC of the pharmacy accepting the prescription drugs for re-dispensing shall ensure that conditions of transportation to the location, storage at the location and, during the return from the location, are such as to prevent deterioration or contamination by any means that would affect the efficacy or toxicity of the product to be re-dispensed;

(iv) The prescription drugs accepted for re-dispensing must have been initially dispensed as a unit dose package or unit of issue package;

(v) At least six (6) month expiration dating on the medications is required for returns; and

(vi) The pharmacy must meet the requirements pursuant to the Wyoming Drug Donation Program Act and have become a participating donation site.

(b) The following prescription drugs shall not under any circumstances be returned to the pharmacy for re-dispensing:

(i) Any prescription drug declared to be a controlled substance under state or federal law or regulation;

(ii) Any prescription drug dispensed in other than a unit dose package or unit of issue package;

(iii) Any partial or opened containers including packaged cards, manufactured unit dose or unit of issue packages; and

(iv) Any prescription drug not labeled in accordance with this chapter.

(c) When prescription drugs are returned, the following shall apply:

(i) Prescription drug products in manufacturer's unit dose or unit of issue package may be re-dispensed as often as necessary, provided that the integrity of the product and package are maintained and the product remains in date;

(ii) Prescription drug products that have been prepackaged or repackaged into unit dose and unit of issue package in the pharmacy may be re-dispensed one time only, provided that the integrity of the product and package are maintained, and then only in the package in which originally dispensed, except as provided in (iii) below; and

(iii) Prescription drug products which have been prepackaged or repackaged into unit of issue packages may be removed from such packages for dispensing in a traditional dispensing system. These drug products shall remain in their prepackaged unit of issue package until actual dispensing in a traditional dispensing system.

(d) In hospitals that have a licensed institutional pharmacy, the pharmacy may accept prescription drugs for re-dispensing or reissue from all areas of the hospital under the effective control of professionally qualified personnel. The labeling and packaging of such drugs shall meet the requirements of this chapter.

(e) When a drug has been packaged and prepared pursuant to a prescription order, but has not been delivered to either location or to the ultimate consumer, it may be returned to stock. A record shall be made indicating a return to stock and date of such return.

Section 16. Validity of Prescriptions.

A prescription written outside the scope of practice of the prescribing practitioner shall not be considered a valid prescription.

Section 17. Reinstatement of Registered Pharmacist License After Failure to Renew, Returning from Inactive Status, Issuance of Duplicate License.

(a) If a person requests reinstatement of their registered pharmacist license when said license has lapsed only for failure to pay renewal fees, the person shall:

(i) Write a letter requesting consideration of reinstatement;

(ii) Pay all back renewal fees, including annual fines, up to a maximum of five (5) years;

(iii) Provide copies of approved continuing education (CE) certificates for those years the license was lapsed, to a maximum of five (5) years. All CE certificates must be from approved providers;

(iv) Provide at least two (2) recent letters from a pharmacist or a pharmacy owner attesting to good character;

(v) If licensed outside Wyoming, provide a letter from the board of pharmacy in the state where licensed and currently practicing. This letter must state current license status and indicate if the license has been subject to any investigation or disciplinary action by the Board;

(vi) Complete two (2) fingerprint cards, provided by the Board, and include a check made payable to the Wyoming State Board of Pharmacy in the amount of fifty dollars ($50.00) to cover the cost of the criminal background history; and

(vii) Provide a notarized employer affidavit attesting to the active practice of pharmacy in the year preceding the date of the application for reinstatement. Active practice requires that the pharmacist work a minimum of four hundred (400) hours during this time period.

(b) Minimum competency for an inactive pharmacist shall be established to the satisfaction of the Board. When a registered pharmacist has been out of the practice of pharmacy for an extended period of time and wishes to reactivate that license, the Board shall determine on an individual basis the requirements needed to reactivate that license. The requirements may include the following.

(i) Pass a jurisprudence examination;

(ii) Internship under direct supervision. The internship period may vary depending upon how long the individual was out of practice; or

(iii) Board interview.

Section 18. Prescriptions in General.

(a) To be valid, the prescription, as defined in W.S. § 33-24-136(b), shall contain the following information:

(i) Name of patient;

(ii) Name and strength of drug;

(iii) Quantity to be dispensed;

(iv) Directions for using the drug;

(v) Date of issuance by practitioner;

(vi) Recognizable signature of the practitioner. The signature can be digital or electronic as defined in this chapter;

(vii) Prescriptions for controlled substances shall indicate the DEA number and address of the prescribing practitioner and address of the patient; and

(viii) In the case of a verbal order, the name of the authorized agent if conveyed by other than the prescribing practitioner.

(b) All verbal orders shall be recorded on a written or electronic prescription memorandum and filed, in accordance with W.S. § 33-24-136(a).

(c) Prescriptions may be transmitted by the pharmacist in written form; verbally, including telephone; fax; and electronic transmission. Schedule II controlled substance prescriptions may be transmitted by fax if they meet the conditions as outlined in this chapter. Controlled substance prescriptions may be transmitted electronically only to the extent allowed by federal and state law.

(d) Prescriptions received from out-of-state practitioners are valid only to the extent a practitioner licensed in Wyoming may prescribe that medication in Wyoming.

(e) The patient shall have the exclusive right to freedom of choice for any pharmacy to dispense prescription orders. No collaborative practice agreement between prescriber and pharmacy shall require that prescription orders be transmitted from the prescriber to only that pharmacy.

(f) The pharmacist shall be required to determine the accuracy and authenticity of all prescriptions received. Practitioners or their agents shall provide voice verification, when requested by the pharmacist. If refused, the prescription shall not be filled.

Section 19. Transmission of Prescription by Fax Machines.

(a) Prescriptions transmitted by fax shall include the following:

(i) Practitioner's recognizable signature;

(ii) A notation that this is a fax prescription;

(iii) Telephone number and fax number of the practitioner;

(iv) Name, address, telephone number and fax number of the pharmacy to which the prescription is being faxed;

(v) Date and time of fax; and

(vi) Name of the individual acting as the practitioner's agent if other than the practitioner.

(b) The originating fax prescription shall be put into the practitioner's patient file. It shall not be given to the patient.

(c) All fax machines used in transmitting prescriptions shall be programmed with a fax identification number so that the document received will show the sender's fax identification number.

(d) The fax machine for any receiving pharmacy shall be in the prescription department to protect patient confidentiality and shall utilize non-fading paper.

(e) Prescriptions for Schedules III, IV and V controlled substances may be transmitted by fax. Schedule II controlled substance prescriptions may be transmitted by fax if the Schedule II controlled substance prescription meets one of the following conditions:

(i) A prescription written for a Schedule II controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion;

(ii) A prescription written for a Schedule II controlled substance for a resident of a long-term care facility; or

(iii) A prescription written for a Schedule II controlled substance for a "terminally ill" patient. The pharmacist shall so annotate a faxed Schedule prescription as being for a "terminally ill" patient.

(f) The fax copy received by the pharmacist shall be deemed the original prescription order and shall be maintained as required by statute.

(g) A faxed prescription may be dispensed only by the pharmacy receiving the fax.

Section 20. Prescription Refill Information.

(a) Prescription refill permission may be obtained in written fax or electronic form, or by verbal verification.

(b) If prescription refill authorization is obtained by fax, the authorizing practitioner shall initial the document. All other requirements for valid prescriptions shall apply, including the pharmacist's responsibility to determine authenticity of information obtained by fax.

Section 21. Fax Machines in General.

Using fax equipment to circumvent documentation, authenticity, verification or other standards of pharmacy practice shall be considered unprofessional conduct.

Section 22. Therapeutic Equivalents.

(a) Therapeutic equivalents do not include therapeutic substitutions. Therapeutic equivalent is defined in W.S. § 33-24-147(a)(v). Therapeutic substitution is that class of drug having the same or similar action, but not the identical composition.

(b) Pharmaceuticals that are considered to be therapeutic substitution instead of generic substitution shall not be used by retail/non-resident pharmacies. An institutional pharmacy using a formulary may reach a written agreement with members of the medical staff under which therapeutic substitution is permitted for use of formulary drugs.

Section 23. Specific Requirements for Licensure of Non-Resident Pharmacies to Ship Prescription Drugs into the State.

(a) Any pharmacy operating from outside this State that ships, mails or delivers, in any manner, a dispensed prescription drug or legend drug to a patient in this State shall obtain

and hold a non-resident pharmacy license and, if applicable, a controlled substance registration.

(b) Said pharmacy license and controlled substance application shall be on forms supplied by the Board staff and shall be accompanied by the following information:

(i) A copy of the pharmacy license from the state of residence;

(ii) A copy of the latest inspection report from the state of residence;

(iii) A copy of current DEA registration;

(iv) A list of partners, members, or principal officers and registered agent for service of process, if any; and

(v) A list of all registered pharmacists and pharmacy technicians, specifying the PIC.

(c) Pharmacy license and controlled substance registrations shall be renewed annually by July 1.

(d) The Board office shall be notified of any change in ownership or PIC within thirty (30) days.

(e) Each non-resident pharmacy shall comply with statutory or regulatory requirements of the Board including, but not limited to, the "Wyoming Drug Identification Act" (W.S. § 33-24-201 through 204) and the "Wyoming Generic Substitution Act" (W.S. § 33-24-146 through -151).

(f) Each non-resident pharmacy shall maintain records of all prescriptions dispensed to patients in the State in readily retrievable form.

(g) Each non-resident pharmacy shall maintain pharmacy hours that permit the timely dispensing of prescriptions to patients in this State and provide a toll-free telephone service to facilitate communication between patients in this State and a pharmacist who has access to patient records.

(h) Counseling shall be accomplished on new prescriptions either verbally_or by written information accompanying the dispensed prescription.

(i) The Board may revoke, deny, or suspend the license and registration of any non-resident pharmacy for violations of W.S. § 33-24-152 and this chapter.

Section 24. Fees (including examination, re-examination, license, license renewal, registration, registration renewal, mailing list and late fees).

(a) The Board shall charge the following fees:

(i) Pharmacist licensure by examination or re-examination shall be seventy-five dollars ($75.00) paid to the Board, plus the NABP fee for the NAPLEX® and the MPJE® paid to NABP;

(ii) Pharmacist licensure by reciprocity shall be two hundred dollars ($200.00) paid to the Board plus the NABP fee for licensure transfer application and the MPJE® paid to NABP;

(iii) Pharmacist licensure renewal shall be one hundred dollars ($100.00) per year;

(iv) Pharmacy intern licensure shall be fifteen dollars ($15.00) and shall be renewed annually by September 30. Renewal fee shall be fifteen dollars ($15.00);

(v) Pharmacy technician licensure fee shall be fifty dollars ($50.00);

(vi) Pharmacy technician-in-training permit shall be fifteen dollars ($15.00);

(vii) Pharmacy technician renewal fee shall be fifty dollars ($50.00) per year;

(viii) Resident retail pharmacy license and renewals shall be one hundred fifty dollars ($150.00) per year;

(ix) Non-resident pharmacy license and renewals shall be three hundred dollars ($300.00) per year;

(x) A prescription drug manufacturer, distributor, reverse distributor, or wholesaler license and renewals shall be two hundred seventy-five dollars ($275.00) per year;

(xi) Medical Oxygen manufacturer or distributor license and renewals shall be one hundred dollars ($100.00) per year;

(xii) Outsourcing Facilities license and renewals shall be three hundred dollars ($300.00) per year;

(xiii) Third Party Logistics Provider license and renewals shall be two hundred seventy-five dollars ($275.00) per year;

(xiv) Wholesale Distributors of prescription drugs for non-human use license and renewals shall be two hundred seventy-five dollars ($275.00) per year;

(xv) Methamphetamine Precursor retail distributor license and renewals shall be twenty-five dollars ($25.00) per year;

(xvi) Ancillary Drug Supply permit and renewals shall be twenty-five dollars ($25.00) per year;

(xvii) Institutional pharmacy license and renewals shall be one hundred fifty dollars ($150.00) per year;

(xviii) The Board shall charge a two hundred fifty dollar ($250.00) fee for preparing and sending mailing lists of pharmacists, pharmacy technicians, pharmacy interns pharmacy technicians-in-training, pharmacies, controlled substance registrants and drug distributors. Each list shall constitute a separate mailing list. Federal and state agencies shall be exempt from payment of fees for mailing lists;

(xix) The Board shall charge a thirty-five dollar ($35.00) fee to verify the license of any non-resident pharmacy, manufacturer, distributor, wholesaler or reverse distributor; and

(xx) Duplicate licenses may be issued upon request when a licensee's name changes or the license becomes damaged or destroyed. There shall be a twenty five dollar ($25.00) fee charged for the duplicate license.

(b) The Board shall assess a late fee, in addition to the license or registration renewal fee, of licenses or registrants, as follows:

(i) A pharmacist whose license renewal application is postmarked or hand delivered to the Board office after December 31 shall be assessed a late fee of seventy-five dollars ($75.00) in addition to the license renewal fee;

(ii) A pharmacy intern whose license renewal application is postmarked or hand delivered to the Board office after September 30 shall be assessed a late fee of fifteen dollars ($15.00) in addition to the license renewal fee;

(iii) A pharmacy technician whose license renewal application is postmarked or hand delivered to the Board office after December 31 shall be assessed a late fee of thirty five dollars ($35.00) in addition to the license renewal fee;

(iv) A resident pharmacy whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

(v) A non-resident pharmacy whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of three hundred dollars ($300.00) in addition to the license renewal fee;

(vi) A manufacturer, distributor, or wholesaler of prescription drug products (drugs or oxygen) whose license renewal application is postmarked or hand delivered to the

Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

(vii) A medical oxygen distributor whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of one hundred dollars ($100.00) in addition to the license renewal fee;

(viii) An outsourcing facility whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of three hundred dollars ($300.00) in addition to the license renewal fee;

(ix) A third party logistics provider whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred seventy-five dollars ($275.00) in addition to the license renewal fee;

(x) A wholesale distributor of prescription drugs for non-human use whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred seventy-five dollars ($275.00); and

(xi) An institutional pharmacy whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

Section 25. Ancillary Drug Supply for Nursing Homes Hospices, Extended Care Facilities or Intermediate Care Facilities.

(a) Nursing homes, hospices, extended care facilities, or intermediate care facilities licensed by the Wyoming Department of Health may be issued a permit by the Board to maintain an ancillary supply of drugs, both scheduled and non-scheduled subject to approval by the Board. The drugs maintained in the ancillary drug supply shall remain the property of the pharmacy to which the permit was jointly issued.

(i) The pharmacy servicing the facility or facilities listed in this Chapter shall make application to the Board, on an application form provided by the Board. The Board may issue a permit, if the conditions of this section are met, in the name of the facility and the pharmacy authorizing the storage and use of an ancillary drug supply at the facility. This registration shall be valid until June 30 of each year. The permit must be renewed annually.

(ii) The fee for the permit shall be twenty-five dollars ($25.00) annually; and

(iii) The permit may be revoked by the Board, if conditions as outlined in this Section are not followed, or for other violations of the Wyoming Pharmacy Act or Wyoming Controlled Substances Act and/or Rules promulgated under said Acts.

(b) The ancillary drug supply shall be kept in a tamper-evident, sealed and secured container or secured automated dispensing device and used for:

(i) An emergency situation;

(ii) To temporarily replace unavailable medications; or

(iii) As a starter dose for the purpose of starting the initial therapy for a patient residing in a facility.

(c) The facility and the pharmacy servicing the facility shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, resident confidentiality and maintenance of the quality, potency and purity of the ancillary drug supply, including the formulary.

(i) Copies of the most recent drug supply policy and procedure manual shall be on file at both the facility and the pharmacy servicing the facility.

(ii) The ancillary drug supply policy and procedure manual shall be reviewed and approved annually by the Consultant Pharmacist of the facility and the facility's Director of Nursing.

(d) The ancillary drug supply stored in an automated dispensing device shall only be stocked and restocked by a pharmacist licensed by this Board or a registered pharmacy technician or pharmacy intern under his or her supervision.

(e) Drugs administered from the ancillary drug supply shall be limited to the following:

(i) A legend drug order given by the practitioner to a nurse for administration to a resident of a facility. Enough medication may be taken to cover dosing for ninety-six (96) hours or less, until the next scheduled delivery from the pharmacy. The pharmacist must be notified of the removal of medication within forty-eight (48) hours, to review the practitioner's order and resident's profile for potential contraindications and adverse drug reactions; and

(ii) Removal of any controlled substance can only be done after the pharmacist has received an order from the practitioner or verified that a prescription exists. No controlled substance can be removed from the ancillary box until the pharmacist grants access.

(f) If the pharmacy servicing the facility discontinues its service, the Board must be notified and the permit surrendered. If the new pharmacy provider desires to maintain an ancillary drug supply, the new pharmacy provider must make application to the Board.

(g) Facilities described in this section are exempt if the pharmacy providing their ancillary drug supply is physically located at the same site as the facility and this pharmacy possesses a DEA registration and is licensed by the Board.

Section 26. Reinstatement of a Revoked or Suspended Pharmacist or Pharmacy Technician License.

(a) A pharmacist or pharmacy technician whose license has been revoked or suspended by the Board may file an application, on a form supplied by the Board, requesting a hearing to present evidence to show why the license should be reinstated subject to the following:

(i) A pharmacist or pharmacy technician whose license was revoked by the Board may not file an application requesting a hearing until thirty-six (36) months have elapsed from the date the order revoking the pharmacist or pharmacy technician license became final;

(ii) A pharmacist or pharmacy technician whose license was suspended by the Board may not file an application requesting a hearing until one-half (1/2) of the suspension so ordered by the Board has elapsed;

(iii) A pharmacist shall submit an application fee of two hundred fifty dollars ($250.00) and pay for the cost of the hearing, if the Board issues an order denying reinstatement. The application fee is nonrefundable;

(iv) A pharmacy technician shall submit an application fee of one hundred twenty five dollars ($125.00) and pay for the cost of the hearing, if the Board issues an order denying reinstatement. The application fee is nonrefundable;

(v) The applicant must complete all questions and provide all information requested on the application;

(vi) An incomplete application and the accompanying fee will be returned and a hearing date will not be set by the Board; and

(vii) In the application, the pharmacist or pharmacy technician shall authorize any health professional who has examined or treated the applicant to disclose a diagnosis and the reasons for it to the Board and the Board staff.

(b) Applications received by the Board will be reviewed by the Executive Director. The Executive Director shall:

(i) Review the application for completeness. If information or attachments are missing, the application and fee will be returned to the applicant with a letter stating the reason(s) for the rejection; and

(ii) If the application is complete, the Executive Director, in consultation with a Compliance Officer, a member of the Board and the Board's Prosecuting Attorney shall make a decision if the evidence submitted supports reinstatement. The Executive Director will notify the applicant whether the Board staff will support or oppose the request for reinstatement. If

not, a hearing for reinstatement shall be scheduled by the Executive Director, if requested by the applicant.

(c) The Executive Director may require the applicant to submit to an examination by a health professional chosen by Board staff. The health professional shall report on the examination to Board staff and may testify at a hearing on reinstatement. Cost for the examination shall be the responsibility of the applicant.

(d) To be reinstated, a pharmacist must prove that he or she has been rehabilitated so that further violation of Wyoming Statutes and Board rules is not likely to occur, and that he or she is competent to practice pharmacy. The Board may, as a condition to establish competency, require successful completion of one or more of the following:

(i) The NAPLEX® with a minimum score of 75;

(ii) The MPJE® with a minimum score of 75; or

(iii) An internship, not to exceed 1,200 hours, as prescribed by the Board.

(e) To be reinstated, a pharmacy technician must prove that he or she has been rehabilitated so that further violation of Wyoming Statutes and Board rules is not likely to occur, and that he or she is competent to function as a pharmacy technician. The Board, as a condition to establish competency, may require successful completion of the PTCB Pharmacy Technician Certification Examination.

Section 27. Collaborative Pharmacist Care.

(a) A pharmacist planning to engage in collaborative practice shall have on file at the pharmacist's place of practice a written, signed collaborative practice agreement approved by the Board. This collaborative practice agreement allows the pharmacist, acting within the pharmacist's collaborative scope of practice, to conduct MTM approved by a prescribing practitioner acting within the scope of the practitioner's current practice.

(b) The collaborative practice agreement shall include:

(i) The names of the prescribing practitioner and the pharmacist who are parties to the collaborative practice agreement;

(ii) The specific types of MTM decisions that the pharmacist is allowed to make, which shall include:

(A) The types of diseases, drugs or drug categories involved, and the extent of MTM allowed in each case;

(B) The methods, procedures, decision criteria and plan the pharmacist is to follow when conducting MTM; and

(C) The procedures the pharmacist is to follow in the course of conducting MTM, including documentation of decisions and a plan or appropriate mechanism for communication and reporting to the prescribing practitioner concerning specific decisions. Documentation of decisions shall occur in the prescribing practitioner patient medical record. If the medical record is not available at the practice site, a copy of the documentation of decisions will be sent to the prescribing practitioner.

(iii) A method for the prescribing practitioner to monitor compliance with the collaborative practice agreement and clinical outcomes when MTM by the pharmacist has occurred and to intercede when necessary;

(iv) A provision that allows the prescribing practitioner to override the collaborative practice agreement whenever deemed necessary or appropriate;

(v) A provision allowing the practitioner, pharmacist and patient or patient's agent, parent or guardian to cancel the collaborative practice agreement at any time by written notice to all parties. The pharmacist shall retain the original notice of cancellation for two (2) years; and

(vi) The signatures of the pharmacist and prescribing practitioner who are entering into the collaborative practice agreement and the dates when signed.

(c) MTM shall occur only for a particular patient pursuant to a specific written order from the prescribing practitioner. The written order shall conform to the format established by the Board and shall include the following as a minimum:

(i) Patient's name, gender, date of birth, height and weight;

(ii) Allergies;

(iii) Medical diagnosis;

(iv) All current medication(s), including current dosages (including any laboratory test);

(v) Method of communicating information between pharmacist and practitioner;

(vi) Frequency of practitioner follow-up;

(vii) Date the order will be renewed (specific order must be renewed annually); and

(viii) Signatures of the practitioner, pharmacist and patient or the patient's agent, parent or guardian, and date signed.

(d) A pharmacist providing MTM for a patient shall obtain written consent from the patient or the patient's agent, parent or guardian prior to providing this service. MTM shall not be implemented for a particular patient, if the patient or patient's agent, parent or guardian refuses to give written consent after being informed of the responsibility for payment.

(e) At a minimum, the written collaborative practice agreement shall be reviewed and renewed annually. If necessary, the collaborative practice agreement may be revised. The Board must approve all revisions, once signed by the pharmacist and the prescribing practitioner, prior to implementation. The Board shall review and approve all collaborative practice agreements, including revisions, prior to implementation. This shall be accomplished as follows:

(i) The Board shall appoint a Collaborative Practice Advisory Committee. The Committee shall be composed of five (5) members. Composition shall be two (2) pharmacists currently licensed by the Board and in active practice in Wyoming, one of whom is a current member of the Board; two (2) physicians currently licensed by the Wyoming State Board of Medicine and in active practice in Wyoming one of whom is a current member of the Board of Medicine; and the Board of Pharmacy Executive Director;

(ii) A pharmacist who has developed a collaborative practice agreement shall forward five (5) copies of the signed collaborative practice agreement to the Board. The Executive Director shall convene the Committee to review pending collaborative practice agreements. The Committee shall have authority to recommend approval or rejection of the collaborative practice agreement;

(iii) The recommendation of the Committee shall be reported to the Board at their next regularly scheduled meeting or as needed. The Board's decision will be delivered to the pharmacist and prescribing practitioner within ten (10) days of the Board's decision; and

(iv) The pharmacist submitting a collaborative practice agreement or revisions to an approved collaborative practice agreement to the Board shall not practice under the collaborative practice agreement until notified of approval by the Executive Director.

(f) A pharmacist and prescribing practitioner entering into a collaborative practice agreement must be currently licensed by their respective boards and authorized to practice in this State.

(g) Nothing in this section shall be interpreted to permit a pharmacist to accept delegation of a physician's authority outside the limits included in W.S. § 33-26-402 of the Medical Practice Act and the Wyoming State Board of Medicine regulations.

Section 28. Electronic Prescription Transmission.

(a) Prescriptions of electronic transmission shall fulfill these requirements to be valid:

(i) Be transmitted to a licensed pharmacy of the patient's choice, exactly as transmitted by the prescribing practitioner or designated agent;

(ii) Identify the transmitter's telephone number for verbal confirmation of the time and date of transmission and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state laws and regulations;

(iii) Be transmitted by an authorized practitioner using a digital or an electronic signature unique to the practitioner, if the transmission is from computer to computer or from computer to fax machine; and

(iv) The electronic transmission shall be deemed the original prescription drug order, provided it is readily retrievable through the pharmacy computer system and meets those requirements outlined in W.S. § 33-24-136. The electronic transmission shall be maintained for two (2) years from the date of last dispensing;

(b) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of the prescription communicated by electronic transmission consistent with existing federal or state laws and regulations;

(c) All electronic equipment for receipt of prescriptions communicated by way of electronic transmission shall be maintained to prevent unauthorized access;

(d) Hard copy prescriptions presented to the patient that are generated from electronic media utilizing an electronic signature shall be applied to paper that utilizes security features that will ensure that the prescription is not subject to any form of copying or alteration;

(e) Prescriptions may be transmitted by fax to fax, as allowed in this chapter;

(f) Prescriptions submitted by electronic transmission shall include all the features listed in this chapter;

(g) Electronic prescriptions for controlled substances shall include the requirements of 21 CFR § 1311.10, including:

(i) The practitioner may issue a prescription for a Schedule II, III, IV or V controlled substance electronically if an electronic prescription application is used that has been certified by a third party auditor to ensure that the electronic prescription application records, stores and transmits the prescription accurately and consistently and that the individual practitioner has obtained a two-factor authentication credential for signing;

(ii) The electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner and the contents of the prescription must not be altered during transmission between the practitioner and pharmacy; and

(iii) The pharmacy receiving the electronic prescription must determine the third-party certification has found that the pharmacy application accurately and consistently imports, stores and displays the information required for the prescription, including the number of refills and the practitioner's digital signature.

Section 29. Resident Retail Pharmacy Closure or Change of Ownership.

(a) Resident Retail Pharmacy Closure. Not less than twenty-one (21) days prior to a resident retail pharmacy, licensed by the Board, permanently ceasing operation, the Board shall receive written notice of the following:

(i) The last day the retail pharmacy will be open for business;

(ii) The proposed disposition of all prescription files, both hard copy and electronic records;

(iii) The proposed disposition of all prescription drug inventory, including controlled and non-controlled prescription drug products;

(iv) The proposed method of communicating to the public the last day the pharmacy will be open for business, the location of prescription records after the pharmacy closes, and how the patients can arrange for transfer of their prescription records to a pharmacy of their choice. Included in this communication shall be a description of the method of transfer of prescription records, including the last day a transfer may be made from the pharmacy closing and the initial date the prescription may be transferred from the pharmacy that acquired the prescription records. Communication to the public must begin no later than fourteen (14) days prior to the last day the pharmacy will be open for business;

(v) If prescription records are not transferred to another pharmacy, the name, address and telephone number of the custodian of prescription records must be provided. Prescription records must be maintained for two (2) years from the date of closure;

(vi) The scheduled date to have all signage removed from the exterior and interior of the building that includes the wording "drug," "pharmacy," "drugstore," "Rx," "Apothecary" or other terms or symbols that might indicate or signify by any advertising medium that such an establishment is a licensed pharmacy;

(vii) The name, address and telephone number of the custodian of records for the following documents, which must be maintained for two (2) years from the date of closure:

(A) Completed DEA 222 forms or retrievable electronic equivalent;

(B) Invoices for purchases of Schedule III, IV and V controlled substances; and

(C) Patient signature logs.

(viii) The date the Drug Enforcement Administration (DEA) was contacted regarding the closure and that all invoices and DEA 222 forms referencing the sale of controlled substances at closure, blank DEA 222 forms, and the DEA registration certificate were returned to the regional DEA office;

(ix) At the close of business on the last day the retail pharmacy is open for business, a controlled substance inventory, including all Schedule II, III, IV and V controlled substances, shall be taken. This inventory shall be dated and signed by the PIC. A copy shall be provided to the Board;

(x) An inspection of the pharmacy shall be conducted by the Board after the retail pharmacy has closed for business and all prescription drug stock has been removed. At the time of inspection, the following documents shall be provided to the Compliance Officer:

(A) A copy of the final controlled substance inventory;

(B) Documentation, as noted in this chapter, regarding notification to the public of the closure of the retail pharmacy;

(C) The Wyoming retail pharmacy license;

(D) Documentation of the transfer of all prescription drug inventory (controlled and non-controlled) to a third party authorized to have such possession of inventory. Under no circumstance may prescription drug inventory remain in the possession of a person or business not authorized by law to have possession;

(E) Any changes to information previously provided to the Board as required in this chapter.

(xi) It is unprofessional conduct for a retail pharmacy to close in a manner other than that prescribed in this chapter; and

(xii) If a retail pharmacy purchases the patient prescription records (electronic and hard copy prescription), those records shall be maintained by the acquiring retail pharmacy for a minimum of two (2) years from the date of closure.

(b) Resident Retail Pharmacy Change of Ownership. When a change of ownership necessitates a change of DEA registration number, the following is required:

(i) Not less than twenty-one (21) days prior to a resident retail pharmacy, licensed by the Board, changing ownership, without closing, the Board shall receive written notice of the following:

(A) The last day the seller will have ownership of the retail pharmacy;

(B) The proposed disposition of all prescription files, including both hard copy and electronic records;

(C) The proposed transfer of the prescription drug inventory, including controlled and non-controlled prescription drug products;

(D) The proposed method of communicating to the public the change in ownership, not later than fourteen (14) days prior to the date the ownership will change;

(E) The name, address and telephone number of the custodian of records for the following documents of the seller, which must be retained for two (2) years from the date of the transfer of ownership:

(I) Completed DEA 222 forms or retrievable electronic equivalent;

(II) Invoice for purchases of Schedule III, IV and V controlled substances; and

(III) Patient signature logs.

(F) The date the DEA was contacted regarding the change of ownership and confirmation that all invoices and DEA 222 forms referencing the sale of controlled substances at closure, blank DEA 222 forms, and the DEA registration certificate were delivered to the regional DEA office.

(ii) At the close of business on the last date the pharmacy is under the prior ownership, a controlled substance inventory, including all Schedule II, III, IV and V controlled substances shall be taken. This inventory shall be dated and signed by the PIC from the prior and the new ownership. A copy shall be provided to the Board;

(iii) An inspection of the pharmacy shall be conducted by the Board after the change in ownership. The following documents shall be provided to the Compliance Officer:

(A) Documentation of the transfer of all controlled and non-controlled prescription drug inventory will be provided to the Board. Under no circumstances may prescription drug inventory remain in the possession of the person or business not authorized to have possession;

(B) The Wyoming retail pharmacy license of the prior owner;

(C) Any changes to information previously provided to the Board as required in this chapter;

(D) Information necessary to process a new Wyoming retail pharmacy license, including information about the new PIC; and

(E) Information necessary to process a new Wyoming controlled substance registration and federal DEA registration.

(iv) It is unprofessional conduct for a retail pharmacy to transfer ownership in a manner other than that prescribed in this chapter.

Section 30. Institutional Pharmacy Closure.

(a) Not less than twenty-one (21) days prior to an institutional pharmacy licensed by the Board permanently ceasing operation, the Board shall receive written notice of the following:

(i) The last day the institutional pharmacy will be open for business;

(ii) The proposed disposition of all prescription drug inventory including controlled and non-controlled prescription drug products;

(iii) The name, address and telephone number of the custodian of records for the following documents, which must be maintained for two (2) years from the date of closure:

(A) Completed DEA 222 forms or retrievable electronic equivalent;

(B) Invoices for purchases of Schedule III, IV and V controlled substances; and

(C) Patient specific records.

(iv) The date the DEA was contacted regarding the closure and confirmation that all invoices and DEA 222 forms referencing the sale of controlled substances at closure, blank DEA 222 forms and the DEA registration certificate were delivered to the regional DEA office.

(b) At the close of business on the last day the institutional pharmacy is open for business, a controlled substance inventory, including all Schedule II, III, IV and V controlled substances shall be taken. This inventory shall be dated and signed by the PIC. A copy shall be provided to the Board.

(c) An inspection of the pharmacy shall be conducted by the Board after the institutional pharmacy has closed for business and all prescription drug stock has been removed. At the time of inspection, the following documents shall be provided to the Compliance Officer:

(i) A copy of the final controlled substance inventory;

(ii) The Wyoming institutional pharmacy license;

(iii) Documentation of the transfer of all prescription drug inventory (controlled and non-controlled) to a third party authorized to have such possession of inventory. Under no circumstances may prescription drug inventory remain in the possession of a person or business that is not authorized by law to have possession; and

(iv) Any changes to information previously provided to the Board, as required in this chapter.

(d) It is unprofessional conduct for an institutional pharmacy to close in a manner than that prescribed in this chapter.

Section 31. Drug Samples.

It is unprofessional conduct for a licensee in an institutional or a retail pharmacy to distribute or dispense prescription drug samples.

Section 32. Centralized Prescription Processing.

(a) Definitions specific to this Section:

(i) "Centralized prescription processing," as used in this Section, means the processing by a pharmacy of a request from another pharmacy to refill a prescription drug order or to perform functions such as prospective or retrospective drug use review, claims adjudication, refill authorizations and therapeutic interventions.

(ii) "Dispensing pharmacy," as used in this Section, means a pharmacy that may outsource the processing of a prescription drug order to another pharmacy licensed by the Board.

(iii) "Central fill pharmacy," as used in this Section, means a pharmacy that processes a prescription drug order that was outsourced by a dispensing pharmacy licensed by the Board.

(iv) "Real-time," as used in this Section, means the transmission of information through data links so rapid that the information is available to the dispensing pharmacy and requesting pharmacy sites simultaneously.

(b) Minimum requirements:

(i) A dispensing pharmacy may outsource prescription drug order processing to another pharmacy licensed by the Board, provided the pharmacies:

(A) Have the same owner;

(B) Have entered into a written agreement, which complies with federal and state laws and regulations, specifying the services to be provided and the responsibilities and accountabilities of each pharmacy;

(C) Share a real-time database; and

(D) Maintain the original prescription at the dispensing pharmacy for a time period not less than two (2) years from the date last filled or refilled.

(ii) The PIC of the central fill pharmacy shall ensure that:

(A) The pharmacy maintains and uses storage or shipment containers and shipping processes that ensure drug stability and potency. Shipping processes shall include the use of appropriate packaging material or devices that ensure the drug is maintained at a temperature range that will maintain the integrity of the medication throughout the delivery process; and

(B) The dispensed prescriptions are shipped in containers sealed in such a manner as to show evidence of opening or tampering.

(iii) A resident dispensing or central fill pharmacy shall comply with the provisions of W.S. § 33-24-113 and this Section.

(iv) A dispensing or central fill pharmacy dispensing compounded non-sterile or sterile pharmaceuticals shall comply with the provisions of Chapter 13 or Chapter 17 of these rules.

(c) Notifications to patients. A pharmacy that outsources prescription processing to another pharmacy shall:

(i) Notify patients that their prescription may be outsourced to another pharmacy prior to outsourcing the prescription via posted signage, written notification or refill telephone message; and

(ii) If the prescription is delivered to the patient directly by the central fill pharmacy, the pharmacist employed by the central fill pharmacy shall ensure that the patient receives written notice of available counseling. Such notice shall include days and hours of availability, location of pharmacy and a toll-free telephone number the patient may utilize to contact a pharmacist for counseling or to answer questions. Such notice shall be included in each prescription delivery to a patient.

(d) Prescription labeling.

(i) The prescription label shall clearly indicate which pharmacy filled the prescription and which pharmacy dispensed the prescription; and

(ii) The prescription label shall comply with this chapter.

(e) Policies and Procedures. A policy and procedures manual relating to centralized processing shall be maintained at both pharmacies and shall be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operation. The manual shall:

(i) Outline the responsibilities of each of the pharmacies;

(ii) Include a list of the names, addresses, telephone numbers and all license/registration numbers of the pharmacies involved in centralized prescription processing;

(iii) Include policies and procedures for:

(A) Notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription processing and providing the name of that pharmacy;

(B) Protecting the confidentiality and integrity of patient information;

(C) Dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received;

(D) Complying with federal and state laws and regulations;

(E) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;

(F) Identifying the pharmacist responsible for each aspect of prescription preparation including, but not limited to, the drug regimen review, the initial electronic entry, any changes or modifications to the prescription record or patient profile and the final check of the completed prescription;

(G) Identifying the pharmacist responsible for making the offer to counsel the patients as required by Chapter 9 of these rules; and

(H) Documentation of annual review of the written policies and procedures.

(f) Records.

(i) Records shall be maintained in a real-time electronic database;

(ii) Each pharmacy shall comply with all the laws and rules relating to the maintenance of records and be able to produce an audit trail showing all prescriptions dispensed by the pharmacy and each pharmacist's or technician's involvement in dispensing;

(iii) The dispensing pharmacy shall maintain records which indicate:

(A) The date and time the request for processing was transmitted to the central fill pharmacy; and

(B) The date and time the dispensed prescription was received from the central fill pharmacy by the dispensing pharmacy, including the method of delivery (e.g., private, common or contract carrier) and the name of the person accepting delivery.

(iv) The central fill pharmacy shall maintain records which indicate the date the prescription was shipped to the dispensing pharmacy.

Section 33. Automated Storage and Distribution Systems.

(a) Before using an automated storage and distribution system, a PIC shall:

(i) Ensure that the automated storage and distribution system and the policies and procedures comply with this chapter; and

(ii) Notify the Board in writing of the intent to use an automated storage and distribution system, including the type or name of the system.

(b) The PIC shall establish policies and procedures for appropriate performance and use of the automated storage and distribution system that:

(i) Ensure that the automated storage and distribution system is in good working order while maintaining appropriate recordkeeping and security safeguards. This is to include the ability to store at the required temperature;

(ii) Ensure that an automated storage and distribution system used by a pharmacy that allows access to drug or devices by a patient:

(A) Only allows patient access to prescriptions that:

(I) Do not require an offer to counsel by a pharmacist as specified in W.S. § 33-24-136(c);

(II) Are properly labeled and verified by a pharmacist before placement into the automated storage and distribution system and subsequent release to patients; and

(III) Are not a Schedule II controlled substance under the Wyoming Controlled Substances Act.

(B) Allows a patient to choose whether or not to use the system;

(C) Is located inside a building in a wall of a licensed pharmacy where the pharmacy staff has access to the device from within the pharmacy and patients have access from outside the pharmacy and is attached to the wall in such a manner that prevents unauthorized removal;

(D) Provides a method to identify the patient and only release the identified patient's prescriptions;

(E) Is secure from access and removal of drugs or devices by unauthorized individuals;

(F) Provides a method for a patient to obtain consultation with a pharmacist, if requested by the patient; and

(G) Prevents dispensing of refilled prescriptions, if a pharmacist determines that the patient requires counseling.

(iii) Ensure that an automated storage and distribution system used by a pharmacy that allows access to drugs or devices for the purposes of administration only by authorized licensed personnel based on a valid prescription order or medication order.

(A) Provides for adequate security to prevent unauthorized individuals from accessing or obtaining drugs or devices; and

(B) Ensures the filling, stocking or restocking of all drugs or devices in the system may be done only by a pharmacist, pharmacy intern or pharmacy technician.

(iv) Implement an ongoing quality assurance program that monitors compliance with the established policies and procedures of the automated storage and distribution system and federal and state law.

(c) The PIC shall:

(i) Ensure the policies and procedures for the performance and use of an automated storage and distribution system are prepared, implemented and complied with;

(ii) Review and document annually and, if necessary, revise the policies and procedures required under this Section; and

(iii) Make the policies and procedures available for employee reference and inspection by the Board within the pharmacy and at any location outside the pharmacy where the automated storage and distribution system is used.

(d) The Board may prohibit a PIC from using an automated storage and distribution system if the pharmacy licensee or the pharmacy licensee's employees do not comply with the requirements of this Section.

Section 34. Electronic Records of Prescriptions.

Pursuant to W.S. § 33-24-136, a written or electronic record of a prescription shall be maintained and available for inspection by agents of the Board for a period of two (2) years from the date it is filed, as follows:

(a) The pharmacy system shall ensure the validity and retrievability of the original prescription information;

(b) A pharmacy shall be authorized to maintain an exact digitized image of the prescription drug order in an electronic record-keeping system;

(c) Faxed prescriptions received in electronic format may be electronically stored and maintained in a readily retrievable format;

(d) Electronically transmitted prescriptions may be electronically stored and maintained in a readily retrievable format;

(e) A pharmacy may retain any hard copy prescriptions in numerical or date order; and

(f) Disposal of the hard copy must be in a secure destruction method to ensure privacy and confidentiality of the contents.

Section 35. Drug Disposal Including Controlled Substances.

Information for patients regarding disposal of their personal prescription drugs that are outdated, unusable, or no longer prescribed is hereby incorporated by reference.

Section 36. Dangerous Substance List.

Pursuant to W.S. § 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,* as the official listing of Dangerous Substances for the State of Wyoming is hereby incorporated by reference.

Section 37. Incorporation by Reference.

(a) Any code, standard, rule or regulation incorporated by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (c) of this section.

(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

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 rule incorporated by reference in these rules is further identified as follows:

(i) The standard incorporated by reference in this section of these rules is "Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)," 36th Edition, 2016 as existing on January 17, 2017 including amendments adopted by the Food and Drug Administration (FDA) as of that date. The products in this list have been approved under section 505 of the federal Food, Drug, and Cosmetic Act. Copies of this standard can be obtained from the US Department of Health and Human Services, Food and Drug Administration, Office of Medical Products and Tobacco, center for Drug Evaluation and Research, Office of Generic Drugs, Office of Generic Drug Policy at the following location: www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ApprovedDrugProductswithTherapeuticEquivalenceEvaluationsOrangeBook/default.htm.

(ii) The incorporated standard for disposal of personal prescription drugs is available on the internet at: www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm;

(iii) The incorporated standard for disposal of controlled substances by DEA registrants is available on the internet at www.deadiversion.uisdoj.gov/fed_regs/rules/2014/2014-20926.pdf; and

(iv) The standard incorporated by reference in these rules is the Federal Register Volume 79. No. 174, Tuesday, September 9, 2014, Department of Justice, Drug Enforcement Administration, 21 CFR Parts 1300, 1301, 1304, specifically § 1317.30 through § 1317.95 disposal of Controlled Substances: Final Rule. Copies of this rule can be obtained from the DEA at http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf.

GENERAL PRACTICE OF PHARMACY REGULATIONS

CHAPTER 2

Section 1. Authority.

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

Section 2. Purpose.

The purpose of this regulation is to coordinate the requirements for pharmacy services by providing minimum standards, conditions, and physical guidelines for facilities and pharmacists in professional settings.

Section 3. Scope ~~of Chapter~~.

This ~~C~~chapter applies to any person, partnership, corporation, limited liability company, or other entity engaging in the practice of pharmacy within the state.

Section 4. Definitions.

(a) "Active pharmacy practice" means a pharmacist who engages in the practice of pharmacy, as defined in W.S. § 33-24-124, a minimum of four hundred (400) hours per calendar year.

(b) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(i) A practitioner (or by his or her authorized agent); or

(ii) The patient or research subject at the direction of the practitioner.

(c) "~~Emergency~~ Ancillary kit" means a tamper-evident sealed and secured container or secured automated dispensing device containing drugs.

(d) "Audit trail" means a record showing who has accessed an information technology application and what operations the user performed during a given period.

(e) "Authentication" means verifying the identity of the user ~~as a prerequisite~~prior to allowing access to the information application.

(f) "Automated Dispensing Device" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage,

packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

(g) "Board of Pharmacy" or "Board" means the Wyoming State Board of Pharmacy.

(h) "Collaborative pharmacy practice" is that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol and in collaboration to provide patient care services to achieve optimal medication use and desired patient outcomes.

(i) "Collaborative practice agreement" means a written voluntary agreement, ~~written and signed,~~ between a pharmacist and a prescribing practitioner that defines a collaborative practice.

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

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

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

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

However, "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with the labeling.

(k) "Confidential information" means information maintained by the pharmacist in the patient's records, or communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or, as the patient directs, to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being, and to such other persons or governmental agencies authorized by law to investigate controlled substance law violations.

(l) "Consultant pharmacist" means a pharmacist who establishes policies and procedures for the distribution and storage of drugs, visits the facility on a regularly scheduled basis, but is not physically present at the facility for a set number of hours on a daily basis, and conducts prospective and retrospective drug utilization reviews, including the identification of problems and recommendations for resolution of identified problems for residents of the facility.

(m) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(n) “Device” means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part of accessory, which is required under federal law to bear the label, “Caution: Federal law restricts this device to sale by or on the order of a physician.”

(o) “Digital signature” means an electronic identifier that:

(i) Is intended by the party using it to have the same force and effect as a manual signature;

(ii) Is unique to the authorized signer;

(iii) Is capable of verification;

(iv) Is under the sole control of the authorized signer;

(v) Is linked to the prescription in such a manner, that, if the prescription information is changed, the signature is invalidated; and

(vi) Conforms to Wyoming State Statute and Board Rules and Regulations.

(p) “Dispense” means the interpretation, evaluation and implementation of a prescription drug or nonprescription drug under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient, research subject or an animal.

(q) “Distribute” means the delivery of a drug or device other than by administering or dispensing.

(r) “Dosage form” means the physical formulation or medium in which the product is manufactured and made available for use including, but not limited to, tablets, capsules, oral solutions, aerosols, inhalers, gels, lotions, creams, ointments, transdermals and suppositories.

(s) “Drug” means an article recognized as a drug in any official compendium, or supplement thereto, designated for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals.

(t) “Drug therapy management” means the same as medication therapy management as defined in this Chapter.

(u) “Electronic prescription” means a prescription that is generated on an electronic application and transmitted as an electronic data file.

(v) “Electronic signature” means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person’s approval of the information contained in the message.

(w) "Electronic transmission" means:

(i) Transmission of the digital representation of information from one computer or other similar electronic device to another computer, which is authenticated by a digital signature; or

(ii) Transmission of the electronic representation of information from one computer or other similar electronic device to a facsimile (fax) machine, which is authenticated by an electronic signature.

(x) "Foreign pharmacy graduate" means a pharmacist whose undergraduate pharmacy degree was conferred by a recognized school of pharmacy outside of the ~~50~~ United States, the District of Columbia and Puerto Rico. United States citizens who have completed their pharmacy education outside the United States are foreign pharmacy graduates. Foreign nationals who have graduated from schools in the United States are not foreign pharmacy graduates.

(y) "Labeling" means the process of preparing and affixing a label to any drug container, exclusive of the labeling by a manufacturer, packager or distributor.

(z) "Medication therapy management" (also known as "drug therapy management") is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medical therapy management (MTM) services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. ~~Medication therapy management~~ MTM encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice. MTM services may be performed without a collaborative practice agreement. These services may include, but are not limited to, the following, according to the individual needs of the patient:

(i) Performing or obtaining necessary assessments of the patient's health status;

(ii) Formulating a medication treatment plan;

(iii) Selecting, initiating, modifying or administering medication therapy;

(iv) Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;

(v) Performing a comprehensive medication review to identify, resolve and prevent medication-related problems, including adverse drug events;

(vi) Documenting the care delivered and communicating essential information to the patient's other primary care providers;

(vii) Providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;

(viii) Providing information, support services and resources designed to enhance patient adherence with his or her therapeutic regimens;

(ix) Coordinating and integrating ~~Medication therapy management~~ MTM services within the broader health care management services being provided to the patient;

(x) Such other patient care services as may be allowed by law; or

(xi) Ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, as it directly relates to MTM, provided:

(A) The pharmacy or service is certified by the US Department of Health and Human Services, as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA); or

(B) The tests do not otherwise require a physician's order and the pharmacy or service has obtained a CLIA Certificate of Waiver from the US Department of Health and Human Services; and

(C) The pharmacist is qualified to direct the laboratory.

(aa) "Non-resident pharmacy" means a licensed pharmacy located outside this ~~s~~State where drugs are dispensed and/or pharmaceutical care is provided to residents within this state.

(bb) "Paper prescription" means a prescription created on paper or computer generated to be printed or transmitted via fax that includes a manual signature.

(cc) "Patient confidences" as used in WYO. STAT. ANN. § 33-24-101(b)(4)(C)~~(c)(iii),~~ means information transmitted by the prescribing practitioner or agent to the pharmacist or agent for the purpose~~s~~ of treating the patient and information transmitted by the patient or agent to the pharmacist or agent for the purpose~~s~~ of treatment, and includes the patient's name, address, medical condition and drugs lawfully prescribed for the patient. The pharmacist may release otherwise confidential information pertaining to the patient's treatment to a minor's parent or guardian, the patient's third-party payor or the patient's agent.

(dd) "Patient counseling" means the ~~oral~~verbal communication by the pharmacist of information, to the patient or caregiver, in order to improve therapy by ensuring proper use of drugs and devices. Patient counseling may be supplemented with printed materials.

(ee) "Pharmacist care" (also known as pharmaceutical care) is patient care activities provided by a pharmacist, with or without the dispensing of drugs or devices, intended to achieve positive clinical outcomes and to optimize the patient's health-related quality of life.

(ff) "Pharmacist's collaborative scope of practice" means those duties and limitations of duties agreed upon by a pharmacist and the collaborating practitioner (subject to Board approval and applicable law), and includes the limitations implied by the specialty practiced by the collaborating practitioner.

(gg) "Pharmacist-in-Charge" ("PIC") means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws, rules ~~and regulations~~ pertinent to the practice of pharmacy and the distribution of drugs.

(hh) "Pharmacy" means an area(s) where drugs are dispensed and/or pharmacist care is provided.

(ii) "Pharmacy intern" is described in Chapter 3 of these rules.

(jj) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which he/she practices to prescribe drugs in the course of professional practice.

(kk) "Prepackage" means to prepare a drug in a container in advance of actual, immediate need for dispensing, prior to the receipt of an order. Such packaging may be in a unit dose or unit of issue package for use in a unit dose dispensing system or in a container suitable for a traditional dispensing system.

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

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

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

(iii) "Rx Only."

(mm) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient.

(nn) "Readily retrievable" means ~~that certain~~ records ~~are~~ kept in such a manner that they can be separated out from all other records and produced for review within forty-eight (48) hours.

(oo) "Registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy.

(pp) "Remodeled pharmacy" means an existing retail pharmacy that is relocated to a different address, or a pharmacy that undergoes remodeling at ~~its present location, and the~~ a cost ~~of such remodeling is~~ equal to or greater than twenty-five thousand dollars ($25,000.00).

(qq) "Repackage" means to prepare a unit dose or unit of issue package or traditional dispensing system package for dispensing pursuant to an existing order.

(rr) "State Board," as used in W.S. § 33-24-136(b), shall mean the boards of medicine, dental examiners, nursing, podiatry, optometry and veterinary medicine of the State of Wyoming and their similar counterpart boards of any of the states in the United States of America.

(ss) "Traditional dispensing system" means a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages.

(tt) "Unit dose dispensing system" means a drug distribution system that is in a pharmacy and uses unit dose packages or unit of issue packages that enable distribution of packaged doses in a manner that preserves the identity and the integrity of the drug.

(uu) "Unit dose package" means a package that contains one unit of medication.

(vv) "Unit of issue package" means a package that provides multiple units of doses separated in a medication card or other similarly designed container.

(ww) ~~"Wholesale distributor" means any person or firm engaged in wholesale distribution of drugs including, but not limited to, a manufacturer; repackager; own-label distributor; private-label distributor; third-party logistics provider; jobber; broker' warehouse, including manufacturers' and distributors' warehouses, chain drug warehouse and wholesale drug warehouses; independent wholesale drug trader; and any retail pharmacy that conducts wholesale distribution."~~"Wholesale distributor" is defined in Chapter 8, of these rules.

Section 5. Pharmacist Licensure by Examination.

(a) The Board shall utilize those standardized examinations as prepared and administered by the National Association of Boards of Pharmacy (NABP). These standardized examinations shall include the following:

(i) North American Pharmacist Licensing Examination (NAPLEX®); and

(ii) Multistate Pharmacy Jurisprudence Examination (MPJE®).

(b) Applicants for licensure by examination will be licensed, provided they:

(i) Submit a properly completed "Pharmacist License by Examination" application, as provided by the Board, with the proper fee and fee/fingerprints for a criminal background check. However, any applicant who has on file at the Board office a criminal background history dated within twelve (12) months of the date of application need not resubmit fee/fingerprints for a criminal background history;

(ii) Pass the NAPLEX® with a minimum score of 75;

(A) Candidates who do not receive a passing grade on the NAPLEX® shall be allowed two (2) retakes, for a total of three (3) examinations.

(B) All retakes require payment of fees plus a ~~ninety one (91)~~ forty-five (45) day waiting period, as required by NABP.

(iii) Pass the MPJE® for Wyoming with a minimum score of 75;

(A) Candidates who do not receive a passing grade on the MPJE® for Wyoming may retake the examination for a maximum of five (5) attempts.

(B) All retakes require payment of fees, plus a thirty (30) day waiting period, as required by NABP.

(iv) Meet the required practical experience requirement of 1,200 internship hours as specified in Chapter 3 of these rules;

(v) Complete all requirements within two (2) years of the date of application to the Board office;

(vi) Meet the requirements of W.S. § 33-24-116; and

(vii) ~~Receive at the Board~~ Ensure the Board receives the results of a criminal background history report from the Wyoming Division of Criminal Investigation (DCI).

(c) Applicants who have applied for score transfer of their NAPLEX® examination to Wyoming will be licensed by examination provided they meet the following requirements:

(i) The NAPLEX® score transferred is 75 or more;

(ii) A properly completed "Pharmacist Licensure by Examination" application, as provided by the Board, with the proper fee, has been submitted to the Board office;

(iii) Pass the MPJE® for Wyoming with a minimum score of 75;

(A) Candidates who do not receive a passing grade on the MPJE® for Wyoming may retake the examination for a maximum of five (5) attempts.

(B) All retakes require payment of fees, plus a thirty (30) day waiting period, as required by the NABP.

(iv) The required practical experience requirement of 1,200 internship hours is met, as specified in Chapter 3 of these rules;

(v) All requirements completed within one (1) year of the date of the NAPLEX® examination, which was utilized for the score which was transferred to Wyoming;

(vi) Board receipt of a criminal background history report from the DCI; and

(vii) Meet the requirements of W.S. § 33-24-116.

(d) No candidate will be licensed until the required practical experience, as specified in Chapter 3 of these rules has been met.

(e) Candidates failing to meet all requirements within the time period allowed in this chapter must file a new application, including payment of the fees or, if applicable, seek licensure by license transfer, as outlined in this chapter.

(f) The Board reserves the right to require an interview with any applicant seeking licensure by examination to practice pharmacy in Wyoming.

(g) The Board shall charge fees to cover administrative costs, which shall include one (1) wall certificate and a renewal certificate for the current license year.

(h) Foreign pharmacy graduates, holding a FPGEC® Certificate issued by the Foreign Pharmacy Graduate Examination Committee ®, may apply for licensure as a pharmacist under this section. To be eligible for FPGEC® certification, applicants must satisfy the following requirements established by the FPGEC®:

(i) Provide v~~V~~erification of educational equivalency of an applicant's foreign pharmacy education and the applicant's licensure or registration as a pharmacist outside the United States;

(ii) Pass~~ing~~ the Foreign Pharmacy Graduate Equivalency Examination (FPGEE®); and

(iii) ~~Obtaining a total score of 550 or higher on the paper based Test of English as a Foreign Language (TOEFL®), or 213 or higher on the computer-based TOEFL®, and 50 or higher on the Test of Spoken English ™ (TSE®); or~~Obtain an acceptable score on the Test of English as a Foreign Language Internet-based Test (TOEFL® iBT), with minimal scores of ~~18~~21 for listening, ~~21~~22 for reading, 26 for speaking and 24 for writing.

(iv) ~~In lieu of the TOEFL® and TSE®, obtaining an acceptable score of the Test of English as a Foreign Language Internet-based Test TOEFL® iBT), with minimal scores of 18 for listening, 21 for reading, 26 for speaking and 24 for writing.~~

Section 6. Pharmacist Licensure by Reciprocal License Transfer.

Any pharmacist, who is licensed by examination and is in good standing in any state which is a member of the NABP and who desires to be licensed by reciprocity into this state, shall proceed in the manner outlined by the NABP after first submitting the "Preliminary Application for Transfer of Pharmacist Licensure" obtained from the NABP.

(a) All candidates for license transfer shall be required to:

(i) File all appropriate applications with the Board;

(ii) Pay the required application fee;

(iii) Complete the two (2) fingerprint cards provided by the Board ~~in order to conduct a~~ for the criminal background check;

(iv) Pay the required criminal background check fee;

(v) Pass the MPJE® for Wyoming;

(vi) Prove good moral character;

(vii) Prove they have been in active pharmacy practice, as defined in this chapter, for the year preceding the date of their application for license transfer. Applicants failing to show proof must complete an internship in Wyoming approved by the Board of no less than four hundred (400) hours;

(viii) Meet all requirements under the Wyoming Pharmacy Act and these ~~Board~~ rules ~~and Regulations~~; and

(ix) If applying as a foreign pharmacy graduate, possess a~~nd~~ FPGEC® Certificate.

(b) The Board must receive the applicant's criminal background history report from the DCI before a pharmacist license by transfer will be issued.

(c) The Board shall not issue a pharmacist license by license transfer until all conditions under this chapter have been met.

(d) All applications for ~~transfer of~~ licensure by ~~(~~reciprocity~~)~~ shall expire one (1) year from date of issue by the NABP~~, if not filed with the Board and licensure completed~~.

(e) The Board reserves the right to require an interview with any applicant seeking licensure by ~~license transferby~~ reciprocity to practice pharmacy in Wyoming.

(f) In the event of rejecting an application, the fees paid to the Board will not be refunded.

(g) The Board will accept licensure by reciprocity ~~transfer~~ for pharmacists licensed in California after January 1, 2004.

Section 7. Minimum Structural and Equipment Requirements to Operate a Retail Pharmacy.

(a) All retail pharmacies operating in ~~Wyoming~~ this State must meet the following requirements:

(i) The pharmacy shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with adequate sewage disposal;

(ii) The pharmacy shall be properly lighted and ventilated. The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of pharmaceuticals;

(iii) The pharmacy shall have adequate shelving; there shall be adequate counter space ~~on which to work~~; the working surface shall be kept clear and uncluttered at all times for the preparation or compounding of prescriptions to meet the requirements of the pharmacy. Any pharmacy where compounding prescriptions occurs must meet the structural and equipment requirements identified in Chapter 13 of these rules;

(iv) A fax machine or similar electronic equipment capable of producing an identical document shall be located in the pharmacy;

(v) A separate refrigerator located in the pharmacy, ~~which is~~with sufficient ~~in~~ capacity to serve the needs of the pharmacy, ~~and is~~ equipped with a thermometer~~, and~~ which provides a storage temperature of 36-46 degrees Fahrenheit (2-8 degrees Centigrade). The use of such refrigerator shall be limited to the storage of drugs. If a freezer compartment is utilized, it must maintain a temperature of -13 to 14 degrees Fahrenheit (-20 to -10 degrees Centigrade);

(vi) Class A prescription balance or electronic scale with 10 mg sensitivity;

(vii) A professional reference library (text or electronic format) that shall include the following:

(A) Current Wyoming pharmacy laws;

(B) Current edition of *Facts and Comparisons* or a comparable reference accepted by the Board;

(C) Current drug interaction text that provides, at a minimum, quarterly updates;

(D) Wyoming State Board of Pharmacy quarterly newsletter by access to the Board website; and

(E) The current edition (as incorporated by reference in this Chapter), with supplements, of the U.S. Food and Drug Administration (FDA) "~~o~~Orange ~~b~~Book" or an alternate reference that provides the same information as the FDA "~~o~~Orange ~~b~~Book." Proven access to the Board website link to the Orange Book meets this requirement.

(viii) Pharmacies must maintain adequate security to deter theft of drugs by personnel or public. Security requirements for new or remodeled pharmacies must meet the requirements of this chapter. No person other than the pharmacist, intern or technician employed by the pharmacy shall be permitted in the pharmacy without the express consent of the PIC. If the pharmacy is located in a facility in which the public has access and the pharmacy's hours of operation are different from the rest of the facility, the pharmacy must be designed so that it can be securely locked and made inaccessible when the pharmacy is not open;

~~(A) If the pharmacy is located in a facility in which the public has access and the pharmacy's hours of operation are different from the rest of the facility, the pharmacy must be designed so that it can be securely locked and made inaccessible when the pharmacy is not open.~~

(ix) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition;

(x) If automated counting devices are utilized, the pharmacy shall have a method to calibrate and verify the accuracy of the automated counting device and shall verify the accuracy and document doing so on a quarterly basis;

(xi) Consecutive numbering of all prescriptions must be maintained, along with appropriate printing equipment to product prescription drug labels; and

(xii) In addition to the requirements identified in this chapter, all pharmacies involved in the preparation of sterile compounded products must meet the requirements of Chapter 17 of these rules~~, Sterile Compounding~~.

(b) In addition to the requirements of this chapter, except for a change of ownership of an existing pharmacy, an individual or business who opens a new pharmacy or remodels an existing retail pharmacy ~~after July 1, 2010 shall meet the following requirements~~ shall provide to the Board staff no later than thirty (30) calendar days prior to commencing construction or remodeling the pharmacy, a set of blueprints or other acceptable documents, which indicate the physical layout of the planned or remodeled pharmacy.

~~(i) Provide a set of blueprints or other acceptable documents, which indicate the physical layout of the planned or remodeled pharmacy, to the Board no later than thirty (30) calendar days prior to commencing construction or remodeling of the pharmacy; and~~

(c) The proposed new pharmacy or pharmacy to be remodeled ~~must~~ shall meet the following minimum standards:

(i) The pharmacy shall consist of no less than 500 square feet;

(ii) The pharmacy shall include an identified counseling area, which is apart from the cash register, apart from the prescription "pick up" area, and offers sufficient privacy

for counseling. A separation of three (3) feet is the minimum space between patients to allow for privacy during counseling. Pharmacies that do not provide prescription services to "Walk-in" customers are not required to have a counseling area;

(iii) Located within the pharmacy, but not counted in the square footage requirements of the pharmacy, shall be restroom facilities, access to which shall be limited to pharmacy staff;

(iv) Access to the pharmacy shall be secured as follows:

(A) If the pharmacy is located within another business, which does not have identical hours of operation, the pharmacy shall be secured with solid core or metal doors with a deadbolt and a locking doorknob. If glassed areas are utilized, then adequate intrusion detectors must be in place. Pharmacy walls must extend to the roof or provide security acceptable to the Board. The pharmacy shall meet all other applicable federal or state regulations concerning security access.

(B) Those pharmacies not included in (~~I~~A) ~~must~~ shall be secured with solid core, metal or safety glass exterior doors secured with a deadbolt, and must utilize an adequate intrusion detector. If the pharmacy shares a common wall with another business, this wall must extend to the roof. The pharmacy shall meet all other applicable federal or state regulations concerning security access.

(v) A separate refrigerator, sufficient in capacity to serve the needs of the pharmacy staff, shall be available for storage of employees' food or beverage. This refrigerator shall be identified for "Employee Use Only~~.~~;" and

(vi) All prescription data shall be processed utilizing electronic data processing equipment and shall be sequentially numbered. There shall be adequate computer terminals and printers available to process anticipated prescription volume for the new or remodeled pharmacy.

(d) Upon written request, and for good cause, the Board may waive any of the requirements of this chapter. A waiver that is granted under this section shall only be effective when issued by the Board in writing.

(e) For a change in ownership of a retail or institutional pharmacy, the Board shall be notified at least twenty-one (21) days before the change.

Section 8. Licensing of Facilities.

(a) Prior to the issuing of the registration to operate a pharmacy or prescription department in Wyoming, the Board will inspect the pharmacy for minimum standards including space, fixtures, sanitation, reference library, technical equipment and security. The application will include the number of hours the pharmacy will be in operation per week.

(b) The facility application shall list the names of all licensed pharmacists employed, specifically identifying the Pharmacist-in-Charge (PIC). The PIC determines which employees shall have access to the pharmacy.

(c) The Board shall be notified within seven (7) days of every change in PIC. A controlled substance inventory is required when there is a change in PIC, at the time of the change. This inventory shall include the signatures of both the outgoing and incoming PIC, and the date and time the inventory was taken. If the inventory cannot be conducted with both pharmacists, then the incoming PIC shall conduct an inventory. A copy of the controlled substance inventory and signed Certification of Responsibilities as Pharmacist-in-Charge (PIC) shall be forwarded to the Board office within fifteen (15) days of conducting the inventory.

(d) When a pharmacy changes ownership, the original license becomes void and a new license must be secured by the new owner or owners. A new license is required even if there is no change in the name of the pharmacy or in the registered PIC of the pharmacy.

In the case of a corporation, limited liability company or partnership holding a pharmacy license, the Board shall be notified and a new license applied for any time the majority of stock in the corporation is sold or a majority of the partners of the partnership or members of the limited liability company change. This shall constitute new ownership. Requirements for the change of ownership are the same as outlined in this section.

(e) A pharmacy license registers the pharmacy to which it is issued only at the location specified on the application and is not transferable.

(f) The Board shall be notified in writing at least thirty (30) days before a pharmacy change of address. The new location shall be inspected by the Board prior to issuance of an amended pharmacy license for the new location. The new location must meet all requirements for a new or remodeled pharmacy, as noted in this chapter.

(g) All licenses and certificates issued by the Board shall be displayed in a prominent place in the facility and always in view of the public.

(h) Resident Pharmacy Licenses shall indicate “Institutional” or “Retail.” ~~and sub-specialties, including, but not limited to: long-term care, non-sterile compounding, nuclear or sterile compounding.~~

Section 9. Pharmacist-in-Charge (PIC).

Every licensed pharmacy must be in the continuous daily charge of a pharmacist. A pharmacist shall be designated as the PIC and shall have direct control of the pharmacy services of said pharmacy.

(a) A pharmacist may not serve as the PIC unless said pharmacist is physically present in the pharmacy a minimum of thirty-two (32) hours per week, except for time periods of less than thirty (30) days when absent due to illness, family illness or death, scheduled

vacation or other authorized absence, every week, or eighty percent (80%) of the time the pharmacy is open, if opened less than forty (40) hours per week.

(b) A pharmacist may not serve as PIC for more than one pharmacy at a time. The name of the PIC shall be designated on the application of the pharmacy for the license and in each renewal period. A pharmacist may seek a waiver from the Board to serve as PIC for more than one pharmacy, provided those requirements for number of hours physically present in the pharmacy are met.

(c) It shall be the responsibility of the person, partnership, firm, or corporation holding a pharmacy license to notify the Board immediately of the disability ~~for a period exceeding thirty (30) days~~ of the PIC for a period exceeding thirty (30) days ~~who will have complete control over the pharmacy services of said~~ the ~~pharmacy~~.

(d) A corporation or other non-pharmacist owner must comply strictly with the above provisions and provide a PIC who will have complete control of the pharmacy services of ~~said~~ the pharmacy.

(e) Responsibilities~~y~~ ~~as~~of the PIC include~~s~~ requiring compliance with ~~that~~ all federal and state pharmacy laws and regulations ~~are complied with and enforced~~. It shall be the duty of the PIC to report all pharmacy violations within their facility to the Board, with the single exception that, whenever a PIC or staff pharmacist reports a pharmacist or pharmacy technician to the Wyoming Professional Assistance Program (WPAP) for suspected substance abuse, no further reporting to the Board regarding the name of the suspected substance abuse impaired pharmacist or pharmacy technician needs to be done. Any pharmacy technician-in-training or pharmacy intern suspected of substance abuse and reported to WPAP shall be reported to the Board.

(f) Additional responsibilities of the PIC shall be to:

(i) Establish policies and procedures for the procurement, storage, compounding and dispensing of pharmaceuticals;

(ii) Supervise the professional employees of the pharmacy;

(iii) Supervise the non-professional employees of the pharmacy;

(iv) Establish and supervise the recordkeeping for the security of all pharmaceuticals;

(v) Report any significant loss or theft of drugs to the Board and other authorities;

(vi) Ensure that all professional staff, ~~to include~~ including registered pharmacists, interns, pharmacy technicians-in-training and registered pharmacy technicians, ~~has~~ have valid licenses or registrations in good standing and that all certificates are on display.

Pharmacists must report any change of address or place of employment to the Board within fifteen (15) days of the change;

(vii) Ensure that all pharmacy licenses, including state and federal controlled substances registration, are valid and posted;

(viii) Develop and implement a procedure for drug recall, including a quarantine area designated separately from other drugs awaiting return; and

(A) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit or damaged prescription drugs or prescription drugs that are otherwise unfit for dispensing.

(B) The prescription drugs found to be unacceptable shall be quarantined from the rest of the stock until examination and determination that the prescribed drugs are not outdated, damaged, deteriorated, misbranded, counterfeit, contraband or adulterated.

(ix) Assure that all expired drug products are removed from active stock and placed in an area designated for return.

(g) Every pharmacy shall have at least one registered pharmacist on duty and physically present in the building at all times that the pharmacy is open for the transaction of business. If the pharmacist is absent from the building where there is a licensed retail pharmacy, the prescription department must be locked and kept so until that pharmacist's return. A sign stating "Prescription Department Closed – No Registered Pharmacist on Duty" shall be conspicuously posted.

(i) ~~If the pharmacist is absent from the building where there is a licensed retail pharmacy, the prescription department must be locked and kept so until that pharmacist's return. A sign stating "Prescription Department Closed – No Registered Pharmacist on Duty" shall be conspicuously posted.~~

(h) No pharmacy shall be permitted to operate without a PIC.

Section 10. Transfer of Prescription Orders Between Prescription Drug Outlets.

A prescription label or a written copy of a prescription order from another pharmacy may be issued for informational purposes only and shall not be considered to be a valid prescription order. A pharmacist who receives such a label or prescription order copy shall either contact the prescribing practitioner for authorization to dispense the prescription or, alternatively, shall comply with this section.

(a) A pharmacist, pharmacy technician or pharmacy intern ~~will~~shall transfer prescription order information for non-controlled substances upon the request of a patient. Transfer of prescription order information for the purpose of refilling a prescription is subject to

the following requirements:~~. The information is communicated directly by one pharmacist, pharmacy intern or pharmacy technician to another pharmacist, or the information is sent to the receiving pharmacist via fax, or the information may be electronically transferred between pharmacies. A pharmacy intern may receive a transferred prescription for non-controlled substances if the transfer is initiated by a pharmacist, not another pharmacy intern or pharmacy technician. Pharmacies electronically transferring information must satisfy all information requirements of a transferred prescription that is communicated directly by one pharmacist to another pharmacist, including those requirements in W.S. § 33-24-136a.~~

(i) The information is communicated verbally by one pharmacist or pharmacy intern to another pharmacist;

(ii) The information is sent to the receiving pharmacy via fax by a pharmacist, pharmacy intern, or pharmacy technician with the consent of the supervising pharmacist;

(iii) The information is electronically transferred between pharmacies by a pharmacist, pharmacy intern or pharmacy technician with the consent of the supervising pharmacist;

(iv) A pharmacy intern may receive a transferred prescription for non-controlled substances if the transfer is initiated by a pharmacist, not another pharmacy intern or pharmacy technician; or

(v) Pharmacies electronically transferring information must satisfy all information requirements of a transferred prescription including those requirements in W.S. § 33-24-136.

(b) The transferring pharmacist, pharmacy technician or pharmacy intern shall:

(i) Write the word "void" across the face of the original prescription order to make the order invalid or electronically document that the prescription has been voided; and

(ii) Record on the reverse side of the invalidated prescription order or electronic document:

(A) His/her name;

(B) The name of the receiving pharmacist;

(C) The name of the receiving pharmacy;

(D) The telephone number of the receiving pharmacy; and

(E) The date of the transfer.

(c) The pharmacist or pharmacy intern receiving the transferred prescription order information shall ~~reduce the transferred information to writing~~create a written or electronic record of the prescription, write the word "transfer" or a word of similar import on the face of the transferred prescription order or electronically document that the prescription has been transferred, and provide all information required by law or regulation to be on the prescription order, including:

(i) The name of the patient, including the date of birth, if available;

(ii) The name of the prescribing practitioner and DEA number, if a controlled substance;

(iii) The date of issue of the original prescription order;

(iv) The date of the initial compounding and dispensing of the original prescription order;

(v) The number of refills authorized;

(vi) The number of valid refills remaining;

(vii) The date of the last refill of the original prescription order;

(viii) The prescription order number from which the prescription order information was transferred;

(ix) The name of the transferring pharmacist or pharmacy intern; and

(x) The name and telephone number of the transferring pharmacy.

(d) The transferring pharmacy shall retain the original prescription order.

(e) The receiving pharmacy shall retain the transferred prescription order.

(f) The pharmacist or pharmacy intern at the receiving pharmacy at the time of the dispensing of the transferred prescription shall inform the patient that the prescription order is now invalid at the pharmacy from which it was transferred.

(g) A transferring pharmacy shall comply with all requirements of this regulation, including invalidation of the prescription order and deactivation of the order in the computer.

(h) Nothing in this ~~regulation~~ rule shall be deemed to permit the transfer of a prescription order for a Schedule II controlled substance.

(i) A prescription order for a controlled substance in Schedule III through V may be transferred only one time, that transfer being from the pharmacy where the prescription was originally filled. It shall not be further transferred by, or to, any other pharmacy. However,

pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the practitioner's authorization.

(j) The transfers of Schedules III, IV and V controlled substances are subject to the following requirements:

(i) The transfer must be communicated directly between two licensed pharmacists;

(ii) The transferring pharmacist must do the following:

(A) Write the word "VOID" on the face of the invalidated prescription; or for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record;

(B) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record; and

(C) Record the date of the transfer and the name of the pharmacist transferring the information.

(iii) For paper prescriptions and prescriptions received ~~orally~~verbally, and reduced to writing or an electronic record by ~~the~~a pharmacist, the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing or an electronic record all information required ~~to include~~including:

(A) Date of issuance of original prescription;

(B) Original number of refills authorized on original prescription;

(C) Date of original dispensing;

(D) Number of valid refills remaining and date(s) and locations of previous refills;

(E) Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;

(F) Name of pharmacist who transferred the prescription; and

(G) Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled.

(iv) For an electronic prescription being transferred electronically, the transferring pharmacist ~~must~~shall provide the receiving pharmacist with the following information in addition to the original electronic prescription data:

(A) The date of the original dispensing;

(B) The number of refills remaining and the date(s) and locations of previous refill(s);

(C) The transferring pharmacy's name, address, DEA registration number and prescription number for each dispensing;

(D) The name of the pharmacist transferring the prescription; and

(E) The name, address, DEA registration number and prescription number from the pharmacy that originally filled the prescription, if different.

(v) The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription under this chapter.

(k) The original and transferred prescription(s) of controlled substances in Schedules III, IV and V must be maintained for a period of two (2) years from the date of last dispensing.

(l) Pharmacies electronically accessing the same prescription record for controlled substances in Schedules III, IV and V must satisfy all information requirements of a manual mode for prescription transfer.

(m) When a pharmacist receives a paper or ~~oral~~verbal prescription ~~that indicates~~ indicating that ~~it~~ the prescription was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription has~~d~~ not dispensed the prescription, that pharmacy must mark the electronic version as void or canceled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.

(n) A prescription order for a non-controlled prescription drug may be transferred from one pharmacy to another pharmacy only so long as there are refills remaining and each pharmacy can establish that a valid refill existed at the time of dispensing.

(o) The original and transferred prescription(s) must be maintained for a period of two (2) years from the date of last dispensing.

Section 11. Labeling Prescription Drug Containers.

(a) All original or refill prescription drug containers utilized in a traditional dispensing system shall be labeled as follows:

(i) name of the patient;

(ii) brand or generic name of the drug product dispensed, unless otherwise specified;

(iii) drug strength and quantity;

(iv) the name, address, and telephone number of the pharmacy;

(v) the practitioner's name;

(vi) the serialized number of the prescription;

(vii) the date the prescription was filled or refilled;

(viii) purpose for use where appropriate;

(ix) directions for use; including accessory cautionary information as required for patient safety;

(x) the identifying initials of the dispensing pharmacist; and

(xi) any other information required by federal or state law.

(b) ~~Effective January 1, 2004,~~ ~~a~~All original or refill prescription drug containers utilized in a traditional dispensing system shall be labeled with the product's physical description, including any identification code that may appear on the tablets and capsules. A waiver will be granted for new drugs for the first one hundred-twenty (120) days on the market and ninety (90) days ~~on~~ for drugs ~~for~~ which the national reference file has no description on file.

(c) All unit does or unit of issue packaging shall be labeled as follows:

(i) Brand name and/or generic name of the prescription drug;

(ii) Strength;

(iii) Manufacturer's lot number;

(iv) Manufacturer's expiration date. If prepackaged or repackaged by the pharmacy, the expiration date shall be the lesser of the manufacturer's expiration date of twelve (12) months from the date of prepackaging or repackaging;

(v) All unit of issue packaging dispensed shall include the following information on the label, in addition to that required by this chapter;

(A) Name, address and telephone number of the pharmacy;

(B) Prescription number;

(C) Name of the patient;

(D) Name of the practitioner;

(E) Directions for use;

(F) Date dispensed;

(G) Initials of dispensing pharmacist;

(H) Accessory cautionary labels for patient safety; and

(I) Quantity of medication.

(vi) All unit of issue packaging dispensed by a retail pharmacy to residents of long-term care facilities, as defined in Chapter 15 of these rules, as well as prescription drugs dispensed from hospital emergency room departments, as described in Chapter 12 of these rules, shall be labeled with the product's physical description, including any identification code that may appear on the tablets and capsules.

Section 12. Child-Resistant Packaging.

(a) The Consumer Product Safety Commission enforces the Poison Prevention Packaging Act (PPPA), which requires that all prescription medication shall be dispensed in child-resistant packaging.

(b) Unless the prescription drug is expressly exempted from the federal regulations, the drug must be dispensed in a child-resistant package. Exceptions to this requirement do exist as follows:

(i) The purchaser may request either a one-time or a blanket waiver from the requirement. A one-time request shall be documented on the prescription or patient profile records by the pharmacist; or

(ii) The ~~physician~~practitioner, at the request of the patient, may request a one-time waiver. However, the ~~physician~~practitioner cannot request a blanket waiver.

(c) Child-resistant prescription containers cannot be reused for refills of prescriptions. However, glass containers may be reused, provided that a new safety closure is used.

Section 13. Record of Refills.

The following information shall be recorded in a readily retrievable manner when a prescription is filled: date refilled, quantity, and pharmacist's initials. If a refill was not authorized on the original prescription or, if no refills remain, the pharmacist may contact the prescriber to obtain a new prescription. If authorization is obtained, the name of the practitioner authorizing ~~this~~the prescription and, if applicable, the name of the agent transmitting the prescription, must be recorded, as well as the number of refills authorized.

Both the supervising pharmacist and the intern must initial any prescription or prescription refilled by the intern.

Section 14. ~~Doctor~~Practitioner/Patient Relationship as Affecting Prescriptions.

(a) Upon learning that a ~~patient/practitioner~~ practitioner/patient relationship has been terminated for reasons other than discharge of the patient by the practitioner, a pharmacist utilizing his/her professional judgment may honor a patient's request for remaining medication refills, for a period of not exceeding twelve (12) months.

(b) It shall be unprofessional conduct for a resident or non-resident pharmacy, or ~~a~~ pharmacist, to dispense, sell or offer to sell prescription drugs to persons located with in this ~~the~~ State, or any other state, on the basis of a prescription generated solely through an internet practitioner consultation questionnaire ~~physician consultation~~. ~~Furthermore,~~ ~~a~~All pharmacies or pharmacists included in this section are prohibited from linking an internet site with or relating ~~the~~ a site~~,~~ to any other site, business or ~~physician~~practitioner that provides prescriptions for medications solely on the basis on an ~~online medical~~ internet practitioner consultation questionnaire.

Section 15. Return or Exchange of Prescription Drugs.

(a) Pharmacies (institutional or retail) are prohibited from accepting from patients or their agents any dispensed prescription drug for re-dispensing, unless the following are met:

(b) ~~Prescription drugs may be accepted for re-dispensing if all the following are met:~~

(i) ~~Pharmacies may accept~~ If previously dispensed drugs ~~for return~~are returned from locations that employ persons who are licensed to administer drugs, and the prescription drugs were maintained under the control of those persons licensed to administer drugs~~.~~;

(ii) The prescription drugs shall ~~only~~ be returned to the pharmacy from which they were originally dispensed~~.~~;

(iii) The PIC of the pharmacy accepting the prescription drugs for re-dispensing shall ensure that conditions of transportation to the location, storage at the location~~,~~ and, during the return from the location, are such as to prevent deterioration ~~and/~~or contamination by any means that would affect the efficacy ~~and/~~or toxicity of the product to be re-dispensed~~.~~;

(iv) ~~P~~The prescription drugs accepted for re-dispensing must have been initially dispensed as a unit dose package or unit of issue package~~.~~;

(v) At least six (6) month expiration dating on the medications is required for returns; and

(vi) The pharmacy must meet the requirements pursuant to the Wyoming Drug Donation Program Act and have become a participating donation site.

(b) The following prescription drugs shall not under any circumstances be returned to the pharmacy for re-dispensing:

(i) Any prescription drug declared to be a controlled substance under state or federal law or regulation;

(ii) Any prescription drug dispensed in other than a unit dose package or unit of issue package~~.~~;

(iii) Any partial or opened containers including packaged cards, manufactured unit dose or unit of issue packages; and

(iv) Any prescription drug not labeled in accordance with this chapter.

(c) When prescription drugs are returned, the following shall apply:

(i) Prescription drug products in manufacturer's unit dose or unit of issue package may be re-dispensed as often as necessary, provided that the integrity of the product and package are maintained and the product remains in date;

(ii) Prescription drug products that have been prepackaged or repackaged into unit dose and unit of issue package in the pharmacy may be re-dispensed one time only, provided that the integrity of the product and package are maintained, and then only in the package in which originally dispensed, except as provided in (iii) below; and~~. Partially used unit of issue packages may not be emptied and the drugs removed and repackaged, nor may additional units of medication be added to partially used unit of issue packages.~~

(iii) Prescription ~~D~~drug products which have been prepackaged or repackaged into unit of issue packages may be removed from such packages for dispensing in a traditional dispensing system. These drug products shall remain in their prepackaged unit of issue package until actual dispensing in a traditional dispensing system.

(d) In hospitals that have a licensed institutional pharmacy, the pharmacy may accept prescription drugs for re-dispensing or reissue from all areas of the hospital under the effective control of professionally qualified personnel. The labeling and packaging of such drugs shall meet the requirements of this chapter.

(e) When a drug has been packaged and prepared pursuant to a prescription order, but has not been delivered to either location or to the ultimate consumer, it may be returned to stock. A record shall be made ~~on the prescription memorandum and the pharmacy's computer~~ indicating a return to stock and date of such return.

Section 16. ~~Scope of Practice~~Validity of Prescriptions.

A prescription written outside the scope of practice of the prescribing practitioner shall not be considered a valid prescription.

Section 17. Reinstatement of Registered Pharmacist License After Failure to Renew, Returning from Inactive Status, Issuance of Duplicate License.

(a) If a person requests reinstatement of their registered pharmacist license when said license has lapsed only for failure to pay renewal fees, the person shall:

(i) Write a letter requesting consideration of reinstatement;

(ii) Pay all back renewal fees, including annual fines, up to a maximum of five (5) years;

(iii) Provide copies of approved continuing education (CE) certificates for those years the license was lapsed, to a maximum of five (5) years. All CE certificates must be from approved providers~~.~~;

(iv) Provide at least two (2) recent letters from a pharmacist or a pharmacy owner attesting to good character;

(v) If licensed outside Wyoming, provide a letter from the board of pharmacy in the state where licensed and currently practicing. This letter must state current license status and indicate if the license has been subject to any investigation or disciplinary action by the Board;

(vi) Complete two (2) fingerprint cards, provided by the Board ~~office~~, and include a check made payable to the Wyoming State Board of Pharmacy in the amount of fifty dollars ($50.00) to cover the cost of the criminal background history; and

(vii) Provide a notarized employer affidavit attesting to the active practice of pharmacy in the year preceding the date of the application for reinstatement. Active practice requires that the pharmacist work a minimum of four hundred (400) hours during this time period.

(b) Minimum competency for an inactive pharmacist shall be established to the satisfaction of the Board. When a registered pharmacist has been out of the practice of pharmacy for an extended period of time and wishes to reactivate that license, the Board shall

determine on an individual basis the requirements needed to reactivate that license. The requirements ~~will~~ may include the following.

(i) Pass a jurisprudence examination;

(ii) Internship under direct supervision. The internship period may vary depending upon how long the individual was out of practice; or

(iii) Board interview.

Section 18. Prescriptions in General.

(a) To be valid, the prescription, as defined in W.S. § 33-24-136(b), shall contain the following information:

(i) Name of patient;

(ii) Name and strength of drug;

(iii) Quantity to be dispensed;

(iv) Directions for using the drug;

(v) Date of issuance by practitioner;

(vi) Recognizable signature of the practitioner. The signature can be ~~a~~ digital or electronic ~~signature~~ as defined in this chapter;

(vii) Prescriptions for controlled substances shall indicate the DEA number and address of the prescribing practitioner and address of the patient; and

(viii) In the case of a~~n oral~~ verbal order, the name of the authorized agent if conveyed by other than the prescribing practitioner.

(b) All ~~oral~~verbal orders shall be recorded on a written or electronic prescription memorandum and filed, in accordance with W.S. § 33-24-136(a).

(c) Prescriptions may be transmitted by the pharmacist in written form; ~~orally~~verbally, including ~~by~~ telephone; ~~by~~ fax; and ~~by~~ electronic transmission. Schedule II controlled substance prescriptions may be transmitted by fax if they meet the conditions as outlined in this chapter. Controlled substance prescriptions may be transmitted electronically only to the extent allowed by federal and state law.

(d) Prescriptions received from out-of-state practitioners are valid only to the extent a practitioner licensed in Wyoming may prescribe that medication in Wyoming.

(e) The patient shall have the exclusive right to freedom of choice for any pharmacy to dispense ~~his/her~~ prescription orders. No collaborative practice agreement between prescriber and pharmacy shall require that prescription orders be transmitted from the prescriber to only that pharmacy.

(f) The pharmacist shall be required to determine the accuracy and authenticity of all prescriptions received. Practitioners or their agents shall provide voice verification, when requested by the pharmacist. If refused, the prescription shall not be filled.

Section 19. Transmission of Prescription by Fax Machines.

(a) Prescriptions transmitted by fax shall include the following:~~all of the features listed in this chapter, including the practitioner's recognizable signature.~~

(a) ~~Other requirements for fax prescriptions include:~~

(i) Practitioner's recognizable signature;

(ii) A notation that this is a fax prescription;

(iii) Telephone number and fax number of the practitioner;

(iv) Name, address, telephone number and fax number of the pharmacy to which the prescription is being faxed;

(v) Date and time of fax; and

(vi) Name of the individual acting as the practitioner's agent if other than the practitioner.

(b) The originating fax prescription shall be put into the practitioner's patient file. It shall not be given to the patient.

(c) All fax machines used in transmitting prescriptions shall be programmed with a fax identification number so that the document received will show the sender's fax identification number.

(d) The fax machine for any receiving pharmacy shall be in the prescription department to protect patient confidentiality and shall utilize non-fading paper. ~~Alternatively, a non-fading photocopy of manually written copy of the faxed prescription shall be stapled to the fax.~~

(e) Prescriptions for Schedules III, IV and V controlled substances may be transmitted by fax. Schedule II controlled substance prescriptions may be transmitted by fax if the Schedule II controlled substance prescription meets one of the following conditions:

(i) A prescription written for a Schedule II controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion;

(ii) A prescription written for a Schedule II controlled substance for a resident of a long-term care facility; or

(iii) A prescription written for a Schedule II controlled substance for a "terminally ill" patient. The pharmacist shall so annotate a faxed Schedule prescription as being for a "terminally ill" patient.

(f) The fax copy received by the pharmacist shall be deemed the original prescription order and shall be maintained as required by statute.

(g) A faxed prescription may be dispensed only by the pharmacy receiving the fax.

Section 20. Prescription Refill Information.

(a) Prescription refill permission may be obtained in written fax or electronic form, or by ~~oral~~verbal verification~~, including telephone~~.

(b) If prescription refill authorization is obtained by fax,~~ it shall be initialed by the authorizing practitioner on~~ the authorizing practitioner shall initial the document. All other requirements for valid prescriptions shall apply, including the pharmacist's responsibility to determine authenticity of information obtained by fax.

Section 21. Fax Machines in General.

Using fax equipment to circumvent documentation, authenticity, verification or other standards of pharmacy practice shall be considered unprofessional conduct.

Section 22. Therapeutic Equivalents.

(a) Therapeutic equivalents do not include therapeutic substitutions. Therapeutic equivalent is defined in W.S. § 33-24-147(a)(v). Therapeutic substitution is that class of drug having the same or similar action, but not the identical composition.

(b) Pharmaceuticals that are considered to be therapeutic substitution instead of generic substitution shall not be used ~~for~~by retail/non-resident pharmacies. An ~~institutional hospital~~ pharmacy using a formulary may reach a written agreement with members of the medical staff under which therapeutic substitution is permitted for use of formulary drugs.

Section 23. Specific Requirements for Licensure of Non-Resident Pharmacies to Ship Prescription Drugs into the State.

(a) Any pharmacy operating from outside this State that ships, mails or delivers, in any manner, a dispensed prescription drug or legend drug to a patient in ~~Wyoming~~ this State shall obtain and hold a non-resident pharmacy license and, if applicable, a controlled substance registration.

(b) Said pharmacy license and controlled substance ~~registration~~application shall be on forms supplied by the Board staff and shall be accompanied by the following information~~. Applicant shall~~:

(i) ~~Submit~~ A copy of the pharmacy license from the state of residence;

(ii) ~~Submit~~ A copy of the latest inspection report from the state of residence;

(iii) ~~Submit~~ A copy of current DEA registration;

(iv) ~~Submit~~ A list of partners, members, or principal officers and registered agent for service of process, if any; and

(v) ~~Submit~~ A list of all registered pharmacists and pharmacy technicians, specifying the PIC.

(c) Pharmacy license and controlled substance registrations shall be renewed annually by July 1 ~~to continue doing business in the State~~.

(d) The Board office shall be notified of any change in ownership or PIC within thirty (30) days.

(e) Each non-resident pharmacy shall comply with statutory or regulatory requirements of the Board including, but not limited to, the "Wyoming Drug Identification Act" (W.S. § 33-24-201 through 204) and the "Wyoming Generic Substitution Act" (W.S. § 33-24-146 through -151).

(f) Each non-resident pharmacy shall maintain records of all prescriptions dispensed to patients in the State in readily retrievable form.

(g) Each non-resident pharmacy shall maintain pharmacy hours that permit the timely dispensing of prescriptions to patients in ~~the~~ this State and provide a toll-free telephone service to facilitate communication between patients in this State and a pharmacist who has access to patient~~'s~~ records.

(h) Counseling shall be accomplished on new prescriptions either verbally ~~orally and/~~or by written information accompanying the dispensed prescription.

(i) The Board may revoke, deny, or suspend the license and registration of any non-resident pharmacy for violations of W.S. § 33-24-152 and this chapter.

Section 24. Fees (including examination, re-examination, license, license renewal, registration, registration renewal, mailing list and late fees).

(a) The Board shall charge the following fees~~, as indicated~~:

(i) Pharmacist licensure by examination or re-examination shall be seventy-five dollars ($75.00) paid to the Board, plus the NABP fee for the NAPLEX® and the MPJE® paid to NABP;

(ii) Pharmacist licensure by reciprocity shall be two hundred dollars ($200.00) paid to the Board plus the NABP fee for licensure transfer application and the MPJE® paid to NABP;

(iii) Pharmacist licensure renewal shall be one hundred dollars ($100.00) per year~~.~~;

(iv) Pharmacy intern licensure shall be fifteen dollars ($15.00) and shall be renewed annually by September 30. Renewal fee shall be fifteen dollars ($15.00);

(v) Pharmacy technician licensure fee shall be fifty dollars ($50.00);

(vi) Pharmacy technician-in-training permit shall be fifteen dollars ($15.00);

(vii) Pharmacy technician renewal fee shall be fifty dollars ($50.00) per year;

(viii) Resident retail pharmacy license and renewals shall be one hundred fifty dollars ($150.00) per year;

(ix) Non-resident pharmacy license and renewals shall be three hundred dollars ($300.00) per year;

(x) A prescription drug manufacturer, distributor, reverse distributor, or wholesaler license and renewals shall be two hundred seventy-five dollars ($275.00) per year;

(xi) Medical Oxygen manufacturer or distributor license and renewals shall be one hundred dollars ($100.00) per year;

(xii) Outsourcing Facilities license and renewals shall be three hundred dollars ($300.00) per year;

(xiii) Third Party Logistics Provider license and renewals shall be two hundred seventy-five dollars ($275.00) per year;

(xiv) Wholesale Distributors of prescription drugs for non-human use license and renewals shall be two hundred seventy-five dollars ($275.00) per year;

(xv) Methamphetamine Precursor retail distributor license and renewals shall be twenty-five dollars ($25.00) per year;

(xvi) Ancillary Drug Supply permit and renewals shall be twenty-five dollars ($25.00) per year;

(xvii) Institutional pharmacy license and renewals shall be one hundred fifty dollars ($150.00) per year;

(xviii) The Board shall charge a two hundred fifty dollar ($250.00) fee for preparing and sending mailing lists of pharmacists, pharmacy technicians, pharmacy interns pharmacy technicians-in-training, pharmacies, controlled substance registrants and drug distributors. Each list shall constitute a separate mailing list. Federal and state agencies shall be exempt from payment of fees for mailing lists;

(xix) The Board shall charge a thirty-five dollar ($35.00) fee to verify the license of any non-resident pharmacy, manufacturer, distributor, wholesaler or reverse distributor; and

(xx) Duplicate licenses may be issued upon request when a licensee's name changes or the license becomes damaged or destroyed. There shall be a twenty five dollar ($25.00) fee charged for the duplicate license.

(b) The Board shall assess a late fee, in addition to the license or registration renewal fee, of licenses or registrants, as follows:

(i) A pharmacist whose license renewal application is postmarked or hand delivered to the Board office after December 31 shall be assessed a late fee of seventy-five dollars ($75.00) in addition to the license renewal fee;

(ii) A pharmacy intern whose license renewal application is postmarked or hand delivered to the Board office after September 30 shall be assessed a late fee of fifteen dollars ($15.00) in addition to the license renewal fee;

(iii) A pharmacy technician whose license renewal application is postmarked or hand delivered to the Board office after December 31 shall be assessed a late fee of thirty five dollars ($35.00) in addition to the license renewal fee;

(iv) A resident pharmacy whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

(v) A non-resident pharmacy whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of three hundred dollars ($300.00) in addition to the license renewal fee;

(vi) A manufacturer, distributor, or wholesaler of prescription drug products (drugs or oxygen) whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

(vii) A medical oxygen distributor whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of one hundred dollars ($100.00) in addition to the license renewal fee;

(viii) An outsourcing facility whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of three hundred dollars ($300.00) in addition to the license renewal fee;

(ix) A third party logistics provider whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred seventy-five dollars ($275.00) in addition to the license renewal fee;

(x) A wholesale distributor of prescription drugs for non-human use whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred seventy-five dollars ($275.00); and

(xi) An institutional pharmacy whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

~~(xii) A pharmacy intern whose license renewal application is postmarked or hand delivered to the Board office after September 30 shall be assessed a late fee of fifteen dollars ($15.00) in addition to the license renewal fee.~~

Section 25. ~~Emergency~~Ancillary Drug Supply for Nursing Homes Hospices, Extended Care Facilities or Intermediate Care Facilities.

(a) Nursing homes, hospices, extended care facilities, or intermediate care facilities licensed by the Wyoming Department of Health may be issued a permit by the Board to maintain an ~~emergency~~ancillary supply of drugs, both scheduled and non-scheduled subject to approval by the Board. The drugs maintained in the ~~emergency~~ancillary drug supply shall remain the property of the pharmacy to ~~whom~~which the permit was jointly issued.

(i) The pharmacy servicing the facility or facilities listed in this ~~C~~chapter shall make application to the Board, on an application form provided by the Board. The Board may issue a permit, if the conditions of this section are met, in the name of the facility and the pharmacy authorizing the storage and use of an ~~emergency~~ancillary drug supply at the facility. This registration shall be valid until June 30 of each year. The permit must be renewed annually.

(ii) The fee for the permit shall be twenty-five dollars ($25.00) annually; and

(iii) The permit may be revoked by the Board, if conditions as outlined in this Section are not followed, or for other violations of the Wyoming Pharmacy Act or Wyoming Controlled Substances Act and/or Rules ~~and Regulations~~ promulgated under said Acts.

(b) The ancillary drug supply shall be kept in a tamper-evident, sealed and secured container or secured automated dispensing device and used for:

(i) An emergency situation;

(ii) To temporarily replace unavailable medications; or

(iii) As a starter dose for the purpose of starting the initial therapy for a patient residing in a facility.

(c) The facility and the pharmacy servicing the facility shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, ~~patient~~resident confidentiality and maintenance of the quality, potency and purity of the ~~emergency~~ancillary drug supply, including the formulary.

(i) Copies of the most recent drug supply policy and procedure manual shall be on file at both the facility and the pharmacy servicing the facility.

(ii) The ~~emergency~~ancillary drug supply policy and procedure manual shall be reviewed and approved annually by the Consultant Pharmacist of the facility and the facility's Director of Nursing.

(d) The ~~emergency~~ancillary drug supply stored in an automated dispensing device ~~may~~ shall only be stocked and restocked by a pharmacist licensed by this Board or a registered pharmacy technician or pharmacy intern under his or her supervision. ~~Discrepancies in controlled substance inventories shall be documented and reported to the Board within seven (7) days of discovery.~~

(e) Drugs administered from the ~~emergency~~ancillary drug supply shall be limited to the following:

(i) A ~~new~~ legend drug order given by the practitioner to a nurse for administration to a ~~patient~~resident of a facility. Enough medication may be taken to cover dosing for ninety-six (96) hours or less, until the next scheduled delivery from the pharmacy. The pharmacist must be notified of the removal of medication within forty-eight (48) hours, to review the practitioner's order and ~~patient's~~ resident's profile for potential contraindications and adverse drug reactions; and

~~(ii) Drugs that a practitioner had ordered for a patient on an as needed basis, if the utilization and administration of those drugs are subject to ongoing review by a pharmacist. The pharmacist must be notified within forty eight (48) hours of the removal of the medication.~~

(ii) Removal of any controlled substance can only be done after the pharmacist has received an order from the practitioner or verified that a prescription exists. No controlled substance ~~medical~~ can be removed from the ~~emergency~~ancillary box until the pharmacist grants access ~~to the emergency drug supply~~.

(f) If the pharmacy servicing the facility discontinues its service, the Board must be notified and the permit surrendered. If the new pharmacy provider desires to maintain an ~~emergency~~ancillary drug supply, the new pharmacy provider must make application to the Board.

(g) Facilities described in this section are exempt ~~from the provisions of this Section, provided that~~ if the pharmacy providing their ~~emergency~~ancillary drug supply is physically located at the same site as the facility and this pharmacy possesses a DEA registration and is licensed by the ~~Wyoming State~~ Board ~~of Pharmacy~~.

Section 26. Reinstatement of a Revoked or Suspended Pharmacist or Pharmacy Technician License.

(a) A pharmacist or pharmacy technician whose license has been revoked or suspended by the Board may file an application, on a form supplied by the Board, requesting a hearing to present evidence to show why the license should be reinstated subject to the following:

(i) A pharmacist or pharmacy technician whose license was revoked by the Board may not file an application requesting a hearing until thirty-six (36) months have elapsed from the date the order revoking the pharmacist or pharmacy technician license became final;

(ii) A pharmacist or pharmacy technician whose license was suspended by the Board may not file an application requesting a hearing until one-half (1/2) of the suspension so ordered by the Board has elapsed;

(iii) A pharmacist shall submit an application fee of two hundred fifty dollars ($250.00) and pay for the cost of the hearing, if the Board issues an order denying reinstatement. The ~~$250.00~~ application fee ~~shall be submitted with the application and~~ is nonrefundable;

(iv) A pharmacy technician shall submit an application fee of one hundred twenty five dollars ($125.00) and pay for the cost of the hearing, if the Board issues an order denying reinstatement. The ~~$125.00~~ application fee ~~shall be submitted with the application and~~ is nonrefundable;

(v) The applicant must complete all questions and provide all information requested on the application;

(vi) An incomplete application and the accompanying fee will be returned and a hearing date will not be set by the Board; and

(vii) In the application, the pharmacist or pharmacy technician shall authorize any health professional who has examined or treated the applicant to disclose a diagnosis and the reasons for it to the Board and the Board staff.

(b) Applications received by the Board will be reviewed by the Executive Director. The Executive Director shall:

(i) Review the application for completeness. If information or attachments are missing, the application and fee will be returned to the applicant with a letter stating the reason(s) for the rejection; and

(ii) If the application is complete, the Executive Director, in consultation with a ~~Board Inspector/~~Compliance Officer, a member of the Board and ~~legal counsel~~the Board's Prosecuting Attorney shall make a decision if the evidence submitted supports reinstatement. The Executive Director will notify the applicant whether the Board staff will support or oppose the request for reinstatement. If not, a hearing for reinstatement shall be scheduled by the Executive Director, if requested by the applicant.

(c) ~~Board staff~~ The Executive Director may require the applicant to submit to an ~~health~~ examination by a health professional chosen by Board staff. The health professional shall report on the examination to Board staff and may testify at a hearing on reinstatement. Cost for the examination shall be the responsibility of the applicant.

(d) To be reinstated, a pharmacist must prove that he or she has been rehabilitated so that further violation of Wyoming Statutes and~~/or~~ Board rules is not likely to occur, and that he or she is competent to practice pharmacy. The Board may, as a condition to establish competency, require successful completion of one or more of the following:

(i) The NAPLEX® with a minimum score of 75;

(ii) The MPJE® with a minimum score of 75; ~~and/~~or

(iii) An internship, not to exceed 1,200 hours, as prescribed by the Board.

(e) To be reinstated, a pharmacy technician must prove that he or she has been rehabilitated so that further violation of Wyoming Statutes and~~/or~~ Board rules is not likely to occur, and that he or she is competent to function as a pharmacy technician. The Board, as a condition to establish competency, may require successful completion of the PTCB Pharmacy Technician Certification Examination.

Section 27. Collaborative Pharmacist Care.

(a) A pharmacist planning to engage in collaborative practice shall have on file at the pharmacist's place of practice a written, signed collaborative practice agreement approved by the Board. This collaborative practice agreement allows the pharmacist, acting within the pharmacist's collaborative scope of practice, to conduct ~~medication therapy management~~ MTM

approved by a prescribing practitioner acting within the scope of the practitioner's current practice.

(b) The collaborative practice agreement shall include:

(i) The names of the prescribing practitioner and the pharmacist who are parties to the collaborative practice agreement;

(ii) The specific types of ~~medical therapy management~~ MTM decisions that the pharmacist is allowed to make, which shall include:

(A) The types of diseases, drugs or drug categories involved, and the extent of ~~medication therapy management~~ MTM allowed in each case;

(B) The methods, procedures, decision criteria and plan the pharmacist is to follow when conducting ~~medication therapy management~~ MTM; and

(C) The procedures the pharmacist is to follow in the course of conducting ~~medication therapy management~~ MTM, including documentation of decisions and a plan or appropriate mechanism for communication and reporting to the prescribing practitioner concerning specific decisions. Documentation of decisions shall occur in the prescribing practitioner patient medical record. If the medical record is not available at the practice site, a copy of the documentation of decisions will be sent to the prescribing practitioner.

(iii) A method for the prescribing practitioner to monitor compliance with the collaborative practice agreement and clinical outcomes when ~~medication therapy management~~ MTM by the pharmacist has occurred and to intercede when necessary;

(iv) A provision that allows the prescribing practitioner to override the collaborative practice agreement whenever deemed necessary or appropriate;

(v) A provision allowing the practitioner, pharmacist and patient or patient's agent, parent or guardian to cancel the collaborative practice agreement at any time by written notice to all parties. The pharmacist shall retain the original notice of cancellation for two (2) years; and

(vi) The signatures of the pharmacist and prescribing practitioner who are entering into the collaborative practice agreement and the dates when signed.

(c) ~~Medication therapy management~~ MTM shall occur only for a particular patient pursuant to a specific written order from the prescribing practitioner. The written order shall conform to the format established by the Board and shall include the following as a minimum:

(i) Patient's name, gender, date of birth, height and weight;

(ii) Allergies;

(iii) Medical diagnosis;

(iv) All current medication(s), including current dosages (including any laboratory test);

(v) Method of communicating information between pharmacist and practitioner;

(vi) Frequency of practitioner follow-up;

(vii) Date the order will be renewed (specific order must be renewed annually); and

(viii) Signatures of the practitioner, pharmacist and patient or the patient's agent, parent or guardian, and date signed.

(d) A pharmacist providing ~~medication therapy management~~ MTM for a patient shall obtain written consent from the patient or the patient's agent, parent or guardian prior to providing this service. ~~medication therapy management~~ MTM shall not be implemented for a particular patient, if the patient or patient's agent, parent or guardian refuses to give written consent after being informed of the responsibility for payment.

(e) At a minimum, the written collaborative practice agreement shall be reviewed~~/~~ and renewed annually. If necessary, the collaborative practice agreement may be revised. The Board must approve all revisions, once signed by the pharmacist and the prescribing practitioner, prior to implementation. The Board shall review and approve all collaborative practice agreements, including revisions, prior to implementation. This shall be accomplished as follows:

(i) The Board shall appoint a Collaborative Practice Advisory Committee. The Committee shall be composed of five (5) members. Composition shall be two (2) pharmacists currently licensed by the Board ~~of Pharmacy~~ and in active practice in Wyoming, one of whom is a current member of the Board; two (2) physicians currently licensed by the Wyoming State Board of Medicine and in active practice in Wyoming one of whom is a current member of the Board of Medicine; and the Board of Pharmacy Executive Director;

(ii) A pharmacist who has developed a collaborative practice agreement shall forward five (5) copies of the signed collaborative practice agreement to the Board. The Executive Director shall convene the ~~Collaborative Practice Advisory~~ Committee to review pending collaborative practice agreements. The Committee shall have authority to recommend approval or rejection of the collaborative practice agreement;

(iii) The recommendation of the ~~Collaborative Practice Advisory~~ Committee shall be reported to the Board ~~of Pharmacy~~ at their next regularly scheduled meeting or as

needed. The Board's decision will be delivered to the pharmacist and prescribing practitioner within ten (10) days of the Board's decision; and

(iv) The pharmacist submitting a collaborative practice agreement or revisions to an approved collaborative practice agreement to the Board shall not practice under the collaborative practice agreement until notified of approval by the Executive Director.

(f) A pharmacist and prescribing practitioner entering into a collaborative practice agreement must be currently licensed by their respective boards and authorized to practice in ~~the~~ this State ~~of Wyoming~~.

(g) Nothing in this section shall be interpreted to permit a pharmacist to accept delegation of a physician's authority outside the limits included in W.S. § 33-26-~~202~~402 of the Medical Practice Act and the Wyoming State Board of Medicine regulations.

Section 28. Electronic Prescription Transmission.

(a) Prescriptions of electronic transmission shall fulfill these requirements to be valid:

(i) Be transmitted to a licensed pharmacy of the patient's choice, exactly as transmitted by the prescribing practitioner or designated agent;

(ii) Identify the transmitter's telephone number for verbal confirmation of the time and date of transmission and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state laws and regulations;

(iii) Be transmitted by an authorized practitioner using a digital or an electronic signature unique to the practitioner, if the transmission is from computer to computer or from computer to fax machine; and

(iv) The electronic transmission shall be deemed the original prescription drug order, provided it is readily retrievable through the pharmacy computer system and meets those requirements outlined in W.S. § 33-24-136. The electronic transmission shall be maintained for two (2) years from the date of last dispensing;

(b) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of the prescription communicated by electronic transmission consistent with existing federal or state laws and regulations;

(c) All electronic equipment for receipt of prescriptions communicated by way of electronic transmission shall be maintained to prevent unauthorized access;

(d) Hard copy prescriptions presented to the patient that are generated from electronic media utilizing an electronic signature shall be applied to paper that utilizes security

features that will ensure that the prescription is not subject to any form of copying ~~and/~~or alteration~~s~~;

(e) ~~However,~~ Prescriptions may be transmitted by fax to fax, as allowed in this chapter;

(f) Prescriptions submitted by electronic transmission shall include all the features listed in this chapter;

(g) Electronic prescriptions for controlled substances shall include the requirements ~~in the~~ of 21 CFR § 1311.10, including~~;~~:

(i) The practitioner may issue a prescription for a Schedule II, III, IV or V controlled substance electronically if an electronic prescription application is used that has been certified by a third party auditor to ensure that the electronic prescription application records, stores and transmits the prescription accurately and consistently and that the individual practitioner has obtained a two-factor authentication credential for signing;

(ii) The electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner and the contents of the prescription must not be altered during transmission between the practitioner and pharmacy; and

(iii) The pharmacy receiving the electronic prescription must determine the third-party certification has found that the pharmacy application accurately and consistently imports, stores and displays the information required for the prescription, including the number of refills and the practitioner's digital signature.

Section 29. Resident Retail Pharmacy Closure or Change of Ownership.

(a) Resident Retail Pharmacy Closure. Not less than twenty-one (21) days prior to a resident retail pharmacy, licensed by the Board, permanently ceasing operation, the Board shall receive written notice of the following:

(i) The last day the retail pharmacy will be open for business;

(ii) The proposed disposition of all prescription files, both hard copy and electronic records;

(iii) The proposed disposition of all prescription drug inventory, including controlled and non-controlled prescription drug products;

(iv) The proposed method of communicating to the public the last day the pharmacy will be open for business, the location of prescription records after the pharmacy closes, and how the patients can arrange for transfer of their prescription records to a pharmacy of their choice. Included in this communication shall be a description of the method

of transfer of prescription records, including the last day a transfer may be made from the pharmacy closing and the initial date the prescription may be transferred from the pharmacy that acquired the prescription records. Communication to the public must begin no later than fourteen (14) days prior to the last day the pharmacy will be open for business;

(v) If prescription records are not transferred to another pharmacy, the name, address and telephone number of the custodian of prescription records must be provided. Prescription records must be maintained for two (2) years from the date of closure;

(vi) The scheduled date to have all signage removed from the exterior and interior of the building that includes the wording "drug," "pharmacy," "drugstore," "Rx," "Apothecary" or other terms or symbols that might indicate or signify by any advertising medium that such an establishment is a licensed pharmacy;

(vii) The name, address and telephone number of the custodian of records for the following documents, which must be maintained for two (2) years from the date of closure:

(A) Completed DEA 222 forms or retrievable electronic equivalent;

(B) Invoices for purchases of Schedule III, IV and V controlled substances; and

(C) Patient signature logs.

(viii) The date the Drug Enforcement Administration (DEA) was contacted regarding the closure and ~~that the DEA was notified~~ that all invoices and DEA 222 forms referencing the sale of controlled substances at closure, blank DEA 222 forms, and the DEA registration certificate ~~will be delivered to the Board for disposition~~were returned to the regional DEA office;

(ix) At the close of business on the last day the retail pharmacy is open for business, a controlled substance inventory, including all Schedule II, III, IV and V controlled substances, shall be taken. This inventory shall be dated and signed by the PIC. A copy shall be provided to the Board;

(x) An inspection of the pharmacy shall be conducted by the Board after the retail pharmacy has closed for business and all prescription drug stock has been removed. At the time of inspection, the following documents shall be provided to the ~~Board Inspector/~~Compliance Officer:

(A) A copy of the final controlled substance inventory;

(B) Documentation, as noted in this chapter, regarding notification to the public of the closure of the retail pharmacy;

(C) The Wyoming retail pharmacy license;

(D) Documentation of the transfer of all prescription drug inventory (controlled and non-controlled) to a third party authorized to have such possession of inventory. Under no circumstance may prescription drug inventory remain in the possession of a person or business not authorized by law to have possession;

(E) Any changes to information previously provided to the Board as required in this chapter~~;~~.

~~(F) The DEA registration certificate and blank DEA 222 forms.~~

(xi) It is unprofessional conduct for a retail pharmacy to close in a manner other than that prescribed in this chapter; and

(xii) If a retail pharmacy purchases the patient prescription records (electronic and hard copy prescription), those records shall be maintained by the acquiring retail pharmacy for a minimum of two (2) years from the date of closure.

(b) Resident Retail Pharmacy Change of Ownership. When a change of ownership necessitates a change of DEA registration number, the following is required:

(i) Not less than twenty-one (21) days prior to a resident retail pharmacy, licensed by the Board, changing ownership, without closing, the Board shall receive written notice of the following:

(A) The last day the seller will have ownership of the retail pharmacy;

(B) The proposed disposition of all prescription files, including both hard copy and electronic records;

(C) The proposed transfer of the prescription drug inventory, including controlled and non-controlled prescription drug products;

(D) The proposed method of communicating to the public the change in ownership, not later than fourteen (14) days prior to the date the ownership will change;

(E) The name, address and telephone number of the custodian of records for the following documents of the seller, which must be retained for two (2) years from the date of the transfer of ownership:

(I) Completed DEA 222 forms or retrievable electronic equivalent;

(II) Invoice for purchases of Schedule III, IV and V controlled substances; and

(III) Patient signature logs.

(F) The date the DEA was contacted regarding the change of ownership and confirmation ~~that the DEA was notified~~ that all invoices and DEA 222 forms referencing the sale of controlled substances at closure, blank DEA 222 forms, and the DEA registration certificate ~~will be delivered to the Board for disposition at the time of the new ownership inspection~~were delivered to the regional DEA office.

(ii) At the close of business on the last date the pharmacy is under the prior ownership, a controlled substance inventory, including all Schedule II, III, IV and V controlled substances shall be taken. This inventory shall be dated and signed by the PIC from the prior and the new ownership. A copy shall be provided to the Board;

(iii) An inspection of the pharmacy shall be conducted by the Board after the change in ownership. The following documents shall be provided to the ~~Board Inspector/~~Compliance Officer:

(A) Documentation of the transfer of all controlled and non-controlled prescription drug inventory will be provided to the Board. Under no circumstances may prescription drug inventory remain in the possession of the person or business not authorized to have possession;

(B) The Wyoming retail pharmacy license of the prior owner;

~~(C) The DEA registration certificate and blank DEA 222 forms from the prior owner;~~

(C) Any changes to information previously provided to the Board as required in this chapter;

(D) Information necessary to process a new Wyoming retail pharmacy license, including information about the new PIC; and

(E) Information necessary to process a new Wyoming controlled substance registration and federal DEA registration.

(iv) It is unprofessional conduct for a retail pharmacy to transfer ownership in a manner other than that prescribed in this chapter.

Section 30. Institutional Pharmacy Closure.

(a) Not less than twenty-one (21) days prior to an institutional pharmacy licensed by the Board permanently ceasing operation, the Board shall receive written notice of the following:

(i) The last day the institutional pharmacy will be open for business;

(ii) The proposed disposition of all prescription drug inventory including controlled and non-controlled prescription drug products;

(iii) The name, address and telephone number of the custodian of records for the following documents, which must be maintained for two (2) years from the date of closure:

(A) Completed DEA 222 forms or retrievable electronic equivalent;

(B) Invoices for purchases of Schedule III, IV and V controlled substances; and

(C) Patient specific records.

(iv) The date the DEA was contacted regarding the closure ~~and that DEA was notified~~ and confirmation that all invoices and DEA 222 forms referencing the sale of controlled substances at closure, blank DEA 222 forms and the DEA registration certificate ~~will be delivered to the Board for disposition~~were delivered to the regional DEA office.

(b) At the close of business on the last day the institutional pharmacy is open for business, a controlled substance inventory, including all Schedule II, III, IV and V controlled substances shall be taken. This inventory shall be dated and signed by the PIC. A copy shall be provided to the Board.

(c) An inspection of the pharmacy shall be conducted by the Board after the institutional pharmacy has closed for business and all prescription drug stock has been removed. At the time of inspection, the following documents shall be provided to the ~~Board Inspector/~~Compliance Officer:

(i) A copy of the final controlled substance inventory;

(ii) The Wyoming institutional pharmacy license;

(iii) Documentation of the transfer of all prescription drug inventory (controlled and non-controlled) to a third party authorized to have such possession of inventory. Under no circumstances may prescription drug inventory remain in the possession of a person or business that is not authorized by law to have possession; and

(iv) Any changes to information previously provided to the Board, as required in this chapter~~;~~.

~~(v) The DEA registration certificate and blank DEA 222 forms.~~

(d) It is unprofessional conduct for an institutional pharmacy to close in a manner than that prescribed in this chapter.

Section 31. Drug Samples.

It is unprofessional conduct for a licensee in an institutional or a retail pharmacy to distribute or dispense prescription drug samples.

Section 32. Centralized Prescription Processing.

~~(a) The purpose of this Section is to provide standards for centralized prescription processing.~~

(a) Definitions specific to this Section:

(i) "Centralized prescription processing," as used in this Section, means the processing by a pharmacy of a request from another pharmacy to refill a prescription drug order or to perform functions such as prospective or retrospective drug use review, claims adjudication, refill authorizations and therapeutic interventions.

(ii) "Dispensing pharmacy," as used in this Section, means a pharmacy that may outsource the processing of a prescription drug order to another pharmacy licensed by the Board.

(iii) "Central fill pharmacy," as used in this Section, means a pharmacy that processes a prescription drug order that was outsourced by a dispensing pharmacy licensed by the Board.

(iv) "Real-time," as used in this Section, means the transmission of information through data links so rapid that the information is available to the dispensing pharmacy and requesting pharmacy sites simultaneously.

(b) Minimum requirements:

(i) A dispensing pharmacy may outsource prescription drug order processing to another pharmacy licensed by the Board, provided the pharmacies:

(A) Have the same owner;

(B) Have entered into a written agreement, which complies with federal and state laws and regulations, specifying the services to be provided and the responsibilities and accountabilities of each pharmacy;

(C) Share a real-time database; and

(D) Maintain the original prescription at the dispensing pharmacy for a time period not less than two (2) years from the date last filled or refilled.

(ii) The PIC of the central fill pharmacy shall ensure that:

(A) The pharmacy maintains and uses storage or shipment containers and shipping processes that ensure drug stability and potency. Shipping processes shall include the use of appropriate packaging material ~~and/~~or devices that ensure the drug is maintained at a temperature range that will maintain the integrity of the medication throughout the delivery process; and

(B) The dispensed prescriptions are shipped in containers sealed in such a manner as to show evidence of opening or tampering.

(iii) A resident dispensing or central fill pharmacy shall comply with the provisions of W.S. § 33-24-11352 and this Section.

(iv) A dispensing or central fill pharmacy dispensing compounded non-sterile or sterile pharmaceuticals shall comply with the provisions of Chapter 13 or Chapter 17 of these rules.

(c) Notifications to patients. A pharmacy that outsources prescription processing to another pharmacy shall:

(i) Notify patients that their prescription may be outsourced to another pharmacy prior to outsourcing the prescription via posted signage, written notification or refill telephone message; and

(ii) If the prescription is delivered to the patient directly by the central fill pharmacy, the pharmacist employed by the central fill pharmacy shall ensure that the patient receives written notice of available counseling. Such notice shall include days and hours of availability, location of pharmacy and a toll-free telephone number the patient may utilize to contact a pharmacist for counseling or to answer questions. Such notice shall be included in each prescription delivery to a patient.

(d) Prescription labeling.

(i) The prescription label shall clearly indicate which pharmacy filled the prescription and which pharmacy dispensed the prescription~~.~~; and

(ii) The prescription label shall comply with this chapter.

(e) Policies and Procedures. A policy and procedures manual relating to centralized processing shall be maintained at both pharmacies and shall be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operation. The manual shall:

(i) Outline the responsibilities of each of the pharmacies;

(ii) Include a list of the names, addresses, telephone numbers and all license/registration numbers of the pharmacies involved in centralized prescription processing;

(iii) Include policies and procedures for:

(A) Notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription processing and providing the name of that pharmacy;

(B) Protecting the confidentiality and integrity of patient information;

(C) Dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received;

(D) Complying with federal and state laws and regulations;

(E) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;

(F) Identifying the pharmacist responsible for each aspect of prescription preparation including, but not limited to, the drug regimen review, the initial electronic entry, any changes or modifications to the prescription record or patient profile and the final check of the completed prescription;

(G) Identifying the pharmacist responsible for making the offer to counsel the patients as required by Chapter 9 of these rules; and

(H) Documentation of annual review of the written policies and procedures.

(f) Records.

(i) Records shall be maintained in a real-time electronic database;

(ii) Each pharmacy shall comply with all the laws and rules relating to the maintenance of records and be able to produce an audit trail showing all prescriptions dispensed by the pharmacy and each pharmacist's or technician's involvement in dispensing; ~~and~~

(iii) The dispensing pharmacy shall maintain records which indicate:

(A) The date and time the request for processing was transmitted to the central fill pharmacy; and

(B) The date and time the dispensed prescription was received from the central fill pharmacy by the dispensing pharmacy, including the method of delivery (e.g., private, common or contract carrier) and the name of the person accepting delivery.

(iv) The central fill pharmacy shall maintain records which indicate the date the prescription was shipped to the dispensing pharmacy.

Section 33. Automated Storage and Distribution Systems.

(a) Before using an automated storage and distribution system, a PIC shall:

(i) Ensure that the automated storage and distribution system and the policies and procedures comply with this chapter; and

(ii) Notify the Board in writing of the intent to use an automated storage and distribution system, including the type or name of the system.

(b) The PIC shall establish policies and procedures for appropriate performance and use of the automated storage and distribution system that:

(i) Ensure that the automated storage and distribution system is in good working order while maintaining appropriate recordkeeping and security safeguards. This is to include the ability to store at the required temperature;

(ii) Ensure that an automated storage and distribution system used by a pharmacy that allows access to drug or devices by a patient:

(A) Only allows patient access to prescriptions that:

(I) Do not require an offer to counsel by a pharmacist as specified in W.S. § 33-24-136(c);

(II) Are properly labeled and verified by a pharmacist before placement into the automated storage and distribution system and subsequent release to patients; and

(III) Are not a Schedule II controlled substance under the Wyoming Controlled Substances Act.

(B) Allows a patient to choose whether or not to use the system;

(C) Is located inside a building in a wall of a licensed pharmacy where the pharmacy staff has access to the device from within the pharmacy and patients have access from outside the pharmacy and is attached to the wall in such a manner that prevents unauthorized removal;

(D) Provides a method to identify the patient and only release the identified patient's prescriptions;

(E) Is secure from access and removal of drugs or devices by unauthorized individuals;

(F) Provides a method for a patient to obtain consultation with a pharmacist, if requested by the patient; and

(G) Prevents dispensing of refilled prescriptions, if a pharmacist determines that the patient requires counseling.

(iii) Ensure that an automated storage and distribution system used by a pharmacy that allows access to drugs or devices for the purposes of administration only by authorized licensed personnel based on a valid prescription order or medication order.

(A) Provides for adequate security to prevent unauthorized individuals from accessing or obtaining drugs or devices; and

(B) Ensures the filling, stocking or restocking of all drugs or devices in the system may be done only by a pharmacist, pharmacy intern or pharmacy technician.

(iv) Implement an ongoing quality assurance program that monitors compliance with the established policies and procedures of the automated storage and distribution system and federal and state law.

(c) The PIC shall:

(i) Ensure the policies and procedures for the performance and use of an automated storage and distribution system are prepared, implemented and complied with;

(ii) Review and document annually and, if necessary, revise the policies and procedures required under this Section; and

(iii) Make the policies and procedures available for employee reference and inspection by the Board within the pharmacy and at any location outside the pharmacy where the automated storage and distribution system is used.

(d) The Board may prohibit a PIC from using an automated storage and distribution system if the pharmacy licensee or the pharmacy licensee's employees do not comply with the requirements of this Section.

Section 34. Electronic Records of Prescriptions.

Pursuant to W.S. § 33-24-136, a written or electronic record of a prescription shall be maintained and available for inspection by agents of the Board for a period of two (2) years from the date it is filed, as follows:

(a) The pharmacy system shall ensure the validity and retrievability of the original prescription information;

(b) A pharmacy shall be authorized to maintain an exact digitized image of the prescription drug order in an electronic record-keeping system;

(c) Faxed prescriptions received in electronic format may be electronically stored and maintained in a readily retrievable format;

(d) Electronically transmitted prescriptions may be electronically stored and maintained in a readily retrievable format;

(e) A pharmacy may retain any hard copy prescriptions in numerical or date order; and

(f) Disposal of the hard copy must be in a secure destruction method to ensure privacy and confidentiality of the contents.

Section 35. Drug Disposal Including Controlled Substances.

Information for patients regarding disposal of their personal prescription drugs that are outdated, unusable, or no longer prescribed is hereby incorporated by reference.

Section 36. Dangerous Substance List.

Pursuant to W.S. § 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,* as the official listing of Dangerous Substances for the State of Wyoming is hereby incorporated by reference.

Section 37. Incorporation by Reference.

(a) Any code, standard, rule or regulation incorporated by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (c) of this section.

(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

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 rule incorporated by reference in these rules is further identified as follows:

(i) The standard incorporated by reference in this section of these rules is "Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)," 36th Edition, 2016 as existing on January 17, 2017 including amendments adopted by the Food and Drug Administration (FDA) as of that date. The products in this list have been approved under section 505 of the federal Food, Drug, and Cosmetic Act. Copies of this standard can be obtained from the US Department of Health and Human Services, Food and Drug Administration, Office of Medical Products and Tobacco, center for Drug Evaluation and Research, Office of Generic Drugs, Office of Generic Drug Policy at the following location: www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ApprovedDrugProductswithTherapeuticEquivalenceEvaluationsOrangeBook/default.htm.

(ii) The incorporated standard for disposal of personal prescription drugs is available on the internet at: www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm;

(iii) The incorporated standard for disposal of controlled substances by DEA registrants is available on the internet at www.deadiversion.uisdoj.gov/fed_regs/rules/2014/2014-20926.pdf; and

(iv) The standard incorporated by reference in these rules is the Federal Register Volume 79. No. 174, Tuesday, September 9, 2014, Department of Justice, Drug Enforcement Administration, 21 CFR Parts 1300, 1301, 1304, specifically § 1317.30 through § 1317.95 disposal of Controlled Substances: Final Rule. Copies of this rule can be obtained from the DEA at http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf.

WHOLESALE DISTRIBUTOR REGULATIONS

CHAPTER 8

Section 1. Authority.

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

Section 2. Purpose.

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

Section 3. Scope.

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

Section 4. Definitions.

(a) "Adulterated" means a drug which:

(i) Consists in whole or in part of any filthy, putrid, or decomposed substance;

(ii) Purports to be or is represented as a drug, the name of which is recognized in an official compendium as listed in W.S. § 33-24-127, and its strength differs from, or its quality and purity falls below, the standard set forth in the compendium; or

(iii) Has been mixed or packed so as to reduce its quality or strength;

(b) "Authenticate" means to affirmatively verify that each transaction listed on the Product Tracing and any other accompanying documentation has occurred in accordance with this Chapter.

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

(d) "Chain Pharmacy Warehouse" means a permanent physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs to chain pharmacies under common ownership and control. Chain Pharmacy warehouses must be licensed as wholesale distributors.

(e) "Co-licensee" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

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

(g) "Contraband Drug" means a drug which is:

(i) Counterfeit;

(ii) Stolen;

(iii) Misbranded;

(iv) Obtained by fraud; or

(v) Purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that drug.

(h) "Counterfeit Drug" means a drug, the container, shipping container, seal, or product labeling which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packet, distributed, or wholesale distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed, distributed, or wholesale distributed by such other manufacturer, processor, packer, or distributor.

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

(j) "Dispenser" means a retail pharmacy, institutional pharmacy, a group of chain pharmacies under common ownership or any other person authorized by law to dispense or administer prescription drugs and does not include a person who dispenses only products to be used in animals.

(k) "Distribute" or "Distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a drug, whether by passage of title, physical movement, or both. The term does not include:

(i) The dispensing or administration of a product pursuant to a prescription;

(ii) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or

(iii) Providing a drug sample to a patient by a practitioner licensed to prescribe such drug.

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

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

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

(o) "Intracompany Transaction" means any transaction between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity.

(p) "Label" means a display of written, printed or graphic matter upon the immediate container of any drug.

(q) "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacturer of prescription drugs.

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

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

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

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

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

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

(iii) "Rx Only."

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

(i) Transaction Information (TI);

(ii) Transaction History (TH); and

(iii) Transaction Statement (TS).

(w) “Reverse Distributor” means any person who receives, takes inventory, and manages the disposition of outdated, expired, or otherwise non-saleable drugs from pharmacies, wholesale distributors, or other entities.

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

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

(z) “Transaction Information” means:

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

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

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

(iv) The container size;

(v) The number of containers;

(vi) The lot number of the product;

(vii) The transaction date;

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

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

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

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

(i) Is authorized under federal law;

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

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

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

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

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

(vii) Did not knowingly alter the transaction history.

(bb) "Wholesale Distribution" means the distribution of prescription drugs to a person other than a consumer or patient, but does not include;

(i) The dispensing of a prescription drug pursuant to a prescription drug order;

(ii) The distribution of a prescription drug or the offer to distribute a prescription drug by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(iii) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(iv) The sale, purchase, or trade of blood and blood components intended for transfusion;

(v) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(vi) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use;

(vii) The distribution of a prescription drug or an offer to distribute a prescription drug among hospitals, chain pharmacy warehouses, pharmacies, or other health care entities that are under common control;

(viii) The distribution of a drug or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repackages it in accordance with federal law.

(ix) The return of recalled, expired, damaged, or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, chain pharmacy warehouse or charitable institution in accordance with Board rules;

(x) The transfer of prescription drugs between pharmacies pursuant to a centralized prescription processing agreement;

(xi) The sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons, including a public health emergency declaration. A drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(xii) The receipt or transfer of a drug by an authorized third-party logistics provider, provided the third-party logistics provider does not take ownership of the drug;

(xiii) The delivery of a prescription drug by a common carrier, provided the common carrier does not take ownership of the drug;

(xiv) The sale or transfer from a pharmacy or pharmacy warehouse of expired, damaged, returned or recalled prescription drugs to the original manufacturer, original wholesale distributor, or to a third party returns processor or reverse distributor:

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

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

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

(cc) "Wholesale Distributor" means any person, (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution of prescription drugs in or into this State.

Section 5. Licensing Requirement.

(a) Every manufacturer, repackager, third-party logistics provider, and wholesale distributor, wherever located, that provide services within this State shall be licensed by the Board and shall annually renew their license using an application provided by the Board. Manufacturers, repackagers, third-party logistics providers and wholesale distributors cannot

operate from a place of residence. Where wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the Board.

(b) The Board shall require the following minimum information from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

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

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

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

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

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

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

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

(F) Any other relevant information the Board requires.

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

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

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

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

(A) Square footage;

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

(C) Terms of lease or ownership;

(D) Address; and

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

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

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

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

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

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

(c) All current wholesale distributor licensees and all applicants for licensure as a third-party logistics provider or wholesale distributor must submit security in the amount of one hundred thousand dollars ($100,000.00) to the Board. The purpose of these funds will be to secure payment for any administrative penalty assessed by the Board, which remains unpaid thirty (30) days after the liability for the payment is final. A separate bond or other equivalent

means of security is not required for each company's separate location or for affiliated companies/groups when such separate location or affiliated companies/groups are required to apply for or renew their wholesale distributor license with the Board. Acceptable forms of security include:

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

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

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

(d) The Board will waive the security requirement, if the wholesale distributor or third-party logistics provider:

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

(ii) Is a publicly held company.

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

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

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

(A) The accreditation body; and

(B) The Board.

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

(iii) Individual or third party inspectors must demonstrate to the Board that they have received training or demonstrate familiarity with the inspection standards. A letter for certification from a training program, a notice from the inspector's employing third party

organization, or other means recognized by the Board shall be accepted as meeting the requirement.

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

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

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

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

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

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

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

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

Section 6. Medical Oxygen Distributors.

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

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

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

Section 7. Outsourcing Facilities.

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

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

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

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

(e) Outsourcing facilities shall:

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

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

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

(iv) Label compounded drugs with:

(A) Required drug and ingredient information;

(B) Facility identification;

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

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

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

Section 8. Third Party Logistics Providers.

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

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

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

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

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

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

Section 10. Repackagers.

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

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

Section 11. Minimum Qualifications.

(a) The Board shall consider the following factors in determining eligibility for, and renewal of, licensure of persons or firms who engage in the wholesale distribution of prescription drugs;

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

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

(iii) The applicant's past experience in the manufacture or distribution of prescription drugs;

(iv) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

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

(vi) Compliance with previously granted licenses related to wholesale distribution of prescription drugs;

(vii) Compliance with the requirements to maintain or make available to the Board or to federal, state or local law enforcement officials those records required to be maintained by wholesale drug distributors; and

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

Section 12. Personnel.

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

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

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

(A) Fingerprint cards and fee for a criminal background check;

(B) Date and place of birth;

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

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

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

(F) A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven (7) years, which manufactured, administered, prescribed,

wholesale distributed, or stored prescription drugs in which such businesses were named as a party in a lawsuit;

(G) A description of any felony criminal offense, or any offense (misdemeanor or felony) involving moral turpitude, or any offense related to the qualifications, functions or duties of that person in connection with the operation of the wholesaler, of which the person, as an adult, was found guilty, regardless of whether adjudication of guilty was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within fifteen (15) days after the disposition of the appeal, submit a copy of the final written order of disposition to the Board; and

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

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

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

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

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

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

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

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

(d) Each licensed manufacturer, repackager, third-party logistics provider and wholesale distributor located outside of this State that distributes prescription drugs in or into

this State shall designate a registered agent in this State with the Office of the Secretary of State for service of process.

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

The following are required for the storage, handling, transport and shipment of prescription drugs and for the establishment and maintenance of records by manufacturers, repackagers, third-party logistics providers and wholesale distributors and their officers, agents, representatives and employees:

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

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

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

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

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

(v) Be free from infestation of any kind;

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

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

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

(b) Wholesale distributors, third-party logistics providers and others involved in the wholesale distribution of controlled substances shall be duly registered with the Drug Enforcement Administration (DEA) and the Board and in compliance with all applicable laws and rules for the storage, handling, transport, shipment and wholesale distribution of controlled substances.

Section 14. Security and Anti-Counterfeiting.

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

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

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

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

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

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

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

(c) Wholesale distributors engaged in wholesale distribution shall be equipped with security measures to protect the integrity of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

(d) All common carriers used by a wholesale distributor shall ensure security via a verifiable security system.

Section 15. Storage of Prescription Drugs.

(a) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the product labeling of such prescription drugs, or with requirements in the current edition of an official compendium such as the USP-NF.

(b) If no storage requirements are established for a prescription drug, the prescription drug may be held at “controlled” room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality and purity are not adversely affected.

(c) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of prescription drugs.

(d) Controlled substances shall be isolated from non-controlled substance drugs and stored in a secure area in accordance with DEA security requirements and standards.

Section 16. Examination of Materials.

(a) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit or contraband, or damaged prescription drugs or prescription drugs that are otherwise unfit for wholesale distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, contraband, suspected of being counterfeit or contraband, or other damage to the contents.

(b) The prescription drugs found to be unacceptable under paragraph "a" above shall be quarantined from the rest of the stock until examination and determination that the prescription drugs are not outdated, damaged, deteriorated, misbranded, counterfeit, contraband, or adulterated.

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

(d) Manufacturers, repackagers, third-party logistics providers and wholesale drug distributors must comply with all reporting requirements and exchange transaction history, transaction information, and transaction statements as outlined in federal law.

Section 17. Returned, Damaged and Outdated Prescription Drugs.

(a) Returns of expired, damaged, recalled or otherwise non-saleable pharmaceutical products shall be only to either the original manufacturer or a third party returns processor. Licensees under this Chapter shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit products into the marketplace.

(b) It is unlawful for a person to knowingly and willfully perform or cause the performance of, or aid and abet any of the following acts in this State:

(i) the manufacture, repackaging, sale, delivery or holding or offering for sale of any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit or has otherwise been rendered unfit for distribution;

(ii) the adulteration, misbranding or counterfeiting of any prescription drug;

(iii) the receipt of any prescription drug or device that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit, or the delivery or proffered delivery of such prescription drug for pay or otherwise;

(iv) the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the product labeling of a prescription drug that results in misbranding;

(v) the forging, counterfeiting, simulation, or false representation of any prescription drug without the authority of the manufacturer, or using any mark, stamp, tag, label or other identification device without the authorization of the manufacturer;

(vi) the purchase or receipt of a prescription drug from a person that is not licensed to distribute prescription drugs to that purchaser or recipient;

(vii) the sale or transfer of a prescription drug to a person who is not legally authorized to receive it;

(viii) the sale or transfer of a prescription from pharmacies to distributors for resale;

(ix) the failure to maintain or provide records;

(x) providing the board of any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter in this Chapter;

(xi) the wholesale distribution of any prescription drug that was:

(A) purchased by a public or private hospital or other health care entity;

(B) donated or supplied at a reduced price to a charitable organization; or

(C) stolen or obtained by fraud or deceit.

(xii) the failure to obtain a license or operating without a valid license when a license is required;

(xiii) the obtaining of or attempt to obtain a prescription drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;

(xiv) the distributing of a prescription drug to the patient without a prescription from a practitioner licensed by law to use or prescribe the prescription drug;

(xv) the distributing of a prescription drug that was previously dispensed by a pharmacy or distributed by a practitioner; or

(xvi) the failure to report any prohibited act as listed in these rules.

(c) Any prescription drug that has been opened or used but is not adulterated, misbranded, counterfeited, contraband or suspect of being counterfeit or contraband, shall be identified as such and shall be quarantined and physically separated from other prescription drugs until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired.

Section 18. Policies and Procedures.

Manufacturers, repackagers, third-party logistics providers and wholesale distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, shipping and wholesale distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors shall include in their written policies and procedures the following:

(a) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

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

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

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

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

(d) A procedure for the destruction of outdated prescription drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of two (2) years, and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements;

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

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

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

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

WHOLESALE DISTRIBUTOR REGULATIONS

CHAPTER 8

Section 1. Authority.

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

Section 2. Purpose.

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

Section 3. Scope.

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

Section 4. Definitions.

(a) "Adulterated" means a drug ~~shall be deemed adulterated if:~~which:

(i) ~~It~~ ~~c~~Consists in whole or in part of any filthy, putrid, or decomposed substance; ~~or~~

(ii) ~~It has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if the methods used in, or the facilities or controls used for, it=s manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to assure that the drug meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or~~Purports to be or is represented as a drug, the name of which is recognized in an official compendium as listed in W.S. § 33-24-127, and its strength differs from, or its quality and purity falls below, the standard set forth in the compendium; or

(iii) ~~Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or~~Has been mixed or packed so as to reduce its quality or strength;

(iv) ~~It bears or contains, for purposes of coloring only, ,a color additive that is unsafe within the meaning of the Federal Food, Drug and Cosmetic Act (Federal Act); or it is a~~

~~color additive, the intended use of which is for purposes of coloring only, and is unsafe with the meaning of the Federal Act.~~

(b) "Authenticate" means to affirmatively verify ~~before any wholesale distribution of a prescription drug takes place~~ that each transaction listed on the ~~Pedigree~~ Product Tracing and any other accompanying documentation has occurred~~,~~ in accordance with this ~~C~~chapter.

(c) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. ~~An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:~~

~~(i) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and~~

~~(ii) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which must be updated by the manufacturer on no less than a monthly basis.~~

(d) "Chain Pharmacy Warehouse" means a permanent physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs to chain pharmacies under common ownership and control. Chain Pharmacy warehouses must be licensed as wholesale distributors.

(e) "Co-licensee" means ~~an instance where two or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with the FDA's implementation of the Prescription Drug Marketing Act~~ a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

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

(g) "Contraband Drug" means a drug which is:

(i) Counterfeit;

(ii) Stolen;

(iii) Misbranded;

(iv) Obtained by fraud; or

(v) Purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that drug.

(h) "Counterfeit Drug" means a drug, the container, shipping container, seal, or product labeling which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packet, distributed, or wholesale distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed, distributed, or wholesale distributed by such other manufacturer, processor, packer, or distributor.

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

(j) "Dispenser" means a retail pharmacy, institutional pharmacy, a group of chain pharmacies under common ownership or any other person authorized by law to dispense or administer prescription drugs and does not include a person who dispenses only products to be used in animals.

(k) "Distribute" or "Distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a drug, whether by passage of title, physical movement, or both. The term does not include:

(i) The dispensing or administration of a product pursuant to a prescription;

(ii) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or

(iii) Providing a drug sample to a patient by a practitioner licensed to prescribe such drug.

(l) ~~"Drop Shipment" means the sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third-party logistics provider, that manufacture's exclusive distributor, or an authorized distributor of record that purchased the product directly from the manufacturer to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug. That wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other persons authorized by law to dispense or administer a drug to a patient. The pharmacy, chain pharmacy warehouse, or other authorized person may receive delivery of the prescription drug directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third-party logistics provider, that manufacturer's exclusive distributor, or an authorized distributor of record. Drop shipments shall be part of the "Normal Distribution Channel."~~ "Drug" means a substance recognized as a drug in any official compendium as listed in W.S. § 33-24-127, designated for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals.

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

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

(o) "Intracompany Transaction" means any transaction between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity.

(p) "Label" means a display of written, printed or graphic matter upon the immediate container of any drug.

(q) "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacturer of prescription drugs. ~~consistent with the FDA definition of "manufacturer" under the FDA's regulations and interpretive guidances implementing the Prescription Drug Marketing Act, including any amendments thereto~~

(r) "Manufacturer's Exclusive Distributor" means ~~anyone~~ an individual or entity who ~~contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have a general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor must be licensed as a wholesale distributor under this Chapter, and to be considered part of the "normal distribution channel" must also be an "authorized distributor of record."~~ purchased the product directly from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

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

(t) ~~"Normal Distribution Channel" means a chain of custody for a prescription drug that goes, directly or by drop shipment, from a manufacturer, the manufacturer's co-licensee, the manufacturer's third-party logistics provider, ,or the manufacturer's exclusive distributor to:~~

(i) ~~An authorized distributor of record and, subsequently, to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or~~

(ii) ~~An authorized distributor of record, then to a chain pharmacy, warehouse and, subsequently, to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or~~

(iii) ~~A chain pharmacy warehouse and, subsequently, ,to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or~~

(iv) ~~An authorized distributor of record and, subsequently, to other authorized distributors of record who subsequently distribute to an office-based healthcare practitioner authorized by law to dispense or administer such drug to a patient; or~~

(v) ~~A pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient.~~

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

(u) "Prescription Drug" or "Legend Drug" means ~~any drug required to be dispensed only by a prescription, by State law or regulations of by Federal law or regulations, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act.~~ a drug which, under federal law, is required to be labeled with one of the following statements:

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

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

(iii) "Rx Only."

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

(i) Transaction Information (TI);

(ii) Transaction History (TH); and

(iii) Transaction Statement (TS).

(w) "Reverse Distributor" means any person who receives, takes inventory, and manages the disposition of outdated, expired, or otherwise non-saleable drugs from pharmacies, wholesale distributors, or other entities.

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

~~(y) "Third Party Logistics Provider" means an entity that:~~

~~(i) Provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition; and~~

~~(ii) Is licensed as a wholesale distributor under this Chapter.~~

~~(iii) To be considered part of the "normal distribution channel" must also be an "authorized distributor of record."~~

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

(z) "Transaction Information" means:

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

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

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

(iv) The container size;

(v) The number of containers;

(vi) The lot number of the product;

(vii) The transaction date;

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

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

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

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

(i) Is authorized under federal law;

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

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

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

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

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

(vii) Did not knowingly alter the transaction history.

(bb) "Wholesale Distribution" means the distribution of prescription drugs ~~by wholesale distributors to persons other than consumers or patient, and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the value of the goods transferred exceeds five percent (5%) of total prescription drug sales revenue of either the transferor or transferred pharmacy during any consecutive twelve (12) month period. Wholesale distribution does not include:~~ to a person other than a consumer or patient, but does not include;

(i) ~~The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug pursuant to a prescription'~~ The dispensing of a prescription drug pursuant to a prescription drug order;

(ii) The ~~sale, ,purchase, or trade~~ distribution of a prescription drug or the offer to ~~sell, purchase, or trade~~ distribute a prescription drug by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(iii) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(iv) The sale, purchase, or trade of blood and blood components intended for transfusion;

(v) Intracompany ~~sales of prescription drugs, ,meaning an transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, ,or any transaction or transfer between co-licensees of a co-licensed product;~~ distribution of any drug between members of an affiliate or within a manufacturer;

(vi) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use;

(vii) The ~~sale, purchase, or trade~~ distribution of a prescription drug or an offer to ~~sell, purchase, or trade~~ distribute a prescription drug among hospitals, chain pharmacy warehouses, pharmacies, or other health care entities that are under common control;

(viii) ~~The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with Board regulations.~~The distribution of a drug or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repackages it in accordance with federal law.

(ix) The return of recalled, expired, damaged, or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, chain pharmacy warehouse or charitable institution in accordance with Board ~~regulations~~rules;

(x) The transfer of prescription drugs between pharmacies pursuant to a centralized prescription processing agreement;

(xi) ~~S~~The sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons, ~~as defined under 21 DFR 203.3(m), including any amendment thereto. For purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage~~ including a public health emergency declaration. A drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(xii) ~~Sale, purchase distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record during a time period for which there is documentation from the manufacturer that the manufacturer is unable to supply a prescription drug;~~ The receipt or transfer of a drug by an authorized third-party logistics provider, provided the third-party logistics provider does not take ownership of the drug;

(xiii) The delivery of a prescription drug by a common carrier, provided the common carrier does not take ownership of the drug; ~~or~~

(xiv) The sale or transfer from a pharmacy or pharmacy warehouse of expired, damaged, returned or recalled prescription drugs to the original manufacturer, original wholesale distributor, or to a third party returns processor or reverse distributor:

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

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

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

(cc) "Wholesale Distributor" means ~~anyone engaged in wholesale distribution of prescription drugs in or into the State, including but not limited to, manufacturers, repackagers, own label distributors, private label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy warehouses and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distribution.~~ any person, (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution of prescription drugs in or into this State.

Section 5. ~~Wholesale Distributor~~ Licensing Requirement.

(a) Every manufacturer, repackager, third-party logistics provider, and wholesale distributor, wherever located, ~~who engages in wholesale distribution~~ that provide services ~~into or~~ within this State shall be licensed by the Board and shall annually renew their license using an application provided by the Board. ~~in accordance with the laws and regulations of this State before engaging in wholesale distribution of prescription drugs.~~ Manufacturers, repackagers, third-party logistics providers and wholesale distributors cannot operate from a place of residence. Where wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the Board.

(b) The Board shall require the following minimum information from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

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

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

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

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

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

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

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

(F) Any other relevant information the Board requires.

(iii) Name(s), business address(es), and telephone number(s) of the ~~a~~ person(s) to serve as the designated representative(s) for each facility of the wholesale distributor that engages in the wholesale distribution of prescription drugs. The Board shall be notified of each change in designated representative within 30 days of the change. ~~Effective January 1, 2009~~ ~~f~~Fingerprints and a fifty dollar ($50.00) fee ~~must~~ shall be submitted for each designated representative application for a criminal background ~~history~~ check and with each application for change in designated representative~~:~~;

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

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

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

(A) Square footage;

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

(C) Terms of lease or ownership;

(D) Address; and

(E) Temperature and humidity controls in accordance with ~~Section 11 below~~ this Chapter.

(vii) A copy of the deed for the property on which the ~~wholesale distributor's~~ entity's establishment is located, if the property is owned by the ~~wholesale distributor~~ entity; or a copy of the wholesale distributor's lease for the property on which the establishment is

located which has an original term of not less than one (1) calendar year (if the establishment is not owned by the ~~wholesale distributor~~entity);

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

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

(x) An electronic copy of the ~~wholesale distributor's~~ entity's written policies and procedures as required by this Chapter~~. (See Section 15(a) through (h)~~;

~~(xi) The applicant shall provide, and attest to, a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding prescription drugs or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts;~~

(b) The information collected pursuant to ~~Section 5(a)(vi) and (x)~~ this Chapter shall be made available only to the Board, a third party recognized by the Board, and to state and federal law enforcement officials. The Board shall make provisions for protecting the confidentiality of the information collected under this section.

(c) ~~Effective January 1, 2009 a~~All current wholesale distributor licensees and all applicants for licensure as a third-party logistics provider or wholesale distributor must submit security in the amount of one hundred thousand dollars ($100,000.00) to the Board. The purpose of these funds will be to secure payment for any administrative penalty assessed by the Board, which remains unpaid thirty (30) days after the liability for the payment is final. A separate bond or other equivalent means of security is not required for each company's separate location or for affiliated companies/groups when such separate location or affiliated companies/groups are required to apply for or renew their wholesale distributor license with the Board. Acceptable forms of security include:

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

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

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

(d) The Board will waive the security requirement, if the wholesale distributor or third-party logistics provider:

~~The purpose of these funds will be to secure payment for any administrative penalty assessed by the board, which remains unpaid thirty (30) days after the liability for the payment is final. A separate bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations~~

~~or affiliated companies/groups are required to apply for or renew their wholesale distributor license with the board. The board will waive the security requirement, if the wholesale distributor:~~

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

(ii) Is a publicly held company.

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

(e) ~~Effective January 1, 2010, all wholesale distributors~~ Each facility licensed by the Board and all applicants for licensure must provide evidence of VAWD® accreditation from the National Association of Boards of Pharmacy or from another third party recognized by the Board ~~to inspect and accredit wholesalers~~ and must undergo the re-accreditation process ~~no less than every three (3) years~~ periodically after initial accreditation. Manufacturing facilities are exempt from this requirement provided the manufacturing facilities are currently registered with the FDA in accordance with Section 510 of the Federal Act.

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

(A) The accreditation body; and

(B) The Board.

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

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

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

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

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

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

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

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

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

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

Section 6. Medical Oxygen Distributors.

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

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

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

Section 7. Outsourcing Facilities.

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

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

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

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

(e) Outsourcing facilities shall:

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

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

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

(iv) Label compounded drugs with:

(A) Required drug and ingredient information;

(B) Facility identification;

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

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

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

Section 8. Third Party Logistics Providers.

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

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

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

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

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

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

Section 10. Repackagers.

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

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

Section 11. Minimum Qualifications.

(a) The Board shall consider the following factors in determining eligibility for, and renewal of, licensure of persons or firms who engage in the wholesale distribution of prescription drugs;

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

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

(iii) The applicant's past experience in the manufacture or distribution of prescription drugs;

(iv) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

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

(vi) Compliance with previously granted licenses related to wholesale distribution of prescription drugs;

(vii) Compliance with the requirements to maintain or make available to the Board or to federal, state or local law enforcement officials those records required to be maintained by wholesale drug distributors; and

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

Section 12. Personnel.

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

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

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

(A) Fingerprint cards and fee for a criminal background ~~history~~check;

(B) Date and place of birth;

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

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

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

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

(G) ~~D~~A description of any felony criminal offense, or any offense (misdemeanor or felony) involving moral turpitude, or any offense related to the qualifications, functions or duties of that person in connection with the operation of the wholesaler, of which the person, as an adult, was found guilty, regardless of whether adjudication of guilty was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within ~~thirty (30)~~ fifteen (15) days after the disposition of the appeal, submit a copy of the final written order of disposition to the Board; and

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

(ii) Have a minimum of two (2) years of verifiable full-time managerial or supervisory experience in a pharmacy or wholesale distributor licensed in this State or another

state where the person's responsibilities included but were not limited to recordkeeping, storage, and shipment of prescription drugs;

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

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

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

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

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

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

(d) Each licensed manufacturer, repackager, third-party logistics provider and wholesale distributor located outside of this State that distributes prescription drugs in or into this State shall designate a registered agent in this State with the Office of the Secretary of State for service of process.

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

The following are required for the storage, handling, transport and shipment of prescription drugs and for the establishment and maintenance of records by manufacturers, repackagers, third-party logistics providers and wholesale distributors and their officers, agents, representatives and employees:

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

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

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

(iii) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution or wholesale distribution, or that are in immediate or sealed secondary containers that have been opened prior to receipt by the wholesale distributor ~~in accordance with Section 12 below~~;

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

(v) Be free from infestation of any kind;

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

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

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

~~(ix) Provide to another wholesale distributor or pharmacy, written or electronic pedigrees for prescription drugs that leave the normal distribution channel in accordance with Section 10 below.~~

(b) Wholesale distributors, third-party logistics providers and others involved in the wholesale distribution of controlled substances shall be duly registered with the Drug Enforcement Administration (DEA) and the Board and in compliance with all applicable laws and rules for the storage, handling, transport, shipment and wholesale distribution of controlled substances.

Section 14. Security and Anti-Counterfeiting.

(a) ~~Facility Security.~~ All facilities used for wholesale drug distribution shall be secure from unauthorized entry as follows:

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

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

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

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

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

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

(c) Wholesale distributors engaged in wholesale distribution shall be equipped with security measures to protect the integrity of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

(d) All common carriers used by a wholesale distributor shall ensure security via a verifiable security system.

~~**Section 15.** Pedigrees.~~

~~(a) Pedigrees shall be required for wholesale distribution of prescription drugs that leave or have ever left the normal distribution channel. Each person who is engaged in wholesale distribution of prescription drugs that leave, or have ever left, the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug. A retail pharmacy or pharmacy intracompany warehouse shall comply with the requirements of this section only if the pharmacy engages in wholesale distribution of prescription drugs.~~

~~(b) The contents of each pedigree shall:~~

~~(i) Include all necessary identifying information concerning each sale in the chain of ownership of product from the manufacturer (or the manufacturer's third-party logistics provider/co-licensed product partner/manufacturer's exclusive distributor) through acquisition and sale by any wholesale distributor or repackager until final sale to a pharmacy or other person furnishing, dispensing, or administering drug. At a minimum, the necessary chain or ownership information shall include:~~

~~(A) Name, address, telephone number, and, if available, the email address of each owner of the prescription drug, ,and each wholesale distributor of the prescription drug;~~

~~(B) Name and address of each location from which the product was shipped, if different from the owner's;~~

~~(C) Transaction dates; and~~

(D) Certification from the designated representative that each recipient has authenticated the pedigree.

(E) A certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate (under penalty of perjury).

(ii) At a minimum, the pedigree shall also include the:

(A) Name of the prescription drug;

(B) Dosage form and strength of the prescription drug;

(C) Size of the container

(D) Number of containers;

(E) Lot number and the National Drug Code of the prescription drug; and

(F) Name of the manufacturer of the finished dosage form.

(iii) Each pedigree or electronic file shall be maintained consistent with 21 CFR 203.60, including any amendments thereto.

(c) Wholesale distributors engaged in wholesale distribution and manufacturers from whom wholesale distributors have acquired prescription drugs shall cooperate with pedigree authentication efforts and provide the requested information in a timely manner.

(d) Each wholesale distributor engaged in wholesale distribution that has distributed a prescription drug for which an acquiring wholesale distributor is conducting a pedigree authentication, shall provide to the acquiring wholesale distributor, upon request, detailed information regarding its acquisition of the prescription drug.

(e) If the wholesale distributor attempting to authenticate the pedigree of the prescription drug is unable to authenticate the pedigree, the wholesale distributor shall quarantine the prescription drug and file a report, as defined by the board, with the board within three (3) business days after completing the attempted prescription drug pedigree authentication;

(f) If the wholesale distributor attempting to authenticate the pedigree of the prescription drug is able to authenticate the pedigree, the wholesale distributor shall maintain records of the authentication for two (2) years, and shall produce them to the board upon request.

~~(g) Wholesale distributors and manufacturers shall maintain an ongoing list of persons with whom they purchase or sell prescription drug products.~~

Section 15. Storage of Prescription Drugs.

(a) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the product labeling of such prescription drugs, or with requirements in the current edition of an official compendium such as the USP-NF.

(b) If no storage requirements are established for a prescription drug, the prescription drug may be held at "controlled" room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality and purity are not adversely affected.

(c) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of prescription drugs.

(d) Controlled substances shall be isolated from non-controlled substance drugs and stored in a secure area in accordance with DEA security requirements and standards.

Section 16. Examination of Materials.

(a) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit or contraband, or damaged prescription drugs or prescription drugs that are otherwise unfit for wholesale distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, contraband, suspected of being counterfeit or contraband, or other damage to the contents.

(b) The prescription drugs found to be unacceptable under paragraph "a" above shall be quarantined from the rest of the stock until examination and determination that the prescription drugs are not outdated, damaged, deteriorated, misbranded, counterfeit, contraband, or adulterated.

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

(d) Manufacturers, repackagers, third-party logistics providers and wholesale drug distributors must comply with all reporting requirements and exchange transaction history, transaction information, and transaction statements as outlined in federal law.

Section 17. Returned, Damaged and Outdated Prescription Drugs.

(a) ~~A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or other persons authorized to administer or dispense drugs or for a pharmacy's intracompany warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy.~~ Returns of expired, damaged, recalled or otherwise non-saleable pharmaceutical products shall be ~~distributed by the receiving wholesale distributor~~ only to either the original manufacturer or a third party returns processor. ~~The returns or exchanges of prescription drugs (saleable or otherwise)k, including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of this Chapter, so long as they are exempt from the pedigree requirement of the FDA;s currently applicable Prescription Drug Marketing Act. Both~~ Licensees under this Chapter ~~and pharmacies for other persons authorized by law to administer or dispense drugs~~ shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit products into the marketplace.

(b) ~~Appropriate documentation shall be made to the pedigree if any prescription drug that was ordered in excess of need by the wholesale distributor from a source outside the normal distribution channel, if identified as such, and which the integrity has been maintained, that is returned to the manufacturer or wholesale distributor from which it was acquired after which the wholesale distributor shall abide by the provisions of these regulations that govern returned, damaged and outdated prescription drugs.~~ It is unlawful for a person to knowingly and willfully perform or cause the performance of, or aid and abet any of the following acts in this State:

(i) the manufacture, repackaging, sale, delivery or holding or offering for sale of any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit or has otherwise been rendered unfit for distribution;

(ii) the adulteration, misbranding or counterfeiting of any prescription drug;

(iii) the receipt of any prescription drug or device that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit, or the delivery or proffered delivery of such prescription drug for pay or otherwise;

(iv) the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the product labeling of a prescription drug that results in misbranding;

(v) the forging, counterfeiting, simulation, or false representation of any prescription drug without the authority of the manufacturer, or using any mark, stamp, tag, label or other identification device without the authorization of the manufacturer;

(vi) the purchase or receipt of a prescription drug from a person that is not licensed to distribute prescription drugs to that purchaser or recipient;

(vii) the sale or transfer of a prescription drug to a person who is not legally authorized to receive it;

(viii) the sale or transfer of a prescription from pharmacies to distributors for resale;

(ix) the failure to maintain or provide records;

(x) providing the board of any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter in this Chapter;

(xi) the wholesale distribution of any prescription drug that was:

(A) purchased by a public or private hospital or other health care entity;

(B) donated or supplied at a reduced price to a charitable organization; or

(C) stolen or obtained by fraud or deceit.

(xii) the failure to obtain a license or operating without a valid license when a license is required;

(xiii) the obtaining of or attempt to obtain a prescription drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;

(xiv) the distributing of a prescription drug to the patient without a prescription from a practitioner licensed by law to use or prescribe the prescription drug;

(xv) the distributing of a prescription drug that was previously dispensed by a pharmacy or distributed by a practitioner; or

(xvi) the failure to report any prohibited act as listed in these rules.

(c) ~~Any prescription drug that is damaged, ,deteriorated, misbranded, ,counterfeit, contraband, suspected of being counterfeit or contraband, adulterated or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other prescription drugs until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired or to a third party returns processor. Notice of prescription drugs identified under this paragraph shall be given to the board and manufacturer or wholesale distributor from which they were acquired within three (3) business days of identification.~~

(d) ~~Any prescription drug whose immediate or sealed outer or secondary containers or product labeling are adulterated, misbranded, counterfeited, contraband, or suspect of being counterfeit or contraband shall be quarantined and physically separated from other~~

~~prescription drugs until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired. Notice of prescription drugs identified under this paragraph shall be given to the board and manufacturer or wholesale distributor from which they were acquired or to a third party returns processor within three (3) business days of identification.~~

(e) ~~If the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality or purity, then the prescription drug shall be destroyed or returned to the supplier unless examination, testing, or other investigation proves that the prescription drug meets appropriate standards of safety, identity, ,strength, quality and purity. In determining whether the conditions under which a prescription drug has been returned cast doubt on the prescription drug safety, identity, strength, quality or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the prescription drug has been held, stored or shipped before or during its return and the condition of the prescription drug and its container, carton or product labeling as a result of storage or shipping.~~

(f) ~~Contraband, counterfeit, or suspected to be counterfeit or contraband drugs, other evidence of criminal activity and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the board and the FDA.~~

(g) ~~The shipping, immediate, or sealed outer or secondary container ort product labeling, and accompanying documentation, suspected of or determined to be counterfeit, contraband, or otherwise fraudulent shall not be destroyed until its disposition is authorized by the board and the FDA.~~

(h) ~~The recordkeeping requirements of this chapter shall be followed for all outdated, damaged, deteriorated, counterfeit, contraband, misbranded or adulterated prescription drugs.~~

(c) Any prescription drug that has been opened or used but is not adulterated, misbranded, counterfeited, contraband or suspect of being counterfeit or contraband, shall be identified as such and shall be quarantined and physically separated from other prescription drugs until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired.

~~Section 18.~~ ~~Electronic Track and Trace Requirements.~~

(a) ~~Electronic track and trace requirements shall not be considered ass a requirement until such time as the FDA implements a uniform electronic track and trace system utilizing widely accepted standard technology that is universally available to manufacturers, wholesalers, and pharmacies and is technically operationally feasible and reliable for manufacturers, wholesale distributors sand pharmacies.~~

(b) ~~After the FDA has implemented a uniform and universally available standard for an electronic track and trace system to initiate, provide, receive or maintain pedigrees, the board shall consult with manufacturers, wholesale distributors and pharmacies and prepare a report before adopting any rules to implement such electronic track and trace system and imposing such requirements on all manufacturers, wholesale distributors and pharmacies. Implementation of the FDA's standards shall satisfy the requirements under section 10 of this chapter.~~

Section 18. Policies and Procedures.

Manufacturers, repackagers, third-party logistics providers and wholesale distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, shipping and wholesale distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors shall include in their written policies and procedures the following:

(a) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

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

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

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

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

(d) A procedure for the destruction of outdated prescription drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of two (2) years, and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements;

(e) A procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of two (2) years,

and the appropriate witnessing of the destruction of any labels, packaging, immediate containers or containers in accordance with all applicable federal and state requirements;

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

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

(h) ~~A procedure for conducting authentication of pedigrees in accordance with this chapter.~~ A procedure for verifying security provisions of common carriers.

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.

LONG TERM CARE PHARMACY SERVICES
CHAPTER 15

Section 1. Authority.

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(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 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.

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.

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.

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:

(I)	ISO Class 3	35.2 m3
(II)	ISO Class 4	352 m3
(III)	ISO Class 5	3,520 m3
(IV)	ISO Class 6	35,200 m3
(V)	ISO Class 7	352,000 m3
(VI)	ISO Class 8	3,520,000 m3

(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**3**°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) 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 snuggly 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.