Notice of Intent to Adopt Rules

Revised July 2013

1. General Information

a. Agency/Board Name
Wyoming State Board of Pharmacy

b. Agency/Board Address
1712 Carey Avenue Suite 200

c. City
Cheyenne

d. Zip Code
82002

e. Name of Contact Person
Mary K. Walker

f. Contact Telephone Number
307-634-9636

g. Contact Email Address
BOP@wyo.gov

h. Date of Public Notice
September 16, 2013

i. Comment Period Ends
November 4, 2013

j. Program

2. Rule Type and Information: For each chapter listed, indicate if the rule is New, Amended, or Repealed.

If "New," provide the Enrolled Act numbers and years enacted: Enrolled Act No. 77 Enacted 2013 (HB0094)

a. Provide the Chapter Number, Short Title, and Rule Type of Each Chapter being Created/Amended/Repealed
Please use the Additional Rule Information form for more than 10 chapters, and attach it to this certification.

Chapter Number:	Short Title:			
1	Rules of Practice and Procedure	☐ New	☒ Amended	☐ Repealed
2	General Practice of Pharmacy Regulations	☐ New	☒ Amended	☐ Repealed
3	Pharmacy Internship Regulations	☐ New	☒ Amended	☐ Repealed
4	Code of Ethics	☐ New	☒ Amended	☐ Repealed
6	Continuing Professional Education Regulations	☐ New	☒ Amended	☐ Repealed
9	Patient Counseling and Prospective Drug Use Review	☐ New	☒ Amended	☐ Repealed
10	Pharmacy Technician Regulations	☐ New	☒ Amended	☐ Repealed
11	Dangerous Drug Regulations	☐ New	☐ Amended	☒ Repealed
12	Institutional Pharmacy Practice Regulations	☐ New	☒ Amended	☐ Repealed
13	Non-Sterile Compounding	☐ New	☒ Amended	☐ Repealed

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

d. ☐ N/A ☐ 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 (Section 5 of the Rules on Rules).

e. A copy of 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: http://pharmacyboard.state.wy.us

* If Item "d" above is not checked, the proposed rules shall be in strike and underscore format.

Additional Rule Information

Revised June 2013

1. General Information

a. Agency/Board Name Wyoming State Board of Pharmacy		
b. Agency/Board Address 1712 Carey Avenue Suite 200	c. City Cheyenne	d. Zip Code 82002
e. Name of Contact Person Mary K. Walker	f. Contact Telephone Number 307-634-9636	
g. Contact Email Address BOP@wyo.gov		
h. Program		

2. Rule Information, Cont.

a. Provide the Chapter Number, Short Title, and Rule Type of Each Chapter being Created/Amended/Repealed

Chapter Number	Short Title	New	Amended	Repealed
15	Long Term Care Pharmacy Services	☐	☒	☐
16	Immunization Regulations	☒	☐	☐
		☐	☐	☐
		☐	☐	☐
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		☐	☐	☐
		☐	☐	☐

3. Public Comments and Hearing Information

a. A public hearing on the proposed rules has been scheduled. ☒ Yes ☐ No

If "Yes:"	Date:	Time:	City:	Location:
	November 5, 2013	1:00 p.m.	Casper	951 N. Poplar, Rm 114

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 Contact Person listed in Section 1 above.

4. Federal Law Requirements

a. These rules are created/amended/repealed to comply with federal law or regulatory requirements. ☒ Yes ☐ No

If "Yes:" Applicable Federal Law or Regulation Citation:

Indicate one (1):

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

☐ The proposed rules exceed minimum federal requirements.

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

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

☐ At the following URL: _____

5. 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.

6. 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	September 16, 2013

Distribution List:

- Attorney General and LSO: Hard copy of Notice of Intent; Statement of Reasons; clean copy of the rules; and strike-through and underline version of rules (if applicable). *Optional:* electronic copies of all items noted (in addition to hard copies) may be emailed to LSO at Criss.Carlson@wyoleg.gov.
- Secretary of State: Electronic version of Notice of Intent sent to Rules@wyo.gov.

BOARD OF PHARMACY WYOMING

Randolph A. (Randy) Harrop , RPh, President
Bessie S. McGirr, RPh, Vice President
John R. McPherson, DDS, Secretary/Treasurer
Charles W. Smith, Public Member
Stephanie McAntee, RPT, Member, Ex-Officio
Kerri J. Kilgore, RPh, Member
Jim Massengill, RPh, Member
Sigsbee W. Duck, RPh,MD,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
H. Richard Burton, 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

September 2013

All 17 chapters have been reviewed and revisions are proposed to reduce the number, the length, and the 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

The proposed rules address the following:

The 2013 legislative change to W.S. § 33-24-157 Immunization administration, Enrolled Act No. 77, House Bill No. 0094 which provides for pharmacist administration of immunizations to healthy individuals age 7 and older. These changes are in Chapter 16 and are proposed after extensive work by board members in committees, meetings with the board of medicine, and discussions during two public board meetings.

Proposed revisions also include updated language for investigations of complaints, hearings, and disciplinary processes in Chapter 1 (Practice and Procedure of the Board of Pharmacy).

Chapter 2 (General Practice of Pharmacy) has been updated in definitions, clarified and complexity reduced in processes including the transfer of prescriptions, absence of a pharmacist, licensing, emergency drug supply for nursing homes, and adding to the prescription drug label “the purpose for use where appropriate”. Chapter 2 also includes requirements for licensure or reinstatement following a felony conviction by a pharmacist or pharmacy technician.

Chapters 3, 4, 6, 9, 11, 12, 13, and 15 have similar updates to definitions, current federal regulations and reductions in complexity.

Proposed revisions to Chapter 10 (Pharmacy Technicians) include a new level of licensure “pharmacy technician specialist” and the pharmacy functions that each level can perform. The intention is to provide more assistance to pharmacists in their increasing responsibilities for patient care due to the complexity of new pharmaceuticals and therapies.

Chapter 11 is proposed to be REPEALED due to outdated regulations. Note: Chapters 5 and 7 were repealed in 2011.

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NOTICE OF INTENT TO ADOPT RULES AND REGULATIONS

September 17, 2013

Agency:	Wyoming State Board of Pharmacy
Address:	1712 Carey Avenue Suite 200 Cheyenne, WY 82002
Contact person:	Mary K. Walker, Executive Director
Telephone:	307-634-9636
Email:	BOP@wyo.gov

Statement of Principal Reasons for Revisions, Wyoming Pharmacy Act Rules and Regulations (see “items of interest” at http://pharmacyboard.state.wy.us)

Statement of Principal Reasons for Revisions, Wyoming Controlled Substances Act (see “items of interest” at http://pharmacyboard.state.wy.us)

PUBLIC COMMENTS WILL BE TAKEN IN WRITING BY EMAIL OR POSTAL SERVICE UNTIL 5:00 p.m. on NOVEMBER 4, 2013

A PUBLIC HEARING IS TO BE HELD IN CASPER, WY, AT 951 NORTH POPLAR, ROOM 114, BEGINNING AT 1:00 p.m. ON NOVEMBER 5, 2013

A copy of the proposed revisions to existing rules in a format that clearly indicates additions to and deletions from existing language may be obtained at the Board’s office at the above address, or website at http://pharmacyboard.state.wy.us

CHAPTER 1

RULES OF PRACTICE AND PROCEDURE

OF THE

WYOMING STATE BOARD OF PHARMACY

Section 1. Authority. These rules are promulgated as authorized by the Act, and pursuant to the Wyoming Administrative Procedure Act, W.S. 16-3-101, et. seq.

Section 2. 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., and the Wyoming Pharmacy Technician Act, W.S. 33-24-301, et. seq.

(b) "Board" means the Wyoming State Board of Pharmacy.

(c) "Contestee" means the person, persons, firm or corporations who are licensees by law under the jurisdiction of said 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).

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

(e) "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 Therapuetic Equivalence Evaluations*, (The Orange Book) as the official listing of Dangerous Substances for the State of Wyoming. (moved from Chapter 11)

(~~e~~ f) "Executive Director" means the Executive Director of the Board.

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

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

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

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

(~~j~~ k) "State" means the State of Wyoming.

~~Section 3. Contests. The Executive Director shall cause a full and complete investigation of all complaints of alleged violations of such gravity as would warrant formal action by the Board, if probable cause is found as to the existence of such violations.~~

~~Upon the completion of such investigation, which shall be conducted without participation by any Board member, the Executive Director shall file a formal action complaint if deemed appropriate. The complaint shall set forth in writing the alleged acts or omissions of acts in violation of the Act of any rules, regulations or orders promulgated thereunder and by authority thereof.~~

~~The person designated by the Office of the Attorney General as attorney for the Board shall assist in the preparation of the complaint and notice as provided for under these Rules.~~

~~Section 4. Notice and Complaint. When the Executive Director desires to file a formal complaint, it shall be prepared and filed with the Board, verified in writing, setting forth:~~

~~(a) The name and address of each contestee.~~

~~(b) The time, place and nature of the hearing.~~

~~(c) The legal authority under which the hearing is to be held.~~

~~(d) A statement, in ordinary and concise language, of the facts upon which the complaint is based, including, when applicable, particular reference to the statutes and rules, regulations or orders that have allegedly been violated.~~

~~(e) At any time prior to the date set for hearing, the Executive Director may amend the original complaint to include a more definite and detailed statement of the facts and matter asserted.~~

~~Section 5. Service of Notice. Notice shall be served by mail at least twenty (20) days prior to the date set for hearing. Notice shall be sent by certified or registered mail with return receipt thereof to the contestees' last known address.~~

~~Section 6. Docket. A contested case shall be assigned a number when a complaint is filed by the Executive Director. The Executive Director shall establish a separate file for each such docketed case, in which shall be systematically placed all papers, pleadings, documents, transcripts, evidence and exhibits.~~

Section 7. Answer or Appearance. The contestee shall file with the Board an answer to the complaint within thirty days of mailing of the complaint. In this answer, the contestee shall state the portions of the complaint, which he admits, and the portions of the complaint, which he denies, and shall set forth any defenses or other challenges to the complaint he may have. Any portions of the complaint, the contestee has not denied in his answer, shall be deemed admitted. Any defense or challenge not raised in the answer shall be deemed waived.

Section 8. Default in Answering or Appearing. In the event of the failure of any contestee to answer or otherwise appear within the time allowed, a default may be entered against him and the allegations as set forth in the Notice and Complaint shall be taken as true and an Order of the Board entered accordingly.

Section 9. Subpoenas. Subpoenas for appearance and to produce testimony, books, papers, documents or exhibits may be issued by the Board or Executive Director, as its agent, on behalf of any party to the contested case.

Section 10. Hearing. All issues and matters set forth in the notice and complaint shall be presented by the Executive Director, Staff or agents and the contestee to the Board. Any contestee may be represented personally or by counsel, provided that such counsel be duly authorized to practice law in this State or is otherwise associated at the hearing with an attorney authorized to practice law in this State. Provided that, when the contestee has made timely and sufficient application for the renewal of a license or a new license to refer to any activity of a continuing nature, the existing license does not expire until the application has been determined by the Board. If, however, the Executive Director alleges that public health, safety or welfare imperatively requires emergency action by the Board summary suspension of a license may be ordered pending proceedings before the Board.

Section 11. Order of Procedure at Hearing. As nearly as may be, hearings shall be conducted in accordance with the following order or procedure.

(a) The Board or hearing officer shall announce that the hearing is convened upon the call of the docket number and title of the matter and case to be heard, and thereupon the Board or hearing officer shall incorporate all pleadings into the record together with the appearance by any contestee and shall note for the record all subpoenas issued and all appearances of record, including contestee and their counsels of record.

(b) The agent, counsel or representative of the Executive Director and Staff shall thereupon proceed to present the Staff's evidence. Witnesses may be cross-examined by contestee.

(c) The contestee shall be heard in the same manner as the Staff's evidence, witnesses and exhibits have been heard and presented.

(d) No opening statement shall be made, but each of the parties may offer rebuttal evidence within the discretion of the Board who shall preside.

(e) Closing statements, at the conclusion of the presentation of evidence, may be made by the parties or counsel. No rebuttal statement may be made by any of the parties to the proceeding. The time for oral argument may be limited by the Board.

(f) After all proceedings have been concluded, the Board or hearing officer shall dismiss and excuse all witnesses and declare the hearing closed. Any party who may wish or desire to tender written briefs of law unto the Board may do so. The Board may take the case under advisement and shall declare unto each of the parties that the decision of the Board shall be announced within due and proper time following consideration of all of the matters presented at the hearing.

Section 12. Witnesses to be Sworn. All persons testifying at any hearing before the Board shall be administered the following oath by the Board or designated hearing officer:

"Do you swear or affirm to tell the truth, the whole truth and nothing but the truth in this hearing? So help you God."

Section 13. Applicable Rules of Civil Procedure to Apply. The rules of practice and procedure contained in the Wyoming Rules of Civil Procedure insofar as the same may be applicable and not inconsistent with the matters before the Board and applicable to the rules, orders and regulations promulgated by the Board shall apply.

Section 14. Attorneys. The filing of an answer or other appearance by an attorney constitutes his appearance for the party for whom the pleading is filed. The Board and all parties shall be notified in writing of his withdrawal from any hearing. Any person appearing before the Board at a hearing in a representative capacity shall be precluded from examining or cross-examining any witness unless such person shall be an attorney licensed to practice law in this State, or a non-resident attorney associated with an attorney qualified to practice law in this State. This rule shall not be construed to prohibit any person from representing himself in any hearing before the Board, but any such person appearing on his own behalf shall not be relieved of abiding by all rules established for the proceedings herein.

Section 15. Attorney General to be Present. In all hearings held upon formal action brought on before the Board, a representative of the Office of the Attorney General of Wyoming shall appear on behalf of the Executive Director or Staff, and shall present all evidence, testimony and legal authority in support of the notice and complaint to be considered by the Board.

In addition, the Office of the Attorney General of Wyoming shall provide an additional representative to appear at the hearing designated as hearing officer and be present to assist and advise the Board in the conduct of the hearing and in the preparation of findings of fact, conclusions of law and recommendations of the Board.

Section 16. Record of Proceedings. When the denial, revocation or suspension of any license is the subject for hearing, it shall be regarded as a contested case and the proceedings, including all testimony, shall be reported verbatim by a court reporter.

~~Section 17. Depositions. In all contested cases coming before the Board, the taking of depositions and discovery shall be available to the parties.~~

~~Section 18. Decision, Findings of Fact and Conclusions of Law and Order. The Board shall, with the assistance of the hearing officer, following the full and complete hearing, make and enter a written decision and order containing Findings of Fact and Conclusions of Law. Such decision and order shall be filed with the Board and shall, without further action, become the decision and order as a result of the hearing. No officer, staff or agent of the Board who participated or advised in the investigation or presentation of evidence at the hearing shall participate or advise in the decision. Upon entry and filing, the Board shall mail copies thereof to each contestee and attorney of record.~~

~~Section 19. Appeals to District Court. Appeals from Board decisions shall be taken to the district court having jurisdiction and proper venue in accordance with applicable statutes and the Wyoming Rules of Appellate Procedure.~~

~~Section 20. Transcript in Case of Appeal. In the case of an appeal to the district court, the appellant shall cause the transcript of the testimony and all other evidence offered at the hearing, to be filed. The transcript shall be verified by the oath of the reporter who took the testimony as a true and correct transcript of the testimony and other evidence in the case. The compensation of the reporter for preparing the transcript of the testimony and all other costs of appeal shall be paid by the appellant.~~

~~Section 21. Rules Not Applicable to Investigations. Nothing contained in these rules shall be applicable to investigations which may be carried on and conducted by the Board or its agents under the provisions of the Act.~~

Section 3. Application Review Process.

(a) Upon receipt of a completed application, the Board Office 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, the Board Office shall forward the application to the Application Review Committee (ARC).

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

(i) Approve the application if the applicant meets all requirements; or

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

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

(i) A preliminary denial letter shall be sent to 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 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, a reconsideration conference shall be held with the ARC, the Assistant Attorney General, and the applicant.

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

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

(d) Application denial hearings

(i) An application denial hearing is a formal contested case hearing conducted pursuant to the Wyoming Administrative Procedure Act.

(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 4. 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 or Board Rules may be submitted by any person or entity, a Board member, or a Board staff member. The written complaint should 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;

(iii) The specific conduct alleged to constitute the violation;

(iv) The name and address of any other witnesses; and

(v) The signature of the complainant.

Section 5. Review of Written Complaint.

(a) Written complaints shall be referred to the Board staff Compliance Officer/Investigator or to an Investigative Board Member (IBM) selected by Board staff from a rotating schedule. License holders against whom charges are made will be advised of the investigation and the nature of the complaint.

(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.

Section 6. 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 shall:

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

(ii) Prepare an investigative report which shall include:

(A) The findings;

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

(C) 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, and consult with the Assistant Attorney General.

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

(i) Send the notice required by Section 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;

(iv) Recommend the Board dismiss the complaint.

(d) The Board may resolve a complaint at any time by:

(i) Accepting a voluntary surrender of a license;

(ii) Accepting conditional terms for settlement;

(iii) Dismissal.

Section 7. Service of Notice and Opportunity to Show Compliance.

Prior to commencement of a formal hearing, the ~~IBM~~ Executive Director shall give notice by mail to the license holder of the facts or conduct which warrant his/her intended action. The notice shall give the license holder an opportunity to show compliance with all lawful requirements for retention of the license within twenty (20) days of the mailing of the notice. Such notice shall be sent to the license holder's last known address ~~both~~ by certified mail ~~with return receipt requested and by first class mail.~~

Section 8. Formal Hearing ~~Procedures~~ Prerequisites.

(a) 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 ~~both~~ certified mail ~~and first class 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 W.S. § 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 9. 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 10. Contested Case Hearings. 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 11. Decisions.

(a) Proposed Decisions:

(i) At the discretion and direction of the ~~Board~~ 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 12. 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 13. 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.

CHAPTER 2

GENERAL PRACTICE OF PHARMACY REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Purpose

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

Section 3. Scope of Chapter.

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

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

(e) "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.

(~~e~~f) "Board of Pharmacy" or "Board" means the Wyoming State Board of Pharmacy.

(gf) "Collaborative pharmacy practice" ~~means a practice in which a prescribing physician makes a diagnosis, maintains ongoing supervision of patient care, and refers the patient to a pharmacist under a protocol allowing the pharmacist to perform patient care functions authorized by the physician under specified conditions or limitations.~~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 licensed independent practitioner ~~Practitioners~~ under protocol and in collaboration with licensed independent ~~P~~practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes.

(~~g~~h) "Collaborative practice agreement" means a voluntary agreement, written and signed, between a pharmacist and a prescribing ~~physician~~ licensed independent practitioner that defines a collaborative practice.

(~~h~~i) "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.

(~~i~~j) "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.

(~~j~~k) "Consultant pharmacist" means a pharmacist who establishes policies and procedures for the distribution and storage of drugs, ~~and~~ 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.

(~~k~~l) "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.

(~~l~~m) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or 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."

(~~m~~n) "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.

(~~n~~o) "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.

(~~o~~p) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(~~p~~q) "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.

(~~q~~r) "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.

(~~r~~s) "Drug therapy management" means the same as medication therapy management as defined in this chapter.

(~~s~~t) "Electronic prescription" means a prescription that is generated on an electronic application and transmitted as an electronic data file.

(~~t~~u) "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.

(~~u~~v) "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 fax machine, which is authenticated by an electronic signature.

(~~v~~w) "*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.

(~~w~~x) "Labeling" means the process of preparing and affixing a label to any drug container, exclusive of the labeling by a manufacturer, ~~packet~~packager, or distributor. ~~(See Section 11 of these Regulations.)~~

(~~x~~y) "Medication therapy management" (also known as "drug therapy management") ~~means the review of drug therapy regimen(s) of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing physician regarding adjustment of the regimen. Decisions involving medication therapy management shall be made in the best interest of the patient. Medication therapy management may include:~~is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed Pharmacist's scope of practice. These services may include, but are not limited to, the following, according to the individual needs of the patient:

(i) ~~Implementing, modifying, and managing drug therapy according to the terms of a collaborative practice agreement and the specific written orders~~Performing or obtaining necessary assessments of the patient's health status;

(ii) ~~Collecting and reviewing patient drug histories~~Formulating a medication treatment plan;

(iii) ~~Obtaining and checking vital signs including, but not limited to, pulse, temperature, blood pressure, and respiration~~Selecting, initiating, modifying, or administering medication therapy;

(iv) ~~Ordering and evaluating the results of laboratory tests directly relating to drug therapy, when performed in accordance with approved protocols applicable to the practice setting~~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 edications,

(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 services within the broader health care management services being provided to the patient, and

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

(xi) Ordering, or performing laboratory assessments and evaluating the response of the patient to therapy, including safety and effectiveness, 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.

(~~y~~z) "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.

(~~z~~aa) "Paper prescription" means a prescription created on paper or computer generated to be printed or transmitted via facsimile that includes a manual signature.

(~~aa~~bb) "Patient confidences", as used in W.S. § 33-24-101(c)(iii), means information transmitted by the prescribing practitioner or agent to the pharmacist or agent for purposes of treating the patient and information transmitted by the patient or agent to the pharmacist or agent for purposes 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.

(~~bb~~cc) "Patient counseling" means the oral communication by the pharmacist of information, as defined in the Board Rules and Regulations, 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.

(~~cc~~dd) "~~Pharmaceutical care" is the provision by a pharmacist of medication therapy management services, with or without the dispensing of drugs or devices, intended to achieve outcomes related to cure, prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.~~"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.

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

(~~ee~~ff) "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.

(~~ff~~gg) "Pharmacy" means an area(s) where ~~prescriptions are filled, counseling occurs, prescription drugs are stored, and patient records and other items required by law for the practice of pharmacy are maintained~~drugs are dispensed and pharmacist care is pro~~b~~vided.

(~~gg~~hh) "Pharmacy intern" ~~a~~is described in Chapter 3 ~~means any person who:~~.

~~(i) Has entered the first professional year in an approved college or school of pharmacy, who is in good standing with the approved college or school of pharmacy, and who has duly registered with the Board; or~~

~~(ii) Those applicants who are graduates of an approved college or school of pharmacy seeking licensure by examination or score transfer who lack the required amount of practical experience for licensure, and who have duly registered with the Board; or~~

~~(iii) Those applicants for reciprocity who have not been in active practice and must complete an internship, and who have duly registered with the Board; or~~

~~(iv) Those applicants for reinstatement of a lapsed license who must complete a required amount of practical experience, and who have duly registered with the Board; or~~

~~(v) Those applicants for licensure who are considered foreign pharmacy graduates and possess a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate who must complete one thousand two hundred (1,200) hours of practical experience for licensure, and who have duly registered with the Board.~~

~~(hh) "Pharmacy technician" means an individual, other than an intern, who performs pharmacy functions under the direct supervision of a licensed pharmacist.~~

(ii) "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.

(jj) "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.

(kk) "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"~~"; or~~

~~(iv) Is a drug included on the Wyoming Dangerous Substance Listing, as referenced in Wyoming Pharmacy Act Rules and Regulations, Chapter 11, and shall be dispensed pursuant to a prescription drug order.~~

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

(mm) "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 hours (48 hr.)

(nn) "Registered Pharmacist" means an individual currently licensed by this State to engage in the practice of pharmacy.

(oo) "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 cost of such remodeling is equal to or greater than twenty-five thousand dollars ($25,000.00).

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

(qq) "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.

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

(ss) "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.

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

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

(vv) "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.

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®);

(ii) Multistate Pharmacy Jurisprudence Examination (MPJE®)

(b) Applicants for licensure by examination will be licensed, provided they ~~meet the following requirements~~:

(i) Submit ~~A~~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 ~~submitted~~ to the Board office. 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, as required by the ~~National Association of Boards of Pharmacy®.~~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® may retake the examination.

(B) All retakes require payment of fees as required by the ~~National Association of Boards of Pharmacy®.~~NABP.

(iv) Meet the required practical experience requirement of 1,200 internship hours, as specified in Chapter 3 of the Board Rules and Regulations.

(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.

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

(A) The Board will only issue a pharmacist license to an applicant who has been convicted of a felony if five (5) years have elapsed since the applicant completed all requirements of the sentence imposed and was released from probation or parole, including full payment of all fines, costs, restitution, or other charges the applicant was ordered to pay.

(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 ~~Multistate Pharmacy Jurisprudence Examination (~~MPJE®~~)~~ for Wyoming with a minimum score of 75.

(A) Candidates who do not receive a passing grade on the MPJE® may retake the examination.

(B) All retakes require payment of fees, as required by the ~~National Association of Boards of Pharmacy®.~~NABP/

(iv) The required practical experience requirement of 1,200 internship hours is met, as specified in Chapter 3 ~~of the Board Rules and Regulations~~.

(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 ~~Wyoming Division of Criminal Investigation (~~DCI~~)~~.

(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 the Board Rules and Regulations,~~ 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~~, and those costs associated in reviewing test questions for the jurisprudence examination (MPJE®)~~.

(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 ~~Foreign Pharmacy Graduate Examination Committee®~~FPGEC:

(i) 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) Passing 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

(iv) In lieu of the TOEFL® and TSE®, obtaining an acceptable score for 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 ~~National Association of Boards of Pharmacy (~~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 ~~any state or~~ 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 criminal background check;

(iv) Pay the required criminal background check fee;

(v) Pass the ~~Multi-State Pharmacy Jurisprudence Examination~~ MPJE®~~)~~;

(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 Act and the Board Rules and Regulations;

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

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

(i) The Board will only issue a pharmacist license to an applicant who has been convicted of a felony if five (5) years have elapsed since the applicant completed all requirements of the sentence imposed and was released from probation or parole, including full payment of all fines, costs, restitution, or other charges the applicant was ordered to pay.

(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 (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 transfer 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 transfer of pharmacists licensed in California after January 1, 2004.

(h) The Board will accept licensure transfer of pharmacists licensed in Florida after January 1, 2001.

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

(a) All retail pharmacies operating in Wyoming 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 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 the Board Rules and Regulations.

(iv) A facsimile 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 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 ~~News, maintained in a binder~~quarterly newsletter by access to the Board website;

(E) The current edition, 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 ~~Pharmacist-in-Charge~~PIC.

(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 produce prescription drug labels.

(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 the Board Rules and Regulations~~.

(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:

(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.

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

(A) The Pharmacy shall consist of no less than 500 square feet.

(B) 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 feet (3 ft.) 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.

(C) Located within the pharmacy, but not counted in the square footage requirement of the pharmacy, shall be restroom facilities, access to which shall be limited to pharmacy staff ~~only~~.

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

(I) 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.

(II) Those pharmacies not included in (~~i~~I) must 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.

(E) 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".

(F) 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.

(c) 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.

(d) 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 all the names of all licensed pharmacists employed, specifically identifying the Pharmacist-in-Charge (PIC). The PIC determines which employees shall have ~~keys~~ access to the pharmacy.

(c) The Board shall be notified within seven (7) days of ~~with~~ every change in ~~Pharmacist-in-Charge (~~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 ~~Pharmacist-in-Charge~~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 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 of a pharmacy change in 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 to 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 ~~Pharmacist-in-Charge~~PIC and shall have direct control of the ~~pharmaceutical affairs~~pharmacy services of said pharmacy. A pharmacist may not serve as the ~~Pharmacist-in-Charge~~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 30 days when absent due to illness, family illness or death, scheduled vacation, or other authorized absence, every week, or eighty (80) percent of the time the pharmacy is open, if opened less than forty (40) hours per week.

A pharmacist may not serve as ~~Pharmacist-in-Charge (~~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.

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 ~~Pharmacist-in-Charge~~PIC and a new ~~Pharmacist-in-Charge~~PIC shall be designated.

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

(b) Responsibility as the ~~Pharmacist-in-Charge (~~PIC~~)~~ includes requiring 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 or pharmacy technician specialist 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.

(c) Additional responsibilities of the ~~Pharmacist-in-Charge~~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, ~~i.e.,~~to include registered pharmacists, interns, pharmacy technicians-in-training, pharmacy technician specialists, and registered pharmacy technicians, have valid licenses or registrations in good standing, and that all certificates are on display. Pharmacists ~~and interns~~ 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 registrations, are valid and posted.

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

(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 prescription drugs are not outdated, damaged, deteriorated, misbranded, counterfeit, contraband, or adulterated.

(ix) Be in full and actual charge of such pharmacy and responsible for whatever goes on in it.

(x) Develop a written policy for delivery of prescription drugs during non-pharmacy hours which shall include, but not be limited to:

(A) An arrangement made ahead of time with the customer that delivery will occur under these circumstances.

(B) An arrangement which guarantees that the offer to counsel and, if accepted, counseling will occur on all new prescriptions.

(C) An arrangement which guarantees the security of the drugs and the confidentiality for the customer.

(D) A plan which provides that such delivery is used only when required by the customer and not used in all instances for delivery after closing hours.

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

(d) 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.

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

(e) No pharmacy shall be permitted to operate without a ~~Pharmacist-in-Charge (~~PIC~~)~~. The Board shall be notified in writing within seven (7) days of any newly designated PIC. The Board shall record the PIC change and issue an amended license.

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 used 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 (a) through (n) this Section.

(a) A pharmacist, pharmacy technician or pharmacy intern will transfer prescription order information for non-controlled substances upon request of a patient. ~~A pharmacist may transfer~~ Transfer prescription order information for the purpose of refilling a prescription is subject to the following requirements. The information is communicated directly by one pharmacist, ~~or~~ pharmacy intern, or pharmacy technician ~~specialist~~ to another pharmacist, or the information is sent to the receiving pharmacist via facsimile, 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 ~~specialist.~~ 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.

(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.

(ii) Record on the reverse side the invalidated prescription order or electronically 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, 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;

(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 ~~which utilizes a computer for recordkeeping of prescription order transactions~~ 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 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; 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.

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

(iii) For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist, the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing all information required to include:

(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 refill(s).

(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.

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

(iv) For electronic prescription being transferred electronically, the transferring pharmacist must 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.

(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 ~~section~~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 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 prescription that indicates that it 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 had 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 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: name of the patient, brand or generic name of the drug product dispensed, unless otherwise specified; drug strength and quantity; the name, address, and telephone number of the pharmacy; the practitioner's name; the serialized number of the prescription; the date the prescription was filled or refilled; purpose for use where appropriate; directions for use; including accessory cautionary information as required for patient safety; the identifying initials of the dispensing pharmacist, and any other information required by federal o~~f~~r State law.

(b) Effective January 1, 2004, 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 drugs for which the national reference file has no description on file.

(c) All unit dose 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; and

(iv) Manufacturer's expiration date, if prepackaged or repackaged by the pharmacy, the expiration date shall be lesser of the manufacturer's expiration date or 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 the Board Rules and Regulations~~, as well as prescription drugs dispensed from hospital emergency room departments, as described in Chapter 12 ~~of the Board Rules and Regulations~~, 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.

(ii) The physician, at the request of the patient, may request a one-time waiver. However, the physician 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 prescription and, if applicable, the name of the agent transmitting the prescription must be recorded, as well 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-Patient Relationship as Affecting Prescriptions.

(a) Upon learning that a patient/practitioner 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 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 within the State, or any other state, on the basis of a prescription generated solely through an Internet questionnaire physician consultation. Furthermore, all pharmacies or pharmacists included in this Section are prohibited from linking an Internet site with or relating the site, in any way, to any other site, business, or physician that provides prescriptions for medications solely on the basis of an online medical consultation questionnaire.

Section 15. Return or~~f~~ 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. However, prescription drugs may be accepted for re-dispensing, if all the following are met:

(i) Pharmacies may accept previously dispensed drugs for return 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) Prescription drugs shall only be returned to the pharmacy from which originally dispensed.

(iii) The ~~Pharmacist-in-Charge~~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) Prescription drugs accepted for re-dispensing must have been initially dispensed as a unit dose package or unit of issue package.

(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 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 packages 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. 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) 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 the date of such return.

Section 16. Scope of Practice.

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

~~Section 17. Identification of a Patient.~~ (Moved to Chapter 6 of CSA Rules)

~~(a) The pharmacist or employee under supervision must verify the identity of the person presenting a controlled substance prescription to the pharmacy for dispensing. This may be done by visual recognition. If identity is not established by visual recognition, a driver's license or similar photo identification form is considered acceptable documentation. The following information must be recorded on the reverse of the prescription, if identification is utilized: name, type of identification, and identification number.~~

~~(b) The name of the person receiving the dispensed drug is to be recorded on the prescription document, patient profile, or signature log, if an agent and not the patient receives the drug.~~

~~(c) This Section shall not apply to pharmacies that mail prescriptions to their patients. A note shall be entered on the prescription or patient's profile with the name and address of where the medication was mailed. Additionally, the date of such mailing shall be entered.~~

Section 1~~8~~7. 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 of 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.

(vii) The Board will only issue a pharmacist license to an applicant who has been convicted of a felony if five (5) years have elapsed since the applicant completed all requirements of the sentence imposed and was released from probation or parole, including full payment of all fines, costs, restitution, or other charges the applicant was ordered to pay.

(viii) 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 include all of the elements of ~~Section 18~~ this Chapter and may include the following:

(i) Pass a jurisprudence examination.

(ii) Internship under direct supervision ~~may be required~~. Internship period may vary depending upon how long the individual was out of practice.

(iii) Board interview.

Section 1~~9~~8. 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.

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

(b) All oral 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 to the pharmacist in written form; orally, including by telephone; by facsimile (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 ~~Wyoming~~ 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 ~~20~~19. Transmission of Prescriptions by Facsimile (Fax) Machines.

Prescriptions transmitted by fax shall include all of the features listed in this Chapter, including the practitioner's recognizable signature.

(a) Other requirements for fax prescriptions include:

(i) A notation that this is a fax prescription.

(ii) Telephone number and fax number of the practitioner.

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

(iv) Date and time of fax~~, if not otherwise programmed into transmission~~.

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

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

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.

(b) 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 or manually written copy of the faxed prescription shall be stapled to the fax.

(c) 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 ~~narcotic~~ 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 substance for a resident of a long-term care facility.

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

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

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

Section 2~~1~~0. Prescription Refill Information.

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

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

Section 2~~2~~1. Facsimile Machines (Fax) in General

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

Section 2~~3~~2. Therapeutic Equivalents.

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 orf similar action, but not the identical composition.

Pharmaceuticals that are considered to be therapeutic substitution instead of generic substitution shall not be used for retail/non-resident pharmacies. A 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 243. Specific Requirements for Licensure of Non-Resident Pharmacies to Ship Prescription Drugs into the State.

(a) Any pharmacy operating from outside the State that ships, mails, or delivers, in any manner, a dispensed prescription drug or legend drug to a patient in Wyoming, shall obtain and hold a non-resident pharmacy license and, if applicable, a controlled substance registration.

(b) Said pharmacy license and controlled substance registration shall be on forms supplied by the Board 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.

(v) Submit a list of all registered pharmacists, specifying the Pharmacist-in-Charge.

(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 ~~Pharmacist-in-Charge~~PIC.

(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).

(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 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.

Counseling shall be accomplished on new prescriptions orally and/or by written information accompanying the dispensed prescription.

(h) 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 2~~5~~4. 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 ~~National Association of Boards of Pharmacy® (~~NABP®~~)~~ fee for the ~~North American Pharmacist Licensure Examination (~~NAPLEX®~~)~~ and the ~~Multistate Pharmacy Jurisprudence Examination (~~MPJE®~~)~~ paid to NABP.

(ii) Pharmacist licensure by reciprocity shall be two hundred dollars ($200.00) paid to the Board plus 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 ~~every twelve (12) months~~annually by September 30. Renewal fee shall be fifteen dollars ($15.00).

(v) Pharmacy technician and pharmacy technician specialist licensure fee shall be fifty dollars ($50.00).

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

(vii) Pharmacy technician and pharmacy technician specialist 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 ~~fifty~~ seventy five dollars

($27550.00) per year. Oxygen manufacturer or distributor license and renewals shall be one hundred dollars ($100.00) per year.

(xi) Institutional pharmacy license and renewals shall be one hundred fifty ($150.00) per year.

(xii) 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.

(xiii) 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.

(xiv) Duplicate licenses may be issued upon request when licensee's name changes or the license become 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 technician or pharmacy technician specialist 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.

(iii) 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.

(iv) 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.

(v) 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.

(vi) 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.

(vii) 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.

(viii) A practitioner Controlled Substance Registrant whose registration renewal application is postmarked or hand delivered to the Board office after June 30 of their renewal year shall be assessed a late fee for forty dollars ($40.00) per year, in addition to the license renewal fee. Move to Chapter 3 Rules, CSA

Section 26 5. Emergency 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 of Pharmacy to maintain an emergency supply of drugs, both scheduled and non-scheduled, subject to approval by the Board. The drugs maintained in the emergency drug supply shall remain the property of the pharmacy to whom the permit was jointly issued.

(i) The pharmacy servicing the facility or facilities listed in Section 26(a)this Chapter shall make application to the Board, on an application 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 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 fifteen twenty five dollars ($215.00) annually.

(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 Substance Act and/or Rules and Regulations promulgated under said Acts.

(b) The number of drugs provided by a pharmacy to a facility listed in this Section 26(a) shall be limited to forty eight (48). Additional quantities require submission of an application listing the additional drugs requested with justification, and must be approved by the Board. The number of doses of each drug available shall be limited to thirty (30) doses of any separate drug dosage form in each emergency supply.

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

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

(ii) The emergency drug supply policy and procedure manual shall be reviewed and approved annually, during the anniversary month of when the original permit was issued by the Board, by the Pharmacist-in-Charge of the pharmacy servicingConsultant Pharmacist of the facility and the facility's director of nursing.

(d) The emergency drug supply may only be stocked and restocked by a pharmacist licensed by this Board or a technician under his or her supervision. Discrepancies in controlled substance inventories shall be documented and reported to the Board of Pharmacy, within seven (7) days of discovery.

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

(i) A new drug order given by the prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or seventy-two (72) hours, whichever is less. The drugs shall be administered only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and patient's profile for potential contradictions and adverse drug reactions.A new legend drug order given by the prescriber to a nurse for administration to a patient of a facility. Enough medication may be taken to cover dosing for seventy-two (72) hours or less, until the next scheduled delivery from the pharmacy. The pharmacist must be notified of the removal of medication, within 48 hours, to review the prescriber's order and patient's profile for potential contraindications and adverse drug reactions.

(ii) Drugs that a prescriber 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.Drugs that a prescriber 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 48 hours, of the removal of the medication.

(iii) Drugs designated by the patient care policy committee or similar facility committee as an "emergency drug" may be administered from the emergency drug supply, pursuant to the order of a prescriber for emergency or immediate administration to a patient of a facility. Within seventy-two (72) hours after administration under this paragraph, the case shall be reviewed by a pharmacist.Removal of any

controlled substance can only be done after the pharmacist has received an order from the prescriber or verified that a prescription exists. No controlled substance medication can be removed from the emergency 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 drug supply, the new pharmacy provider must make application to the Board.

(g) Facilities described in this Section ~~26(a)~~ are exempt from the provisions of this Section ~~26~~, provided that the pharmacy providing their emergency 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 Board of Pharmacy.

Section 2~~7~~6. Reinstatement of a Revoked or Suspended Pharmacist, Pharmacy Technician, or Pharmacy Technician Specialist License.

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

(i) A pharmacist, pharmacy technician specialist or pharmacy technician whose license was revoked by the Board may not file an application requesting a hearing until ~~twelve (12)~~thirty-six (36) months ~~has~~ have elapsed from the date the order revoking the pharmacist or pharmacy technician license ~~has become~~became final.

(ii) A pharmacist, pharmacy technician specialist 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~~, or the order of suspension has become final, whichever is later~~.

(A) A license which has been suspended automatically reinstates when the period of suspension ends if all requirements have been satisfactorily completed and the license has not expired.

(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 specialist or 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.

(vii) In the application, the pharmacist or the 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.

(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 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. ~~or~~, If not~~.~~ ~~A~~ a hearing shall be scheduled by the Executive Director if requested by the applicant for reinstatement. ~~The Executive Director will notify the applicant whether the Board staff will support or oppose the request for reinstatement.~~

(c) Board staff may require the applicant to submit to a 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 ~~North American Pharmacist Licensure Examination (~~NAPLEX®~~)~~ with a minimum score of 75;

(ii) The ~~Multistate Pharmacy Jurisprudence Examination (~~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 or pharmacy technician specialist must prove that he or she has been rehabilitated so that further violation of Wyoming Statutes and/or Board Rules and Regulations is not likely to occur, and that he or she is competent to function as a pharmacy technician or pharmacy technician specialist. The Board, as a condition to establish competency, may require successful completion of the ~~Pharmacy Technician Certification Board (~~PTCB~~)~~ Pharmacy Technician Certification Examination.

(f) The Board will only issue a reinstated license to a pharmacist, pharmacy technician or pharmacy technician specialist ~~license to an applicant~~ who has been convicted of a felony if five (5) years have elapsed since the applicant completed all requirements of the sentence imposed and was released from probation or parole, including full payment of all fines, costs, restitution, or other charges the applicant was ordered to pay.

Section 2~~8~~7. Collaborative ~~Pharmaceutical~~ 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 approved by a prescribing ~~physician~~ licensed independent practitioner acting within the scope of the ~~physician's~~ licensed independent practitioner current practice.

(b) The collaborative practice agreement shall include:

(i) The names of the prescribing ~~physician~~ licensed independent practitioner and the pharmacist who are parties to the collaborative practice agreement.

(ii) The specific types of medication therapy management 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 allowed in each case;

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

(C) The procedures the pharmacist is to follow in the course of conducting medication therapy management, including documentation of decisions and a plan or appropriate mechanism for communication and reporting to the prescribing

~~physician~~ licensed independent practitioner concerning specific decisions. Documentation of decisions shall occur in the prescribing ~~physician's~~ licensed independent practitioner patient medical ~~chart~~ record. If the medical ~~chart~~ record is not available at the practice site, a copy of the documentation of decisions will be sent to the prescribing ~~physician~~ licensed independent practitioner.

(iii) A method for the prescribing ~~physician~~ licensed independent practitioner to monitor compliance with the collaborative practice agreement and clinical outcomes when medication therapy management by the pharmacist has occurred and to intercede when necessary.

(iv) A provision that allows the prescribing ~~physician~~ licensed independent practitioner to override the collaborative practice agreement whenever deemed necessary or appropriate.

(v) A provision allowing the ~~physician~~ licensed independent 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.

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

(c) Medication therapy management shall occur only for a particular patient pursuant to a specific written order from the prescribing ~~physician~~ licensed independent practitioner. The written order shall conform to the format established by the Board ~~of Pharmacy~~ 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 (and including over-the-counter (OTC) and prescription products);

(v) Pertinent lab values;

(vi) Medication therapy management authorized (including any laboratory test);

(vii) Method of communicating information between pharmacist and ~~physician~~ ~~;~~ licensed independent practitioner;

(viii) Frequency of ~~physician~~ licensed independent practitioner follow-up;

(ix) Date order will be renewed (specific order must be renewed annually);

(x) Signatures of ~~physician~~ licensed independent practitioner, pharmacist, and patient or the patient's agent, parent, or guardian and date signed.

(d) A pharmacist providing medication therapy management 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 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/renewed annually. If necessary, the collaborative practice agreement may be revised. The Board ~~of Pharmacy~~ must approve all revisions, once signed by the pharmacist and the prescribing ~~physician~~ licensed independent practitioner, prior to implementation.

(f) 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 ~~of Pharmacy~~. 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 ~~of Pharmacy's~~ decision will be delivered to the

pharmacist and prescribing licensed independent practitioner within ten (10) days of the Board's decision.

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

(g) A pharmacist and prescribing ~~physician~~ licensed independent practitioner entering into a collaborative practice agreement must be currently licensed by their respective board and authorized to practice in the State of Wyoming.

(h) 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 of the Medical Practice Act and the Wyoming State Board of Medicine regulations.

Section 2~~9~~8. 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 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.

(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 alterations.

(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 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.

(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 ~~30~~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.

(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.

(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 Pharmacist-in-Charge. 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.

(xii) If a retail pharmacy purchases the patient prescription records (electronic and hard copy prescriptions), 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, no 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) Invoices for purchases of Schedule III, IV, and V controlled substances.

(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.

(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 Pharmacist-in-Charge 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.

(D) Any changes to information previously provided to the Board as required in this Chapter.

(E) Information necessary to process a new Wyoming retail pharmacy license, including information about the new Pharmacist-in-Charge.

(F) 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 3~~1~~0. 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.

(C) Patient-specific records.

(iv) The date the Drug Enforcement Administration (DEA) was contacted regarding the closure and that 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.

(b) At the close of business on the last day the institutional pharmacy is open for business, a controlled substance inventory, including all Schedules II, III, IV, and V controlled substances shall be taken. This inventory shall be dated and signed by the Pharmacist-in-Charge. 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.

(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 other than that prescribed in this Chapter.

Section 3~~2~~1. Drug Samples.

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

Section 3~~3~~2. Centralized Prescription Processing.

(a) The purpose of this Section is to provide standards for centralized prescription processing.

(b) “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.

(c) “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.

(d) “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.

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

(f) 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; or

(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 Pharmacist-in-Charge 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.

(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 non-resident dispensing or central fill pharmacy shall comply with the provisions or W.S. § 33-24-152 and this Section.

(v) A dispensing or central fill pharmacy dispensing compounded non-sterile or sterile pharmaceuticals shall comply with the provisions of Chapter ~~-~~13 or Chapter 17 ~~13 of the Board Rules and Regulations~~.

(g) Notifications to patients.

(i) A pharmacy that outsources prescription processing to another pharmacy shall:

(A) 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.

(B) 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.

(h) Prescription labeling.

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

(ii) The prescription label shall comply with ~~Section 11 of~~ this Chapter.

(i) 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 operations. The manual shall:

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

(ii) Include a list of the name, address, 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 to the patient, as required by Chapter 9 of the Board Rules and Regulations.

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

(j) 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.

(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:

(A) The date the prescription was shipped to the dispensing pharmacy.

Section 3~~4~~3. Automated Storage and Distribution Systems.

(a) Before using an automated storage and distribution system, a ~~pharmacy licensee or Pharmacist-in-Charge~~PIC shall:

(i) Ensure that the automated storage and distribution system and the policies and procedures comply with ~~Subsection (b)~~this Chapter.

(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) ~~A pharmacy licensee or Pharmacist-in-Charge~~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;

(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 of 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 of 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.

(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.

(B) Ensures the filling, stocking, or restocking of all drugs or devices in the system may be done only by a pharmacist, pharmacy intern, pharmacy technician specialist 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) ~~A pharmacy licensee or Pharmacist-in-Charge~~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.

(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 ~~pharmacy licensee or Pharmacist-in-Charge~~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.

CHAPTER 3

PHARMACY INTERNSHIP REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by the Act,

Section 2. Interns in Pharmacy.

(a) "Intern" means any person who:

(i) Has entered the first professional year in an approved college or school of pharmacy, who is in good standing with the approved college or school of pharmacy, and who has duly registered with the Board; or

(ii) Those applicants who are graduates of an approved college or school of pharmacy seeking licensure by examination or score transfer who:

(A) lack the required amount of practical experience for licensure, and who have duly registered with the Board; or

(B) are awaiting examination for licensure

(iii) Those applicants for reciprocity who have not been in active practice and must complete an internship, and who have duly registered with the Board; or

(iv) Those applicants for reinstatement of a lapsed license who must complete a required amount of practical experience, and who have duly registered with the Board; or

(v) Those applicants for licensure who are considered foreign pharmacy graduates and possess a Foreign Graduate Examination Committee™ (FPGEC®) Certificate who must complete one thousand two hundred (1,200) hours of practical experience for licensure, and who have duly registered with the Board,

(b) Every Intern shall be registered with the Board prior to and throughout employment or training in any capacity as a pharmacy Intern in ~~a resident retail or institutional pharmacy~~ any pharmacy practice setting. Eligible applicants must submit the proper application, waiver form, and two (2) fingerprint cards supplied to applicants by the Board~~. The~~ with a registration fee of fifteen dollars ($15.00), and ~~the~~ a criminal background check fee of fifty dollars ($50.00~~), shall be forwarded with the completed application, waiver form, and two (2) fingerprint cards~~. If the applicant has successfully completed a criminal background ~~history~~ check which is on file at the Board's office, ~~which~~ and is dated within twelve (12) months of the date of application for registration as a pharmacy Intern, the applicant need not resubmit the two (2) fingerprint cards nor remit the fifty dollar ($50.00) fee for a criminal background check.

(c) Upon receipt of a complete application and applicable fees, the application will be reviewed and, if approved, a registration certificate will be issued to the qualified applicant.

(d) Intern registration shall expire annually on September 30. ~~However, registration may be renewed on or before September 30, for a period of one (1) year.~~ Registrants may not renew for multiple years. The fee for renewal of Intern registration shall be fifteen dollars ($15.00). An Intern registration may not be renewed beyond twenty-four (24) months from the date of graduation from an approved college or school of pharmacy where the initial degree in pharmacy is obtained, unless a waiver is obtained from the Board.

(e) ~~Each place of employment and the name of each registered pharmacist serving as the preceptor pharmacist of the Intern shall be supplied to the Board~~. Each employed Intern shall provide the Board with the name of each registered pharmacist serving as the preceptor pharmacist and the place of employment.

(f) Each Intern will complete an evaluation of the ~~P~~ preceptor ~~P~~ pharmacist for non-academic rotations.

(g) Internship credit hours shall not be approved by the Board unless all requirements of this Chapter are met by the Intern.

Section 3. Internship Training Requirements.

(a) The practical experience requirement for licensure as a pharmacist in Wyoming by examination or score transfer shall be met by the successful completion of a clinical clerkship program during a student's ~~fourth professional year~~ tenure at an approved college or of pharmacy, provided the clinical clerkship consists of a minimum of one thousand two hundred (1,200) hours of practical experience.

(b) The Board shall annually review and approve the clinical clerkship program offered by the University of Wyoming, School of Pharmacy.

(c) Experience obtained in another state shall be accepted only if the regulatory agency in the state where the experience is obtained provides satisfactory proof of such experience or the approved college or school of pharmacy provides satisfactory proof of successful completion of a clinical clerkship program during the student's ~~fourth professional year~~ tenure at the approved college or school of pharmacy and provides the total hours of practical experience gained.

(d) The Board may approve up to five hundred (500) hours of practical experience for periods of non-traditional internships. A non-traditional internship is any period of experience other than experience gained in a traditional retail or hospital pharmacy setting. Interns participating in non-traditional internships under this subsection;

(i) May request prior review of the experience by the Board;

(ii) Shall be supervised by a licensed pharmacist if no preceptor pharmacist is available; and

(iii) Shall adhere to all requirements of this Chapter including, but not limited to, proper reporting to the Board on Board-approved forms.

Section 4. Intern Training.

(a) Interns shall, under the direct supervision of the preceptor ~~p~~pharmacist or academic preceptor:

(i) Fill prescriptions, including I.V. orders, and comment on any unusual prescription. Interns shall evaluate prescriptions as to drug, dose, and therapeutic effect. This evaluation may be submitted in written form or discussed orally with the preceptor pharmacist.

(ii) Be instructed in the proper handling of controlled substances and all other drugs requiring special attention, including over-the-counter products.

(iii) Gain familiarity with brand names, generic names, and dosage forms.

(iv) Become familiar with the proper handling of veterinarian products, if pertinent to the practice setting.

(v) Be supervised in the appropriate counseling of patients regarding self-administration of drugs.

~~(vi) Be directed by their preceptor pharmacist if in a hospital or non-traditional pharmacy setting.~~

(vi~~i~~) Make the offer to counsel and provide appropriate counseling to patients regarding self administration of prescription drugs and over-the-counter drug products.

(vii~~i~~) Accept verbal medication orders from a prescribing practitioner.

(~~ix~~viii) Transfer prescriptions, as provided in Board Rules and Regulations, Chapter 2.

(ix) Conduct prospective and retrospective drug utilization reviews, including the identification of problems and steps required to resolve identified problems.

(x~~i~~) Become familiar with medication therapy management, including communicating with health care providers and patients regarding medication management.

(xi~~i~~) Become familiar with pharmacy record-keeping requirements.

(xii~~i~~) Provide pharmaceutical care.

(xiii~~v~~) Compound non-sterile and sterile medications.

(xiv) Administer immunizations under the direct supervision of a pharmacist who is licensed by the Board to prescribe and administer immunizations provided the pharmacy intern has:

(A) Registered with the Board to administer immunizations and paid the ten dollar ($10.00) fee. Registrations shall expire on September 30 of each year;

(B) Successfully completed immunization training as described in Chapter 16;

(C) Current certification in basic cardiopulmonary resuscitation (CPR) offered by the American Heart Association or the American Red Cross;

Section 5. Preceptor Pharmacist Rules.

(a) Definitions of preceptors are as follows:

(i) "Academic preceptor" means a pharmacist who is supervising the training of pharmacy interns provided through an approved academic program and not necessarily licensed as a pharmacist in Wyoming.

(ii) "Preceptor pharmacist" means a pharmacist who is supervising pharmacy interns that are employed by the pharmacy, or are obtaining intern hours outside of a formal academic rotation.

(b) A preceptor pharmacist for pharmacy Interns in Wyoming shall be a licensed pharmacist in Wyoming and active in the profession for a minimum of two (2) years.

(c) A preceptor pharmacist shall register with the Board by application provided by the Board. The initial registration fee and renewal fee shall be ten dollars ($10.00). Preceptor pharmacists' registrations shall expire annually on December 31.

(d) Upon application to the Board and fee payment, a certificate shall be issued to the preceptor pharmacist identifying the preceptor pharmacist and pharmacy or other pharmacy intern training site.

(e) The preceptor pharmacist shall instruct the Intern in the necessity of the strict observance of the Code of Ethics of the pharmacy profession; shall assist the Intern in the performance of professional services so as to enhance the professional ability of the Intern; and shall train the Intern to become oriented in every phase of pharmacy practice, including those topics identified in this Chapter.

(f) A preceptor pharmacist shall not supervise more than two (2) pharmacy interns at one time.

(g) The preceptor pharmacist shall submit to the Board, at the end of each period of employment, an “Intern Evaluation Report” and affidavit, as provided by the Board, for the following:

(i) Applicants for licensure by examination or score transfer who will not have one thousand two hundred (1,200) hours of practical experience after completion of a clinical clerkship during the student’s ~~fourth professional year~~ tenure at an approved college or school of pharmacy.

(ii) Applicants for licensure by reciprocity who do not have the required practical experience, as specified in Board Rules and Regulations, Chapter 2 ~~Section 6~~.

(iii) Applicants for reinstatement of a pharmacist license who must complete a required amount of practical experience.

(iv) Foreign pharmacy graduates who must complete one thousand two hundred (1,200) hours of practical experience for licensure.

CHAPTER 4

CODE OF ETHICS

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

Section 2. Code of Ethics.

(~~d~~ a) A pharmacist has the duty to observe the law, uphold the dignity and honor of the profession and to accept its ethical principles.

(~~a~~ b) A pharmacist shall hold the health and safety of patients to be of first consideration. ~~and shall render to each patient the full measure of ability as an essential health practitioner.~~

(~~b~~ c) A pharmacist shall not condone the dispensing, promoting or distributing of drugs or medical devices which ~~are not of good quality,~~ do not meet standards required by law or which lack therapeutic value for the patient.

(~~c~~ d) A pharmacist shall strive to ~~perfect~~ improve and enlarge professional knowledge and shall utilize ~~and make available~~ that knowledge ~~as required~~ in accordance with professional judg~~e~~ment.

(e) It shall be considered unprofessional conduct for a pharmacist to deliver a prescription drug without having a valid drug order as described in Chapter 2~~, section 19, of the Board's Rules~~ from a practitioner authorized by law to prescribe.

(f) Pharmacists shall not ~~agree to~~ participate in transactions with ~~health professionals or~~ any ~~other~~ person under which fees are divided or ~~which~~ may cause financial or other exploitation in connection with the rendering of professional services.

(g) A pharmacist shall respect the confidential and personal nature of patient records and shall not disclose the information without proper patient authorization except when required by law. ~~However, when the best interest of the patient requires it or~~ ~~I~~ In an emergency medical situation, the patient's records may be released to another pharmacist or other medical personnel involved in treating the patient.

~~(h) A pharmacist shall not agree to practice under terms or conditions which may interfere with or impair the proper exercise of professional judgement or skill.~~

(~~k~~ h) A pharmacist shall not provide practitioners with pre-printed prescription blanks bearing the pharmacy or pharmacist name or address.

~~(i) A pharmacist shall provide professional and financial information to patients, medical staff, and those with whom they conduct business, truthfully, accurately,~~

~~and fully, avoiding misleading statements regarding the nature, cost, or value of the pharmacist's professional services.~~

(h) ~~(n)~~ Any behavior by a pharmacist toward a patient, another licensee, or an employee of a pharmacy that exploits the position of trust, knowledge, emotions or influence of the licensee or any behavior by a pharmacist which involves offers to exchange pharmacy services for some form of sexual gratification shall be considered unprofessional conduct

~~(j) A pharmacist shall not provide untruthful information to the patient or insurance company regarding cost of medication to the patient.~~

~~(l) A pharmacist shall not advertise in an untruthful or misleading manner, including any form of "bait and switch".~~

~~(m) A pharmacist shall not work in an unlicensed pharmacy.~~

CHAPTER 6

CONTINUING ~~PHARMACEUTICAL~~ PROFESSIONAL EDUCATION ~~REGULATIONS~~

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Purpose.

~~Whereas, the practice of the profession of pharmacy is directly related to the public health and welfare of the citizens of this State, these~~ These regulations establish minimum requirements for continuing ~~pharmaceutical~~ professional education for pharmacists ~~which is necessary for a pharmacist~~ to maintain professional competency and improve professional skills.

Section 3. Definitions.

(a) "Approved providers" means sponsors of continuing education programs approved by the Accreditation Council for Pharmacy Education (ACPE), Tripartite Committee on Continuing Education for Pharmacists in Wyoming, Accreditation Council for Continuing Medical Education, American Heart Association, the American Red Cross, and the National Association of Boards of Pharmacy (NABP).

(b) "Contact hour" means a unit of measure equivalent to 50 minutes of live classroom or actual lecture time

(c) "Continuing Education Unit" (CEU) means one (1) continuing education unit shall be equivalent to ten (10) contact hours of continuing pharmaceutical education.

(d) "Continuing pharmaceutical education records" means those certificates issued by approved providers upon completion of approved programs.

(e) "Previous License Period" means the calendar year (January 1 through December 31) immediately preceding the year for which the pharmacist is seeking a license renewal.

Section 4. Continuing Pharmaceutical Education Requirement.

(a) In accordance with W.S. § 33-24-121, all pharmacists must complete and report 12 contact hours (1.2 CEU's) of approved continuing education obtained during the previous license period in order to renew their license to practice pharmacy.

(b) Pharmacists are required to maintain ~~certificates~~ records of completion of approved continuing education for two years from the date of reporting the contact hours on a license renewal application.

(c) Excess continuing education credit shall not be carried forward.

Section 5. Annual Report.

(a) Every pharmacist, who has been licensed for one full year or longer, applying for renewal ~~pursuant to W.S. 33-24-121 (d)~~, shall indicate on their renewal application how many contact hours of approved continuing pharmacy education has been earned during the previous license period.

(b) A pharmacist who is not engaged in an active practice of pharmacy in Wyoming may request inactive license status on their renewal application, and is exempt from the continuing education requirements. A pharmacist requesting inactive license status may not practice pharmacy in Wyoming.

Section 6. Failure to Comply – Active Status.

Any pharmacist actively practicing in this State failing to comply with the provisions of ~~Section 4 and 5 (a) of~~ this Chapter shall not have their license to practice pharmacy renewed. However, any pharmacist may be reinstated under the provisions of the Act upon completion of ~~these~~ requirements.

Section 7. Inactive Status.

A pharmacist who is on inactive status may be reinstated upon completing the continuing pharmaceutical education requirements for each year of inactive status, not to exceed five (5) years.

Section 8. Continuing Education Audits.

(a) The board shall randomly select submitted renewal application<u>s</u> ~~forms~~ for audit and verification of reported continuing education contact hours.

(b) <u>The board shall review records in the NABP database CPE Monitor for compliance with continuing education hours for pharmacists from ACPE approved providers.</u>

(c) Upon ~~written~~ request by the board, a pharmacist shall provide to the board ~~copies~~ <u>records</u> ~~of certificates~~ of completion ~~for all~~ <u>of</u> continuing education contact hours <u>from an approved provider</u> ~~reported during a specified license period.~~ <u>in addition to those recorded in CPE Monitor.</u> Failure to provide all requested records constitutes prima facie evidence of knowingly submitting false or misleading information to the board for the renewal of a license and may subject the pharmacist to disciplinary action by the board.

Section 9. Approved Programs.

(a) Any program presented by an ACPE approved provider subject to the following conditions.

(i) Pharmacists may receive credit for the completion of the same course only once during a license period.

(ii) Proof of participation shall be ~~a copy of the certificate issued~~ the record of completion in CPE Monitor of continuing professional education by an approved ACPE provider~~., which includes name of participant, ACPE program identification number, name of program, contact hours approved, signature and date signed by ACPE approved provider.~~

(b) Courses which are part of a professional degree program or an advanced pharmacy degree program offered by a college of pharmacy which has a professional degree program accredited by ACPE.

(i) Proof of participation shall be a letter signed by the Dean of the school/college of pharmacy indicating enrollment and credit hours of study during the license period in question. No more than 1 contact hour (0.1 CEU) per credit hour will be allowed.

(c) Basic cardiopulmonary resuscitation (CPR) courses which lead to CPR certification or recertification by the American Red Cross or the American Heart Association shall be recognized as approved programs. Pharmacists may receive credit for one contact hour (0.1 CEU) towards their continuing education requirement for completion of a CPR course only once during each license period. Proof of completion of a CPR course shall be the certificate issued by the American Red Cross or the American Heart Association.

(d) Advanced cardiovascular life support course (ACLS) which leads to initial ACLS certification or recertification by the American Heart Association shall be recognized as approved programs. Pharmacists may receive credit for six contact hours (.6 CEUs) towards their continuing education requirement for completion of an ACLS course only once during a license period. Proof of completion of an ACLS course shall be the certificate issued by the American Heart Association.

(e) Pediatric advanced life support course (PALS) which leads to initial PALS certification or recertification by the American Heart Association shall be recognized as approved programs. Pharmacists may receive credit for six contract hours (.6 CEU's) towards their continuing education requirement for completion of a PALS course only once during a license period. Proof of completion of a PALS course shall be the certificate issued by the American Heart Association.

(f) Any program presented by the Tripartite Committee on Continuing Education for Pharmacists in Wyoming.

(i) Proof of completion of a Tripartite Committee sponsored continuing

education program shall be the certificate issued by the Tripartite Committee on Continuing Education for Pharmacists in Wyoming.

(g) Any AMA PRA Category 1 CME program presented by an Accreditation Council for Continuing Medical Education approved provider, provided the program includes in the title a reference to drug therapy.

(i) Proof of completion shall be the certificate issued by the approved provider.

(h) Pharmacist Self-Assessment Mechanism (PSAM) offered by NABP shall be recognized as an approved program. PSAM is an evaluation tool that will assist pharmacists in obtaining objective, non-punitive feedback on their individual knowledge of current practice therapies. The assessment tool is applicable to general pharmacy practice. Pharmacists may receive credit for four contact hours (.4 CEU's) towards their continuing education requirement for completion of a PSAM assessment only once during a license period. Proof of completion of a PSAM assessment shall be the record of completion provided by NABP. The Board will not request the report of ~~you're~~ the assessment evaluation score.

CHAPTER 9

PATIENT COUNSELING AND PROSPECTIVE DRUG USE REVIEW REGULATIONS

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

Section 2. Definitions.

(a) "Reasonable effort" means that degree of effort which a pharmacist of ordinary prudence and accepted professional duty would exercise in similar circumstances.

Section 3. Patient Profile Records.

(a) A ~~patient~~ profile record ~~system~~ shall be maintained by all pharmacies for patients for whom prescriptions are dispensed. The ~~patient~~ profile record ~~system~~ shall provide for the immediate retrieval of information of ~~so that the pharmacist may identify~~ previously dispensed drugs and devices. The pharmacist shall be responsible for ~~assuring that a reasonable effort is made to obtain, record and~~ maintaining the following patient information ~~from the patient or agent~~ for each new prescription:

(i) Full name of the patient for whom the drug is intended;

(ii) Address and telephone number of the patient;

(iii) Patient's age or date of birth and gender;

(iv) A list of all prescription drug orders obtained ~~by the patient~~ at the pharmacy ~~maintaining the patient record~~ during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, ~~name and~~ strength of the drug, the quantity, ~~and~~ date received and the name of the prescriber~~; and~~

(v) Pharmacist comments relevant to the individual's drug therapy, including any ~~other~~ information peculiar to the specific patient or drug.

(b) Each pharmacist or their agent shall make a reasonable effort to obtain the individual's medical history, ~~when significant, from the patient or the patient's agent and shall record~~ any known allergies, drug reactions, idiosyncrasies and chronic conditions or disease states of the patient and the identity of any other medications including over-the-counter drugs or devices currently being used by the patient which may relate to prospective drug review.

~~(c) A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.~~

Section 4. Prospective Drug Use Review.

(a) A pharmacist shall review the patient record and each prescription drug order presented for dispensing ~~for purposes of promoting therapeutic appropriateness~~ by identifying:

(i) Overutilization or underutilization;

(ii) Therapeutic duplication;

(iii) Drug-disease contraindications;

(iv) Drug-drug contraindications;

(v) Incorrect drug dosage or duration of drug treatment;

(vi) Drug-allergy interactions; and

(vii) Clinical abuse/misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber. The pharmacist shall document those steps taken.

Section 5. Patient Counseling.

(a) Upon receipt of a prescription and following a review of the patient's record, a pharmacist or a pharmacy intern shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of the patient. Non-resident pharmacies/pharmacists are not exempt from this regulation. ~~However the discussion shall be performed by the pharmacist in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling.~~ Such elements may include the following:

(i) Name and description of the drug;

(ii) Dosage form, dose, route of administration, and duration of drug therapy;

(iii) Intended use of the drug and expected action;

(iv) Special directions and precautions for preparation, administration, and use by the patient;

(v) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the actions required if they occur;

(vi) Techniques for self-monitoring drug therapy;

(vii) Proper storage;

(viii) Prescription refill information;

(ix) Action to be taken in the event of a missed dose; and

(x) Comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug or refusal of counseling.

(b) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation. Every refusal shall be documented by the pharmacist.

~~(c) Reasonable efforts shall be made to obtain, record and maintain the following patient information generated at the individual pharmacy;~~

~~(i) Name, address, telephone number, date of birth or age and gender;~~

~~(ii) Individual history where significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and~~

~~(iii) Any additional comments relevant to the patient's drug use, including any failure to accept the offer to counsel.~~

(d) Information obtained may be recorded in the patient's manual or electronic profile, in the prescription signature log or in any other system of records and may be considered by the pharmacist in the exercise of professional judgment concerning both the offer to counsel and content of counseling. The absence of any record of a failure to accept the offer to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

~~(e) Alternative forms of patient information may be used to supplement patient counseling when appropriate. This may include, but is not limited to, written information leaflets, pictogram labels or video programs.~~

Section 6. Retrospective Drug Use Review

(a) "Retrospective drug use review" means the monitoring for:

(i) Therapeutic appropriateness;

(ii) Over-utilization and under-utilization;

(iii) Appropriate use of generic products;

(iv) Therapeutic duplication;

(v) Drug-disease contraindications;

(vi) Drug-drug interactions;

(vii) Incorrect dosage;

(viii) Duration of drug treatment; and

(ix) Clinical abuse/misuse after the drug has been dispensed.

~~(b) The Board shall consult in cooperation with the State Medicaid Program, Wyoming Department of Health, regarding Medicaid patient benefits through the authorized Drug Utilization Review Board established by that agency.~~

~~Section 7. Disciplinary Action.~~

~~It shall be grounds for disciplinary action by the Board against the registration of the pharmacy if the Board determines that any person with supervisory responsibilities at the pharmacy sets policies that prevent a licensed pharmacist from providing patient counseling as required by the Act or this Chapter.~~

CHAPTER 10

PHARMACY TECHNICIAN REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Definitions (moved from Chapter 2)

(a) "Pharmacy Technician" means an individual, other than an intern, who performs pharmacy functions under the direct supervision of a licensed pharmacist.

(b) "Pharmacy Technician-in-Training" means an individual who is registered with the Board to receive on-the-job training in preparation for licensure as a pharmacy technician.

(c) "Pharmacy Technician Specialist" means an individual who is certified by the Pharmacy Technician certifying Board (PTCB) with additional education and/or experience and is registered with the Board to perform pharmacy functions.

. ~~Section 8~~ Section 3. Qualifications, ~~Education, Registration~~ and Requirements ~~and Identification of~~ for Pharmacy Technicians, Pharmacy Technician Specialists, and Pharmacy Technicians-In-Training.

A pharmacy technician, pharmacy technician specialist, or pharmacy technician-in-training shall:

(a) Be at least 18 years of age.

(b) ~~Have no felony or gross misdemeanor conviction~~, ~~including following a plea of nolo contendere,or have not received a deferred judgment and sentence for a felony~~, relating to ~~relating to controlled substances or moral turpitude~~. ~~within thirty-six (36) months of the date of application.~~

(b) Complete a background check through the Wyoming Divison of Criminal Investigation (DCI). The Board will only issue a license to an applicant who has been convicted of a felony if five (5) years have elapsed since the applicant completed all requirements of the sentence imposed and was released from probation or parole, including full payment of all fines, costs, restitution, or other charges the applicant was ordered to pay.

(c) Have no history of drug abuse or provide satisfactory evidence of rehabilitation.

(d) Hold a high school diploma or its equivalent.

(e) Have completed requirements for registration. ~~as determined by the Board~~

(f) Wear a name badge with the appropriate designation "Pharmacy Technician",

"Pharmacy Technician Specialist", or a "Pharmacy Technician-In-Training" at all times when in or near the pharmacy area.

(g) Identify themselves as the appropriate level of technician a "Pharmacy Technician or a "Pharmacy Technician-In-Training" in all telephone conversations while on duty in the pharmacy.

Section 9. Section 4 Pharmacy Technician-In-Training Registration; Length of Registration Period; Training; Place of Employment; Change of Employment.

(a) A pharmacy technician-in-training shall apply to the Board for a training permit on an application supplied by the Board and shall pay the fee required before within ten (10) calendar days of starting on-the-job training. This permit shall be valid for two years from the date of original issuance or as long as the individual is enrolled in a pharmacy technology program. It may shall not be renewed. The sponsoring pharmacy, as identified on the application, shall be printed on the technician-in-training permit. A change in sponsoring pharmacy requires immediate submission of an updated application., and a corrected permit may be issued to the technician-in-training by the Board.

(b) A pharmacy technician-in-training may perform pharmacy functions commensurate with his/her ability to perform those tasks as identified in this Chapter 10, section 3, and then only to the extent allowed by the pharmacist-in-charge (PIC). The pharmacy technician-in-training is considered a trainee. and as such the PIC, pharmacists, and pharmacy technicians shall participate in the training of this individual. The supervising pharmacist shall not allow the pharmacy technician-in-training to perform any pharmacy function for which the individual has not demonstrated competency.

(c) A pharmacy technician-in-training may perform pharmacy functions only at the pharmacy location specified on the permit.

Section 3. Section 5. Pharmacy Functions for Technicians-In-Training

The following are those pharmacy functions a licensed pharmacy technician or a registered pharmacy technician-in-training may perform under the direct supervision of a licensed pharmacist:

(a) Retail Pharmacy

(i) Prescription preparation-- retrieving the product from stock, counting, pouring, reconstituting, placing product in a prescription container, and affixing the label.

(ii) Prescription input--making computer entries for new or refill prescriptions, provided the pharmacist meets obligations as outlined in Chapter 9, section 4, "Prospective Drug Use Review".

(iii) Prescription refill authorizations-- contacting the practitioner's office and

obtaining refill authorizations for any prescription provided there are no changes ~~in the prescription order.~~

(iv) Restocking emergency drug supply--restocking drugs for those sites where the pharmacy has an emergency drug permit.

(b) Institutional Pharmacy.

(i) Distributive functions-- stocking: automated drug dispensing units, floor stock, crash carts, after-hour drug cabinets, sterile solutions, and unit dose cart preparation.

(ii) Repackaging into unit dose and/or unit of issue packaging.

(iii) Inspections-- conducting inspections ~~as described in Chapter 12, section 20, "Inspections". Inspections conducted in the pharmacy are not considered a pharmacy function.~~

(iv) Input practitioner medical orders--~~entering information into a patient's profile or medication administration record provided those obligations of a pharmacist as described in Chapter 9, Section 4, "Prospective Drug Review" are met.~~

~~Section 10~~ Section 6.. Pharmacy Technician Registration~~; Renewals; Late Payment~~ Fees; ~~Expired~~ Licenses; ~~Active/Inactive License; Reinstatement; Change of Employment; Change of Address.~~

(a) Individuals shall apply for pharmacy technician licensure by completing an application supplied by the Board, providing evidence of current certification by the Pharmacy Technician Certification Board (PTCB) and paying the required fee.~~ and meeting the requirements of this Chapter 10, Section 8 (a)(b)(c)(d) of the Board's Rules.~~ The Board reserves the right to require an interview of the ~~technician~~ applicant prior to a pharmacy technician license being issued.

(b) A pharmacy technician must apply~~, on a form supplied by the Board,~~ to renew his/her license each year on or before December 31 and submit payment of ~~Along with the application, he must submit copies of required continuing pharmacy education certificates, and payment of~~ the required renewal fee. The Board shall assess a late payment fee for any renewal application postmarked or filed after December 31.

(c) ~~A pharmacy technician's license not renewed by March 31 shall be deemed expired.~~ If the pharmacy technician or pharmacy technician specialist fails to renew before December 31, the license expires ten (10) days after ~~the~~ mailing of a written notice to renew is sent to the holder by certified mail, to the address last recorded for the licensee with the Board. An expired license may be restored by the Board upon compliance with this section no later than March 31 following expiration of the license. A pharmacy technician ~~may~~ shall not practice in this state with an expired technician license.

(d) A pharmacy technician may petition the Board for reinstatement of an expired license. To be considered for reinstatement, the pharmacy technician must submit the following:

(i) A letter requesting reinstatement.

(ii) Payment of annual fees, including late payment fees, for those years which the license was expired up to a maximum of five years.

(iii) Evidence of current certification by the Pharmacy Technician Certification Board (PTCB).

(iv) Proof of continuing pharmacy education for those years the license was expired, up to a maximum of five years.

(e) A pharmacy technician who fails to ~~submit~~ obtain the required number of continuing education credits ~~with a renewal~~ may be issued an "inactive" license. A pharmacy technician may not practice in Wyoming with an "inactive" license. An "inactive" license may be converted to "active" status by providing the necessary hours of continuing education credits for those years the license has been "inactive" to a maximum of five (5) years.

(f) If change of employment or mailing address occurs, the Board shall be notified within 30 days of date of change by the pharmacy technician.

Section 7. Pharmacy Functions for Pharmacy Technicians.

~~(c)~~ A pharmacy technician, ~~but not a pharmacy technician-in-training,~~ may perform the pharmacy functions previously mentioned in this chapter for technicians-in-training as well as the following: ~~pharmacy functions in a retail or institutional pharmacy.~~

(a) Compounding. The prescription order shall ~~first~~ be reviewed by a pharmacist ~~and the decision made to compound determined before assigning to a pharmacy technician~~. The pharmacist-in-charge (PIC) shall certify competency of the pharmacy technician prior to allowing a pharmacy technician to assist the pharmacist in compounding, and annually thereafter. Documentation ~~of the basis~~ of the certification shall remain on file at the pharmacy and be available for inspection by the Board for each pharmacy technician, and shall include, but not be limited to, documentation of the following skills: ~~or knowledge: as required for a specific pharmacy practice.~~

(i) Knowledge and understanding of FDA's Good Manufacturing Practices

(ii) Weights and measures

(iii) Calculations

(iv) Use of torsion balance or electronic scales

(v) Knowledge of various techniques utilized to compound products

(vi) Labeling requirements

(vii) Aseptic technique

(viii) Use and maintenance of laminar and/or vertical flow air hood

(ix) Knowledge in handling chemotherapeutic agents

(x) Dating requirements

(xi) Record keeping requirements

(b) Transfer prescriptions electronically or via facsimile to another pharmacy with consent of the supervising pharmacist.

Section 8. Pharmacy Technician Specialist Requirements and Registration.

(a) A pharmacy technician may qualify for Pharmacy Technician Specialist licensure by having the following:

(i) An active, in good standing, pharmacy technician license with the Board

(ii) A current PTCB certification

(iii) A diploma, certificate, or degree from an ASHP accredited pharmacy technician training program with two years of experience, or at least 5 years of pharmacy technician experience (technician-in-training time does not apply)

(iv) Demonstrated competence as certified by the PIC annually

(v) All other licensing requirements required for pharmacy technicians

Section 9. Pharmacy Functions for a Pharmacy Technician Specialist

A pharmacy technician specialist may perform all pharmacy functions previously mentioned in this chapter as well as the following:

(a) Training of ~~technicians-in-training and pharmacy technicians, and assisting in the training of pharmacy interns.~~ other personnel in pharmacy operations.

(b) Basic label interpretation on OTC products; to include reading the product's printed instructions, and ingredients, and answering questions based on the product's label. Clinical questions including product selection shall be referred to the pharmacist.

(c) Checking the work of pharmacy technicians or technicians-in-training for accuracy in preparing prescription drugs for dispensing, verification of packaging or re-packaging,

verification of non-hazardous sterile compounding, or verification of pulling appropriate products for restocking into automated dispensing devices.

(i) Accuracy rates in checking must be determined by the PIC before the pharmacy technician specialist is allowed to check the work of pharmacy technicians or technicians-in-training

(ii) Accuracy rates in checking must be verified by the PIC at least annually

(d) Receiving a new prescription order ~~verbally~~ from a prescriber, ~~other persons authorized by law, or~~ using a voice messaging system.

(e) Assisting a pharmacist in record-keeping

~~(f) Clarifying the strength, quantity, dosage form, refills, or "as needed" indications of the prescription or drug order with the prescriber.~~

(~~Section 4.~~ Section 10. ~~Responsibilities of the Pharmacist.~~ Pharmacy Functions Not Permitted for all technician levels.

No pharmacy technician, pharmacy technician specialist, or pharmacy technician-in-training shall

~~(a) Receive a new prescription order verbally from a prescriber or other person authorized by law~~.

~~(b)~~ (a) Perform evaluations and interpretations of a prescription and obtain any needed clinical clarifications prior to filling.

~~(c)~~ (b) Review and analyze any clinical data in a patient's medication record. ~~as specified in Chapter 9, section 4, "Prospective Drug Review".~~

(d) (c) Perform professional consultation with any prescriber, nurse, other health care professional or any patient/customer.

(d) Make the offer to counsel.

(e) Counsel.

~~Section 5~~. Section 10. Pharmacy Technician, Pharmacy Technician Specialist, or Pharmacy Technician-In-Training ~~Duties~~ Pharmacy Functions When A Pharmacist Is Absent.

(a) When no pharmacist is in the pharmacy, but at least one supervising pharmacist remains in the building, ~~his~~ the pharmacy technician~~(s)~~, pharmacy technician specialist, or pharmacy technician~~(s)~~-in-training may perform pharmacy functions as outlined in this Chapter ~~10, section 3,~~ provided no prescription product leaves the pharmacy until the pharmacist returns and authorizes the release.

(b) When no supervising pharmacist is in the building~~(i)~~ A retail or institutional pharmacy may not remain open, and staff may not remain in the pharmacy~~. A pharmacy technician, or pharmacy technician-in-training may not remain in the pharmacy, and the pharmacy shall be closed as described in Chapter 2, Section 9 (d).~~

~~(ii) An institutional pharmacy may not remain open. A pharmacy technician, or pharmacy technician-in-training may remain in the pharmacy, but may not perform pharmacy functions. If a drug needs to be removed from the pharmacy, those procedures as outlined in Chapter 12, Section 12 shall be followed.~~

(c) ~~Where there are two or more pharmacists working in a pharmacy, the pharmacy may remain open if a pharmacist leaves the building as long as at least one pharmacist remains in the pharmacy. However, the number of pharmacy technicians, or pharmacy technicians-in-training present in the pharmacy may not exceed the 3 to 1 ratio~~

Section ~~11~~ 12. Pharmacy Technician, and Pharmacy Technician Specialist, Continuing Education Requirements.

(a) Every pharmacy technician, and pharmacy technician specialist, seeking renewal of a pharmacy technician license shall complete ~~and submit,~~ during each calendar year, six (6) contact hours of approved, continuing pharmacy education programs to be applied to the upcoming renewal year.

(b) Excess continuing education hours may not be carried forward to subsequent years.

Section ~~12~~ 13. Continuing Education Audits

(a) The Board shall randomly select submitted renewal applications ~~forms for audit and~~ for verification of reported continuing education contact hours.

(b) The Board shall review records in the NABP database CPE Monitor for compliance with continuing education hours for pharmacy technicians and pharmacy technician specialists.

(c) Upon written request by the Board, a pharmacy technician, or pharmacy technician specialist shall provide to the Board copies of certificates of completion for all continuing education contact hours reported during a specified license period. Failure to provide all requested records ~~or failing to provide continuing education certificates from approved continuing education providers as specified in this Chapter~~ constitutes prima facie evidence of knowingly submitting false or misleading information to the Board for the renewal of a license and may subject the pharmacy technician, or pharmacy technician specialist to disciplinary action by the Board.

Section ~~13~~ 14. Pharmacy Technician, and Pharmacy Technician Specialist Approved Continuing Education Providers.

~~The following are acceptable providers of continuing education for pharmacy technicians and may be submitted to the Board for proof of meeting the continuing education requirement as specified in Chapter 10, Section 11:~~

(a) Pharmacist supervisor at place of employment, utilizing a format for documentation developed by the Board of Pharmacy Staff;

(b) Continuing education hours approved by the Pharmacy Technician Certification Board (PTCB);

(c) Continuing education hours approved by The American Pharmaceutical Association (APhA);

(d) Continuing education hours of providers of continuing education accredited by the American Council on Pharmaceutical Education (ACPE);

(e) Continuing education hours presented by the Wyoming Pharmac~~ists~~y Association (WPhA).

~~Section 6~~.Section 15. Pharmacist/Technician Employee Ratio.

A pharmacist is permitted to be a direct supervisor of three (3) pharmacy technicians and/or technicians-in-training who are performing pharmacy functions and ~~an unlimited number of~~ four total if at least one of them is a pharmacy technician specialist. ~~For the purpose of this rule, the ratio breakdown shall not exceed four (4) technician specialists, OR three (3) pharmacy technicians, and one (1) technician-in-training .technicians shall include registered pharmacy technicians and pharmacy technicians-in-training licensed or registered with the Board~~. A pharmacy technician-in-training who is enrolled with ~~the Casper College, Pharmacy Technician Training Program or the Institute of Business & Medical Careers, Inc. Cheyenne, WY campus, Pharmacy Technician Training Program,~~ an ASHP accredited pharmacy technician training program during required experiential training hours ~~and who possesses a pharmacy technician-in-training permit issued by the Board~~ shall not be included in this ratio.

~~Section 7.~~ Section 16. Legal and Professional Responsibilities ~~of Pharmacist.~~

~~(a)~~ It shall be considered unprofessional conduct for ~~by the PIC or supervising pharmacist to allow~~ a pharmacy technician, pharmacy technician specialist, or pharmacy technician-in-training to violate the Wyoming Pharmacy Act or the Wyoming Controlled Substances Act or their rules or regulations.

~~(b) The pharmacy director/manager shall assure the continuing competency of technicians through education and training to supplement initial training.~~

~~CHAPTER 11~~

~~DANGEROUS DRUG REGULATIONS~~

~~Section 1. Authority.~~

~~These regulations are promulgated as authorized by the Act.~~

~~Section 2. Dangerous Substance List.~~

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*, as the official listing of Dangerous Substances for the State of Wyoming. (Move to Chapter 2

~~Section 3. Additions to Dangerous Substance List.~~

~~Pursuant to § 33-24-131 and Wyoming Administrative Procedure Act § 16-3-101 through §16-3-115, the Board has designated the following drug(s) as a Dangerous Drug(s), and is hereby added to the Dangerous Substance List.~~

~~(a) Ephedrine, all single entity containing products, no exemptions.~~

~~(b) Schedule V antitussive products containing codeine, no exemptions.~~

~~(c) Ephedrine, all combination products, except the following.~~

~~(i) Any ephedrine containing product indicated for topical treatment of hemorrhoids.~~

~~(ii) Any ephedrine containing product which includes as one of the active ingredients, guaifenesin in a quantity equal to or greater than 400mg per dose.~~

CHAPTER 12

INSTITUTIONAL PHARMACY PRACTICE REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Purpose.

The purpose of this Chapter is to provide standards for the conduct, practice activities, and operation of a pharmacy located in a hospital or other inpatient facility that is licensed under the Wyoming Department of Health. The intent of these standards is to establish a minimum acceptable level of pharmaceutical care to the patient so that the patient's health is protected while contributing to positive patient outcomes.

Section 3. Scope of Chapter.

This Chapter applies to any person, partnership, corporation, limited liability company, or other entity engaging in the practice of pharmacy in an Institutional Facility, as defined below, within this state.

Section 4. Definitions.

(a) "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.

(b) "Beyond-Use Date" means a date placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(c) "Clean Room" means a room with a minimum of an ISO Class 7 environment as defined in Chapter 17:

~~(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 specific cleanliness class.~~

(d) "Drug Room" means a secure and lockable location within an inpatient care facility that does not have an Institutional Pharmacy.

(e) "Emergency Drug Cart ("crash cart)" means a cart containing those drugs that may be required to meet the immediate therapeutic needs of ~~inpatients or emergency room~~ patients ~~and are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from such other source.~~

(f) "Floor Stock" means prescription drugs not labeled for a specific patient and maintained at a nursing station or other Institutional Facility department (excluding the Institutional Pharmacy) for the purpose of administration to a patient of the Institutional Facility.

(g) "Formulary" means a continually revised compilation of pharmaceuticals that reflects the current clinical judgment of the pharmacy staff and medical staff of the Institutional Facility.

(h) "Institutional Facility" means a hospital, convalescent home, nursing home, extended care facility, correctional or penal facility, or any other organization, public or private, which provides a physical environment for patients to obtain medical, surgical, and/or nursing services, except those places where physicians, dentists, veterinarians, or other practitioners of the healing arts engage in private office practice.

(i) "Institutional Pharmacy" means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an Institutional Facility, and which is:

(i) Located within the Institutional Facility, or

(ii) Located outside the Institutional Facility but only provides ~~pharmaceutical~~ pharmacy services to institutionalized patients.

(j) "Investigational Drug" means:

(i) a substance in a clinical stage of evaluation not released by the Food and Drug Administration (FDA) for general use or for sale in interstate commerce; or

(j) Commercial drugs that are proposed for a new use, contain a new component, have a new dosage or mode of administration, or are in a new combination or combined in new proportions.

(k) "Medication Order" means a written, electronic, or verbal order from a practitioner (or his/her agent) authorized by law to prescribe medications for administration to a patient.

(l) "Remote Order Processing for Institutional Pharmacies" includes any of the following activities performed for an Institutional Pharmacy from a remote location:

(i) Receiving, interpreting, or clarifying medication orders;

(ii) Entering or transferring medication order data;

(iii) Performing prospective drug use review;

(iv) Obtaining substitution authorizations;

(v) Interpreting and acting on clinical data;

(vi) Performing therapeutic interventions;

(vii) Providing drug information;

(viii) Authorizing the release of a medication for administration**.**

Section 5. Licensing.

(a) All institutional pharmacies shall register annually with the Board of Pharmacy on a form provided by the Board. Institutional Pharmacies that also provide outpatient pharmacy services shall also register as a retail pharmacy.

(b) All Istitutional Pharmacy licenses shall expire on June 30. Renewal notices will be sent by the Board's office at least sixty days prior to June 30.

(c) The fee established in ~~Wyoming Pharmacy Act, Rules and Regulations~~ Chapter 2, ~~Section 25(a)(xi),~~ will be charged for issuance of a new license and renewal. The late fee established in ~~Wyoming Pharmacy Act, Rules and Regulations,~~ Chapter 2, ~~Section 25 (b)(vi),~~ will be charged, in addition to the renewal fee, for any license renewal application that is postmarked after June 30 or is hand-delivered to the Board office after June 30.

Section 6. Change of Ownership.

(a) If an Institutional Pharmacy changes ownership, it must obtain a new and separate registration from the Board. In the case of a corporation, limited liability company, or partnership holding an Institutional 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.

Section 7. Personnel.

(a) A ~~pharmacist, hereinafter referred to as the~~ Pharmacist-in-Charge (PIC), who is licensed to engage in the practice of pharmacy in Wyoming, shall direct each Institutional Pharmacy.

(b) The storage, compounding, repackaging, dispensing, and distribution of drugs by an Institutional Pharmacy shall be under the direction, supervision, and responsibility of the PIC. Depending upon the size and needs of the Institutional Facility, pharmacy service may be provided on a full or part-time basis.

(i) In hospital Institutional Facilities with fifty (50) or more acute care beds, a pharmacist shall be in the hospital Institutional Facility during the time the Institutional Pharmacy is open for pharmacy services, except in case of emergencies. Pharmacy services shall be provided for a minimum of forty (40) hours per week, unless an exception is made upon written request by the hospital Institutional Facility and with express permission of the Board.

(ii) In hospital Institutional Facilities with less than fifty (50) acute care beds, a pharmacist shall be in the hospital Institutional Facility during the time the Institutional Pharmacy is open for pharmacy services. Upon written request by the hospital Institutional Facility, and with the express permission of the Board, the services of a pharmacist may be on a part-time basis, according to the needs of the hospital Institutional Facility. The services of a pharmacist shall be required as follows:

(A) In hospital Institutional Facilities with one to twenty-five (1-25) acute care beds, a pharmacist shall be ~~available~~ on-site a minimum of five (5) hours per week.

(B) In hospital Institutional Facilities with twenty-six to forty-nine (26-49) acute care beds, a pharmacist shall be ~~available~~ on-site a minimum of twenty (20) hours per week.

(iii) In a non-hospital Institutional Facility, a pharmacist shall be available commensurate with the needs of the Institutional Facility. The hours shall be identified on the initial application and provided with each license renewal.

(c) Policies and procedures defining the ~~pharmaceutical~~ pharmacy services to be provided and the responsibilities of the Institutional Pharmacy shall be established. Such policies and procedures shall be made available to the Board ~~and/or its authorized representative~~ upon request.

(d) The responsibilities of the PIC shall include, at a minimum, the following:

(i) Providing the appropriate level of pharmaceutical care services to patients of the Institutional Facility;

(ii) Ensuring that drugs and/or devices are dispensed and distributed safely and accurately ~~as prescribed~~;

(iii) Developing a system for ~~the compounding, sterility assurance, quality assurance, and quality control of sterile pharmaceuticals compounded within the Institutional Pharmacy;~~sterile compounding as required in Chapter 17

~~(iv) Developing a system to assure that all Institutional Pharmacy personnel responsible for compounding and/or supervising the compounding of sterile pharmaceuticals within the Institutional Pharmacy receive appropriate education, training, and competency evaluation;~~

(iv) Providing guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile pharmaceuticals is not performed under direct Institutional Pharmacy supervision;

(v~~i~~) Participating in the development of a Formulary for the Institutional Facility which is approved by the appropriate committee, including the medical staff of the Institutional Facility;

(vi~~i~~) Developing a system to assure that drugs to be administered to inpatients are distributed pursuant to ~~an original or direct copy~~ of the practitioner's Medication Order;

(vii~~i~~) Maintaining records of all transactions of the Institutional Pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials~~, including pharmaceuticals and components used in the compounding of pharmaceuticals~~;

(~~ix~~viii) Participating in those aspects of the Institutional Facility's patient care evaluation program that relate to pharmaceutical utilization and effectiveness as required in Chapter 9 for prospective and retrospective drug use review;

(ix) Assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(x~~i~~) Assuring the legal operation of the Institutional Pharmacy, including meeting all inspection and other requirements of state and federal laws or rules governing the practice of pharmacy; and

(xi~~i~~) Collaborating with the nursing staff and the medical staff to develop a list of standardized concentrations of medications that will be used in the Institutional Facility (e.g., therapeutic heparin intravenous infusions). Pediatric formulations will be considered as a separate listing from adult formations.

(e) The PIC shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the Institutional Pharmacy competently, safely, and adequately to meet the needs of the patients~~ of the Institutional Facility~~. All pharmacists shall assist the PIC in meeting the responsibilities as outlined in ~~Subsection (c) of this Section and in ordering, accounting for, and other administrative duties regarding pharmaceutical products.~~this Chapter

(f) Pharmacy technicians may assist the PIC, and pharmacists provided the ratio of pharmacy technicians, pharmacy technician specialists and pharmacy technicians-in-training to licensed pharmacists does not exceed ~~three-to-one (3:1). The duties of the pharmacy technicians or pharmacy technicians-in-training shall be established by the PIC and may not exceed the responsibilities as outlined in Wyoming Pharmacy Act, Rules and Regulations, Chapter 10~~the requirement of Chapter 10.

(g) The PIC may be assisted by secretarial and clerical assistance ~~as required to assist with record-keeping, report submission, and other administrative duties.~~for non-pharmacy functions as defined in Chapter 10

Section 8. Environment.

(a) The Institutional Pharmacy shall be enclosed and lockable.

(b) The Institutional Pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing, and sterile preparation of drugs prepared in the Institutional Pharmacy, depending on the size and scope of pharmaceutical services provided.

(c) A sink with hot and cold running water, exclusive of restroom facilities, shall be ~~available to all Institutional Pharmacy personnel and shall be maintained in a sanitary condition at all times~~in the Institutional Pharmacy.

(d) The Institutional Pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(e) The Institutional Pharmacy shall be properly lighted and ventilated.

(f) The temperature of the Institutional Pharmacy shall be maintained within a range of 59 to 86 degrees Fahrenheit (15 to 30 degrees Centigrade). The temperature of the refrigerator shall be maintained within a range of 36 to 46 degrees Fahrenheit (2 to 8 degrees Centigrade) and the freezer shall be maintained within a range of –13 to +14 degrees Fahrenheit (-25 to –10 degrees Centigrade).

(g) The Institutional Pharmacy shall store ~~antiseptics, other~~ drugs for external use, ~~and disinfectants~~ separately from internal and injectable medications.

(h) If the Institutional Pharmacy compounds sterile pharmaceuticals, they shall be prepared in accordance ~~with Wyoming Pharmacy Act, Rules and Regulations,~~ Chapter 17.

Section 9. References.

Each Institutional Pharmacy shall maintain in its library at least one current reference (text or electronic format, including online access or PDA) from each category

listed below. ~~The Board reserves the right to accept new references in lieu of the following:~~

(a) Drug Monograph Reference:

~~(i) American Hospital Formulary Service®;~~

~~(ii) Drug Facts and Comparisons®;~~

~~(iii) Thomson's Micromedex®;~~

~~(iv) USPDI® Volume I, Drug Information for the Health Care Professional; or~~

~~(v) Drug Information Handbook (Lexi-Comp)~~

(b) Stability and Incompatibility Reference:

~~(i) Handbook on Injectable Drugs, Lawrence A. Trissel ;~~

~~(ii) King Guide to Parenteral Admixtures; or~~

~~(iii) Thomson's Micromedex®~~

(c) Reference on Drug Availability and Identification:

~~(i) American Hospital Formulary Service®~~

~~(ii) Drug Facts and Comparisons®;~~

~~(iii) American Drug Index or~~

~~(iv) Drug Information Handbook (Lexi-Comp)~~

(d) Drug Interactions:

~~(i) American Hospital Formulary Service®;~~

~~(ii) Thomson's Micromedex®;~~

~~(iii) Drug Interactions Facts ;~~

~~(iv) USPDI® Volume I, Drug Information for the Health Care Professional;~~

~~(v) Drug Information Handbook (Lexi-Comp); or~~

~~(vi) Drug Interactions Analysis and Management (DIAM)~~

(e) Reference on Pharmacology and Therapeutics:

~~(i) Conn's Current Therapy (Rakel and Bope);~~

~~(ii) Drug Information Handbook (Lexi-Comp);~~

~~(iii) Applied Therapeutics: The Clinical Use of Drugs (Koda-Kimble);~~

~~(iv) Pharmacotherapy (DiPiro); or~~

~~(v) Textbook of Therapeutics (Herfindal and Gourley).~~

(f) Current copies of the Wyoming Pharmacy Act and Rules and Regulations, and Wyoming Controlled Substances Act and Rules and Regulations, text or electronic format, and including internet access to the Board website.

(g) Wyoming State Board of Pharmacy Quarterly Newsletter~~, maintained in a binder~~from the Board website.

Section 10. Equipment.

(a) Institutional pharmacies distributing Medication Orders shall have the following equipment:

(i) Refrigerator, including a system or device to monitor the temperature daily to ensure that proper storage requirements are met;

(ii) Computer and software appropriate for the Institutional Facility~~; and~~.

~~(iii) Facsimile capability located in the Institutional Pharmacy.~~

(b) If the Institutional Pharmacy compounds Medication Orders, that require the use of a balance, a Class A prescription balance or electronic scale with 10 mg sensitivity shall be available. Such balance or electronic scale shall be properly maintained by the PIC and may be inspected ~~at least every three (3) years~~ by the Board of Pharmacy.

(c) ~~If the~~An Institutional Pharmacy that compounds sterile pharmaceuticals, ~~the Institutional Pharmacy~~ shall have equipment and supplies listed in ~~Wyoming Pharmacy Act, Rules and Regulations~~ Chapter 17.

Section 11. Security.

(a) No one shall be permitted in the Institutional Pharmacy unless the pharmacist is on duty, except as provided in this Chapter~~, Section 12~~. If the pharmacist must leave the Institutional Pharmacy for an emergency or patient care duties, pharmacy technicians may remain to perform duties as authorized by the ~~Pharmacist-in-Charge (~~PIC~~)~~, provided that the pharmacist remains in the Institutional Facility.

(b) All Institutional Pharmacy areas shall be capable of being locked ~~by key or programmable lock, so as to prevent access by unauthorized personnel~~. The ~~Director~~ PIC shall designate in writing, by title and specific area, those persons who shall have access to specific Institutional Pharmacy areas.

(c) Each pharmacist on duty shall be responsible for the security of the Institutional Pharmacy~~, including provisions for adequate safeguards against theft or diversion of drugs including controlled substances and the records thereof~~.

(d) Pharmacists, technicians, clerical staff, and interns working in the Institutional Pharmacy shall wear identification badges, including name and position, whenever on duty.

(e) The PIC shall be responsible for policies and procedures for the safe distribution and control of prescription blanks ~~bearing identification of the Institutional Facility~~and tamper resistant paper.

Section 12. Absence of Pharmacist.

(a) General. During such times as Institutional Pharmacy services are not available on-site, arrangements shall be made in advance by the ~~Pharmacist-in-Charge (~~PIC~~)~~ for provision of drugs ~~to the medical staff and other authorized personnel of the Institutional Facility~~ by use of Floor Stock ADD, and/or access to the Institutional Pharmacy ~~under the standing order of the PIC~~.

(b) If Floor Stock is used, the following shall prevail:

(i) In the absence of a registered pharmacist, medication for inpatients shall be obtained from a locked cabinet(s) or other enclosure(s) located outside the Institutional Pharmacy to which only authorized nurses, ~~specifically authorized in writing by the PIC,~~ may obtain ~~access by key or combination, and which is sufficiently secure to deny access to unauthorized persons~~.

(ii) The PIC shall~~, in conjunction with the appropriate committee, if any, of the Institutional acility,~~ develop inventory listings of those drugs to be included in such Floor Stock, and shall ensure that:

(A) Such drugs are available ~~therein~~, properly labeled;

(B) Such drugs are prepackaged in appropriately small amounts, unless commercially prepared packages, e.g. ophthalmics, otics, topicals, etc.

(C) All drugs ~~therein~~ shall be checked and replenished as needed;

(D) A record shall be ~~made on a copy of the physician's order or in a separate file or logbook located where the Floor Stock is~~ maintained, and shall include:

(I) The date and time of removal of a drug;

(II) The patient's name and location;

(III) The name, strength, dosage form, and quantity of drug removed; and

(IV) The printed name and signature of the nurse removing the drug.

~~(E) The nurse removing the drug shall leave a direct copy of the new physician's order for the medication with the above record or, if the copy of the physician's order is utilized in place of the log book, then this copy must be left in a designated area where Floor Stock is maintained; and~~

(F) Written policies and procedures are established~~ to implement the requirements of this Paragraph~~.

(c) Access to the Institutional Pharmacy. Whenever any drug is not available from Floor Stock, ~~and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the Institutional Pharmacy, in accordance with the requirements of this Paragraph. Only~~only supervisory or charge nurses may have access to the Institutional Pharmacy and may remove drugs ~~therefrom~~. ~~Such nurses shall be designated in writing by the PIC~~.

(i) Removal of any drug from the Institutional Pharmacy by an authorized nurse must be recorded ~~on a suitable form at the Institutional Pharmacy~~ showing:

(A) The date and time of the removal of the drug;

(B) The patient's name and location;

(C) The name, strength, dosage form, and quantity of drug removed; and

(D) The printed name and signature of the nurse.

(ii) The nurse removing the drug shall leave a copy of the physician's order for the new drug with the above record.

(iii) The quantity of drug removed shall not exceed the amount of medication needed until the Institutional Pharmacy reopens. Drugs, that are usually dispensed as a unit of use package, such as ~~MDIs~~inhalers, otics, topicals, insulin, and ophthalmics, are excluded.

(iv) A procedure shall be established to allow verification by the pharmacist of the drug removed (such as by leaving the identifying container or unit-dose sample of the drug with the records).

(d) If off-site pharmaceutical care is provided whenever an Institutional Pharmacy is closed, then the following requirements must be met:

(i) The Institutional Pharmacy shall have a pharmacist on duty at the Institutional Facility the minimum number of hours required in this Chapter, Section 7.

(ii) Any pharmacist providing off-site pharmaceutical care under this Section shall be licensed to practice pharmacy in Wyoming.

(iii) The Board shall be notified in writing by the Institutional Pharmacy of any arrangement whereby pharmaceutical care is provided off-site. This notification shall include the following:

(A) The name, address, and Wyoming license number of each pharmacist who will be providing this service.

(B) The name, address, and Wyoming license number of each pharmacy exchanging information with the Institutional Facility.

(C) Description of the ~~audio, video, and data~~communication link that will be utilized to exchange information between the Institutional Facility and the off-site pharmacist.

(D) Description of the scope of work of any pharmacist who provides off-site pharmaceutical care ~~under this Section~~.

(E) Description of patient information that is to be shared between the Institutional Facility and the off-site pharmacist. At minimum, the off-site pharmacist shall have access to the patient's medical record.

(iv) A pharmacist providing off-site pharmaceutical care may perform Remote Order Processing, if the pharmacist has access to appropriate patient information, including laboratory results.

(v) A pharmacist providing off-site pharmaceutical care shall provide the following services as a minimum:

(A) Review of any new Medication Order or change in existing Medication Order prior to administration by the nursing staff at the Institutional Facility.

~~(B) Review of all sterile compounding performed by nursing staff. Medications compounded during cardiopulmonary resuscitation or similar medical emergency or procedure shall be exempt from an off-site pharmacist review prior to administration. In all other circumstances, all sterile compounding is subject to review by the off-site pharmacist.~~

(~~C~~B) The off-site pharmacist shall communicate with the Institutional Pharmacy staff on a daily basis or~~, if the Institutional Pharmacy is not~~

~~opened on a daily basis, then communication shall occur~~ whenever the Institutional Pharmacy is open for business.

Section 13. Emergency Outpatient Medication.

(a) Institutional Facilities, which provide for the administration and distribution of emergency pharmaceuticals to outpatients and/or inpatients being discharged during hours when normal community or outpatient Institutional pharmacy services are not available, may:

(i) Allow a designated nurse on the original written or electronic order of a practitioner to administer and distribute medications pursuant to the following requirements:

(A) A written or electronic order of a practitioner authorized to prescribe a drug is presented.

(B) The medication is prepackaged by a pharmacist or a technician under a pharmacist's supervision or is administered and distributed utilizing an automated drug dispensing device;

(C) The quantity of medication administered and distributed is limited to a seventy-two hour (72-hour) supply. Exceptions to the 72-hour supply include: oral pediatric antibiotic preparations ~~(PO)~~, otics, ophthalmics, topicals, ~~or metered dose~~ inhalers, nitroglycerin tablets, nasal sprays, manufacture packaged courses of therapy such as Z-paks or dosepaks; and

(D) The labeling of the administered and distributed medication includes:

(I) Name, address, and telephone number of the Institutional Facility;

(II) Name of patient;

(III) Name of drug, strength, and quantity;

(IV) Directions for use;

(V) Date;

(VI) Accessory cautionary information, as required for patient safety;

(VII) Name of practitioner; and

(VIII) Initials of the nurse administering and distributing the medication.

(b) The order may be in the form of a separate written or electronic prescription or a prescription entered in the patient's medical record. A practitioner must sign the order. A copy of the prescription order must be readily available for review by the pharmacist.

(c) A record shall be maintained for ~~recording~~ all medications administered and distributed from the ~~Institutional Facility's~~ emergency room. The record shall include the following information:

(i) Name of patient;

(ii) Date of issuance;

(iii) Name of drug;

(iv) Patient's Institutional Facility record number; and

(v) Initials of the nurse who administered and distributed the drug.

(d) The emergency room log for drugs administered and distributed after hours shall be ~~reviewed~~ available for review by the pharmacist ~~at least weekly~~. Inventory levels will be compared to drugs administered and distributed. Discrepancies will be reviewed with the emergency room nursing supervisor.

(e) Security of all drugs prepackaged must be maintained in a locked cabinet, ADD or storeroom location in the emergency room area to which only specifically authorized personnel shall have ~~a key or combination~~access.

Section 14. Emergency Drug Carts (crash carts).

Emergency Drug Carts may be used by Institutional Facilities if:

(a) All drug kits are supplied, and kept up-to-date, under the supervision of a licensed pharmacist;

(b) A committee composed of the ~~Pharmacist-in-Charge~~PIC, nursing staff, and medical staff of the Institutional Facility develops a standard drug inventory, including kind and quantity of each drug;

(c) All drug kits are equipped with a breakable seal, and are secure from access by unauthorized persons;

(d) A listing of all drugs, their respective strength, quantity, and location, shall be placed on the cart in a conspicuous location. If the pharmacy which services this Emergency Drug Cart is not located within the Institutional Facility, the name, address, and telephone number of the pharmacy shall be displayed in a conspicuous location;

(e) All drugs are properly labeled;

(f) The drugs are distributed, pursuant to a valid order, by authorized personnel, and the pharmacist is notified of entry into the Emergency Drug Cart; and

(g) The ~~pharmacist~~PIC, nursing staff, and medical staff develop and implement written policies and procedures for using Emergency Drug Carts.

Section 15. Automated Dispensing Devices.

(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 by the Board to~~ ensure the purity, potency, and integrity of the drug, ~~and to~~ protect the drug from diversion, and provided that:

(i) The device shall be stocked with drugs only by or under the supervision of a pharmacist;

(ii) The device shall be used only for the furnishing of drugs for administration to patients of that Institutional 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 drug removed;

(C) The name of the patient for whom the drug was ordered; and

(D) The name or identification code of the nurse removing the drug from the device.

Section 16. Parenteral Medications.

(a) The ~~Pharmacist-in-Charge (~~PIC~~)~~ shall be responsible for the preparation, sterilization, labeling, and dispensing of parenteral medications prepared within the Institutional Facility and shall participate in the education and training, including the provision of appropriate incompatibility information, of all personnel involved in the preparation of parenteral medications.

(b) If intravenous admixtures are prepared within the Institutional Facility, the Institutional Pharmacy shall have adequate equipment, personnel, and space for such preparation. The compounding and labeling of intravenous admixtures, including all total parenteral nutrition, shall be performed by, or under, the direct supervision of a pharmacist; however, if twenty-four hour (24-hour) pharmacy service is not provided at the Institutional Facility, the PIC shall establish written policies and procedures to be

followed in the preparation of intravenous admixtures when the Institutional Pharmacy is closed or in emergency situations.

(c) All admixtures shall be labeled with a distinctive supplementary label, indicating the name and amount of drug added, date and time of addition, ~~expiration~~ beyond use date, and rate of administration, and the name or identification code of the person adding the drug.

(d) The PIC shall be responsible for removing concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride greater than 0.9%) from patient care areas and limiting their access to pharmacists~~, if at all possible~~. If twenty-four hour (24-hour) on-call status for pharmacists is not available, the Institutional Facility must utilize the most trained professional available to process concentrated electrolytes. Training in the safe use of concentrated electrolytes should be conducted by the Institutional Pharmacy for non-pharmacist staff with access to concentrated electrolytes. Evidence of training will be documented and retrievable, and the Institutional Facility will have policies and procedures that detail this process. Premixed large volume intravenous solutions containing electrolytes and premixed potassium bolus doses will be used whenever possible.

Section 17. Practitioner's Orders.

(a) All orders for drugs shall be transmitted to the Institutional Pharmacy by electronic order entry, or by means of an order format, that is capable of producing a direct copy or an electronically reproduced facsimile. A pharmacist shall review the practitioner's order before the initial dose of medication is dispensed provided that, in emergencies or when pharmacy services are not available, the Medication Order shall be reviewed by the pharmacist as soon ~~thereafter~~ as possible. Verification of the accuracy of the medication dispensed and of any transcriptions made of that order shall be documented by the initials of the pharmacist so certifying.

(b) Orders for drugs for use by inpatients shall, at a minimum, contain the patient name and location, drug name, strength, directions for use, date, and practitioner's written or electronic signature or written or electronic signature of the practitioner's agent~~, either written or electronic signatures~~.

(c) Orders for outpatient dispensing shall meet the requirements ~~of Wyoming Pharmacy Act Rules and Regulations,~~ Chapter 2~~, Section 19~~.

Section 18. Dispensing.

(a) If unit-dose packaging is used, medication for each patient, when not supplied by an automated dispensing device, shall be distributed and stored in separate trays, drawers, compartments, or containers assigned to that patient and bearing the patient's name and location.

Section 19. Investigational Drugs and Protocols.

(a) All Investigational Drugs shall be stored in the Institutional Pharmacy and distributed only from the Institutional Pharmacy. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of such drugs shall be available in the Institutional Pharmacy. Investigational Drugs shall be properly labeled and shall be administered only under the personal and direct supervision of the principal physician-investigator or his or her authorized clinician(s) with prior approval of the appropriate committee(s) of the Institutional Facility and with verifications that the patient (or his or her legal designee) has signed the informed consent form.

(b) A copy of all Investigational Drug protocols shall be on file in the Institutional Pharmacy.

Section 20. Inspections.

The ~~Pharmacist-in-Charge~~PIC or his/her designee shall document on at least a quarterly basis an inspection of all drug storage areas in the Institutional Facility. Records of such inspections shall be dated, signed, and maintained so as to be readily retrievable at the Institutional Pharmacy for at least two (2) years. These inspections must ascertain that:

(a) Test reagents, germicides, and disinfectants are stored separately from medications;

(b) External medications are stored separately from internal medications;

(c) ~~Thermolabile d~~Drugs are stored at the proper temperature;

(d) There are no outdated or deteriorated drugs;

(e) All drugs are properly labeled;

(f) Emergency Drug Carts (crash carts) are adequate and in proper supply;

(g) Medication storage areas are locked when not in use, and only authorized individuals have access to these areas;

(h) Distribution and administration of controlled substances are properly and adequately documented;

(i) Telephone numbers of the regional poison control center and other emergency assistance organizations are posted;

(j) Metric-apothecaries' weight and measure conversion tables and charts are available; and

(k) Adequate pharmaceutical reference~~s texts~~ s are available at these areas.

Section 21. Medications brought into the institution by patients.

Whenever patients bring drugs into an Institutional Facility, such drugs shall not be administered unless they can be precisely identified; administration shall be pursuant to a practitioner's order. If such drugs are not to be administered, they shall be delivered to the Institutional Pharmacy, packaged, sealed, and returned to an adult (18 years or older) member of the patient's immediate family (spouse, unless legally separated; adult child; parent; grandparent; adult brother or sister; adult grandchild), the patient's legal guardian or conservator, or the patient's designated agent, or they shall be stored and returned to the patient upon discharge, only after advice is provided regarding continuing the returned medication.

Section 22. Controlled Drugs.

(a) All controlled substances issued by the Institutional Pharmacy to any Institutional Facility department, excluding those controlled substances for which the dispensing and record-keeping are maintained utilizing an automated drug dispensing device, shall be labeled and accompanied with control sheets (proof of use forms) that provide space for recording:

(i) The drug name, strength, and dosage form;

(ii) The date and time of administration;

(iii) The quantity administered;

(iv) Name of patient;

(v) The signature of the nurse who administered the medication, when issued to nursing units; and

(vi) The signature of the practitioner who administered the medication and a witness, when issued to surgery or other specialized areas such as endoscopy labs.

(b) Such drugs shall be limited both in kind and quantity commensurate with the needs of the area to which they are distributed; the Institutional Pharmacy shall maintain a record of such distribution. The ~~Pharmacist-in-Charge (~~PIC~~)~~, in consultation with the Director of Nursing or other appropriate hospital staff, shall establish written requirements for the frequency of controlled substance inventories in drug storage areas outside of the Institutional Pharmacy.

(c) All control sheets must be returned to the Institutional Pharmacy upon completion. The pharmacist shall verify the returned sheets for accountability and control prior to drug reissuance. These control sheets, as well as any records generated, must be maintained so as to be readily retrievable at the Institutional Pharmacy for two (2) years. Records of controlled substance, which are dispensed utilizing an automated ~~drug~~ dispensing device, shall be maintained at the Institutional Pharmacy for two (2) years.

(d) All controlled substances that must be wasted shall be destroyed by a method approved by the PIC. Documentation of all destruction must occur on the control sheet, in the patient's medical record, or utilizing the format available with an automated drug dispensing device, and be signed (written or electronically) by the nurse/physician destroying and one witness who observed the destruction.

(e) Transdermal patches containing controlled substances shall be handled in the following manner:

(i) The PIC, in coordination with the Director of Nursing, will implement a policy requiring all nursing personnel applying a transdermal patch containing a controlled substance to write the date on the patch when it is first applied to a patient.

(ii) All used transdermal patches containing a controlled substance shall be destroyed in front of a witness, and documented ~~in a manner similar to Section 22(d)~~. The destruction will be done in a manner ~~that does not subject the health care worker to exposure to the controlled substance and that makes the patch irretrievable (e.g., using gloves to cut the patch, placing it in a sharps container, cleaning the scissors with alcohol, etc.)~~currently recommended by the FDA.

CHAPTER 13

NON-STERILE COMPOUNDING

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

Section 2. Definitions.

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

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

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

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

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

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

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

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

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

(fd) "Component" means any ingredient used in the compounding of a drug product, including those ingredients that may not appear in the labeling of such product."Master Compounding Record" means an established record of all compounded products from the time of initial compounding that can be followed each time that compound is prepared in the future.

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

Section 3. General Provisions.

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

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

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

(A) Product name;

(B) Lot number;

(C) Expiration date; and

(D) Assay.

(c) Pharmacists may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/practitioner relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by the Board, but not under other circumstances.

(d) Pharmacists shall not offer compounded medications to other pharmacies or licensed entities for resale; except pharmacists may offer for sale compounded medications to practitioners or institutional pharmacies for administration to patients in the practitioner's office or in the institutional facility, provided that the pharmacy does not violate Chapter 8, ~~Section 4(j) of the Board's Rules~~. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not solicit business by distributing unsolicited sampling to practitioners (e.g., like a manufacturer).

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

Section 4. Organization and Personnel.

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

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

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

Section 5. Drug Compounding Facilities.

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

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

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

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

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

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

Section 6. Equipment.

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

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

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

Section 7. Compounding Controls.

(a) ~~There shall be recorded procedures for compounded products to include components, amount, order of procedure, and equipment to ensure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess.~~A Master Compounding Record shall be established for each newly compounded item and followed thereafter to monitor the output and to validate the performance of those compounding processes. The Master Compounding Record shall contain:

(i) Official compound name, strength, and dosage form,
(ii) Calculations required to complete the compound,
(iii) Ingredient(s) description and amounts,
(iv) Compatibility and stability information (references when available)
(v) Equipment required to prepare the compound,
(vi) Mixing instructions,
(vii) Any other factors pertinent to the compound preparation,
(viii) A sample label meeting all legal requirements stated in Chapter 2,
(ix) The generic name, quantity and/or concentration of every active ingredient contained within, and
~~(a)~~(x) An assigned BUD as applicable.

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

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

(i) Capsule weight variation;

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

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

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

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

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

Section 9. Records and Reports.

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

(b) For each drug product compounded in excess or bulk quantities, a log book, in addition to those requirements listed in ~~Section 7(a) of~~ this Chapter, shall be prepared containing the following information:

(i) Name of the product;

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

(iii) Lot number assigned by a pharmacist;

(iv) Beyond use date assigned, as described in ~~Section 8 of~~ this Chapter;

(v) Date of preparation;

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

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

(viii) Quantity prepared.

Chapter 15

Long Term Care Pharmacy Services

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Definitions.

(a) "Long Term Care Facility" means any skilled or intermediate care nursing home, board and care home, or any patient 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 services in a long-term care facility on a regularly scheduled basis.

(c) "Medication Order," as used in these rules means a written, oral, facsimile or electronic order from a practitioner ~~or an oral order from a practitioner~~ or the practitioner's authorized agent 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.

~~Section 3. Applicability of Rules.~~

~~Nothing in these rules shall be deemed to constitute a waiver or abrogation of any of the provisions of board rules or other applicable provisions of state and federal laws and rules, nor should these rules be construed as authorizing or permitting any person not licensed as a pharmacist to engage in the practice of pharmacy.~~

Section ~~4~~ 3. 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 ~~Section 5~~4 of this ~~c~~Chapter.

Section ~~5~~ 4. 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, ~~Section 11~~ of the board's 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 a 24 hour emergency service~~ Providing service twenty-four (24) hours a day, seven (7) days a week, either directly or by contract with another pharmacy. All "on-call" services shall be verifiable by the Board and its inspectors. emergency boxes or automated dispensing devices may be used as outlined in Chapter 2.

(e) Performing prospective drug usage reviews for all new and refill medication orders as described in Chapter 9, ~~Section 4~~ of the board's 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 ~~someone~~ another pharmacy to provide IV services, if the long term care facility is a skilled unit providing such services.

~~(g)~~(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.

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

Section ~~6~~ 5. Consultant Pharmacist Responsibilities

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

(i) The ~~M~~ 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 medications.

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

(b) Patient Drug Regimen Review.

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

(ii) ~~State and federal regulations shall be the minimum standards for an adequate drug regimen review.~~

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

~~(A) Ascertain that patient history and drug utilization is being properly recorded.~~

~~(B) Review drug usage, including both prescriptions and O.T.C.'s.~~

~~(C) Review patient compliance with drug regimen.~~

~~(D) Review drug allergies or sensitivities.~~

~~(E) Determine whether the patient is predisposed to side effects due to disease, illness, or age.~~

~~(F) Determine whether potential exists for significant drug interaction~~

~~(G) Monitor patients' records for signs that indicate abuse or misuse of drugs by the patient or other individuals.~~

~~(H) Make recommendations regarding drug therapy to the physician.~~

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

Section 7. Automated ~~ic~~ Dispensing Device. (See Chapter 2 ~~12, section 15~~

~~or duplicate information below.)~~

(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 provided that:

(i) The device shall be stocked with drugs only by or under the supervision of a pharmacist.

(ii) The device shall be used only for the furnishing of drugs for administration to patients 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 drug removed;

(C) The name of the patient for whom the drug was ordered; and

(D) The name or identification code of the nurse removing the drug from the device.

CHAPTER 16

IMMUNIZATION REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by W.S. 33-24-157.

Section 2. Definitions.

(a) "Healthy Adults" means ~~for the purpose of this chapter~~ those individuals who are ~~nineteen (19)~~eighteen (18) years of age or older and have no absolute contraindications to receive immunizations allowed in this C~~c~~hapter.

(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 this chapter.

(c) "High Risk Adults" means for the purpose of this chapter those adults ~~nineteen (19)~~eighteen (18) years of age or older who may have an absolute or relative contraindication to receive immunizations as allowed by this C~~c~~hapter 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 for the purpose of this chapter those vaccines which a pharmacist may prescribe or administer to healthy adults or those vaccines which may be administered on a specific order of a physician for high risk adults and shall be restricted to the following vaccines:~~"Immunizations" means treatment ~~as~~ 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 ~~and the non-pharmacy area of business~~ that is no less than ~~8 feet by 8 feet~~ 48 square feet and has at least an 8 feet tall partition ~~that is completely solid from the floor to the top~~ to ensure patient safety and confidentiality. The partition cannot be a curtain.

~~(i)~~(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 3. Adu~~i~~lts ~~(age 19~~8 ~~and older)~~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:

~~(ii)~~(i) Human papillomavirus (HPV)

~~(iii)~~(ii) Hepatitis A

~~(iv)~~(iii) Hepatitis B

(iv) Influenza

(v) Measles, mumps, rubella (MMR)

(vi) Meningococcal

(vii) Pneumococcal (Polysaccharide)

(viii) Tetanus, diphtheria, pertussis (Td, Tdap)

(ix) Varicella

(x) Zoster

Section 4. Minors (age 7 through 17).

(a) Vaccines which a pharmacist may prescribe and administer to a minor 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

(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 ~~3~~5. Qualifications.

(a) A pharmacist licensed by the B~~b~~oard may prescribe and administer immunizations to healthy ~~adults~~ 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 Pharmaceutical ists 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"* ;

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

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

(iv)(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 (A.C.P.E.).

(b) (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 46. Registration.

(a) Prior to prescribing or administering immunizations a pharmacist shall submit an application supplied by the bBoard and a $10.00 fee. Provided all requirements of Section 3(a)this Cchapter have been met, the board Board shall issue a registration. Registrations shall expire on December 31 of each year.

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

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

Section 75. 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 adult individual to receive an immunization. The latest notice from CDC may be found at CDC's website (http://www.cdc.gov) or (http://www.cdc.gov/nip/recs/adult-schedule-bw.pdf).

(b) In addition to the requirements of ~~Section 5(a) of~~ this ~~c~~Chapter, the pharmacist shall utilize the manufacturer's package insert for indications, contraindications, adverse reactions, ~~adult~~ 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 and pharmacist~~s~~ administering the vaccine seated with back support and next to each other.

Section ~~6~~8. 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) ~~or (http://www.cdc.gov/nip/publications/VIS/default.htm)~~ .

Section ~~7~~9. Record-keeping.

(a) An Immunization Questionnaire and Consent Form~~, as provided by the board,~~ shall be completed for each ~~person~~ 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;

(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 ~~and waivers~~ 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.

~~(c) The Immunization Questionnaire and Consent Form shall be kept on file for a time period not less than six (6) years from the date of the immunization.A record of the immunization shall be entered into the Wyoming Immunization Registry (WYIR) for all minors.~~

Section 10~~8~~. Emergencies.

(a) A pharmacist authorized to prescribe and administer immunizations under this ~~c~~Chapter may administer auto-inject epinephrine in the management of an acute allergic reaction to an immunization following guidelines issued by the American Pharmac~~y~~ ists 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~~n immunization~~ vaccine administered.

~~(c) If a patient refuses to be observed for the fifteen (15) minutes after the vaccination has been administered, the patient (or parent or legal guardian of a minor) must sign a waiver stating they have discussed with the pharmacist the possible side effects and how to seek treatment.~~

Section 11. 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 ~~Cc~~ chapter.

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