

CHAPTER 2

GENERAL PRACTICE OF PHARMACY REGULATIONS

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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 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.

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

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

(h) “Collaborative practice agreement” means a voluntary agreement, written and signed, between a pharmacist and a prescribing practitioner that defines a collaborative practice.

(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.

(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.

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

(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.

(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.”

(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.

(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.

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

(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.

(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.

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

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

(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.

(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 facsimile (fax) machine, which is authenticated by an electronic signature.

(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.

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

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

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

(ii) Formulating a medication treatment plan;

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

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

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

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

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

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

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

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

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

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

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

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

(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.

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

(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.

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

(dd) "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.

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

(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.

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

(hh) "Pharmacy intern" is described in Chapter 3.

(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 contained 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."

(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:

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

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

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

(B) All retakes require payment of fees, as required by NABP.

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

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

(B) All retakes require payment of fees as required by NABP.

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

(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 a criminal background history report from the Wyoming Division of Criminal Investigation (DCI).

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

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

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

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

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

(B) All retakes require payment of fees, as required by the NABP.

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

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

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

(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 has been met.

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

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

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

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

(i) 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 NABP® and who desires to be licensed by reciprocity into this State, shall proceed in the manner outlined by the NABP® after first submitting the "Preliminary Application for Transfer of Pharmacist Licensure" obtained from the NABP®.

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

(i) File all appropriate applications with the Board;

(ii) Pay the required application fee;

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

(iv) Pay the required criminal background check fee;

(v) Pass the MPJE® for Wyoming;

(vi) Prove good moral character;

(vii) Prove they have been in active pharmacy practice, as defined 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 DCI before a pharmacist license by transfer will be issued.

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

(d) All applications for transfer of licensure (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.

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.

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

(v) A separate refrigerator located in the pharmacy, which is sufficient in capacity to serve the needs of the pharmacy, and is equipped with a thermometer, and which provides a storage temperature of 36-46 degrees Fahrenheit (2-8 degrees

Centigrade). The use of such refrigerator shall be limited to the storage of drugs. If a freezer compartment is utilized, it must maintain a temperature of -13 to 14 degrees Fahrenheit (-20 to -10 degrees Centigrade).

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

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

(A) Current Wyoming pharmacy laws;

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

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

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

(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 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.

(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 requirements of the pharmacy, shall be restroom facilities, access to which shall be limited to pharmacy staff.

(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) 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 access to the pharmacy.

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

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

In the case of a corporation, limited liability company, or partnership holding a pharmacy license, the Board shall be notified and a new license applied for any time the majority of stock in the corporation is sold or a majority of the partners of the partnership or members of the limited liability company change. This shall constitute new ownership. Requirements for the 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 change of a pharmacist. A pharmacist shall be designated as the PIC and shall have direct control of the pharmacy services of said pharmacy. A pharmacist may not serve as the PIC unless said pharmacist is physically present in the pharmacy a minimum of thirty-two (32) hours per week, except for time periods of less than 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 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 PIC who will have complete control over the pharmacy services of said pharmacy.

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

(b) Responsibility as the 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 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 PIC shall be to:

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

(ii) Supervise the professional employees of the pharmacy.

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

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

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

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

(vii) Ensure that all pharmacy licenses, including State and federal controlled substances 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 prescribed drugs are not outdated, damaged, deteriorated, misbranded, counterfeit, contraband, or adulterated.

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

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

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

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

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

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

(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 of the invalidated prescription order or electronic document:

- (A) His/her name;
- (B) The name of the receiving pharmacist;
- (C) The name of the receiving pharmacy;
- (D) The telephone number of the receiving pharmacy; and
- (E) The date of the transfer.

(c) The pharmacist or pharmacy intern receiving the transferred prescription order information shall reduce the transferred information to writing, 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 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 refills(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 an 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 refills(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 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 or 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 the 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, as well as prescription drugs dispensed from hospital emergency room departments, as described in Chapter 12, 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 as the number of refills authorized.

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

Section 14. Doctor-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 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 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 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. 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) 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 this Chapter and may include the following:

- (i) Pass a jurisprudence examination.
- (ii) Internship under direct supervision. Internship period may vary depending upon how long the individual was out of practice.
- (iii) Board interview.

Section 18. Prescriptions in General.

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

- (i) Name of patient.
 - (ii) Name and strength of drug.
 - (iii) Quantity to be dispensed.
 - (iv) Directions for using the drug.
 - (v) Date of issuance by practitioner.
 - (vi) Recognizable signature of the practitioner. The signature can be a digital or electronic signature as defined in this Chapter.
 - (vii) Prescriptions for controlled substances shall indicate the DEA number and address of the prescribing practitioner and address of the patient.
 - (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 by the pharmacist in written form; orally, including by telephone; by fax; and by electronic transmission. Schedule II controlled substance prescriptions may be transmitted by fax if they meet the conditions as outlined in this Chapter. Controlled substance prescriptions may be transmitted electronically only to the extent allowed by federal and State law.
- (d) Prescriptions received from out-of-state practitioners are valid only to the extent a practitioner licensed in Wyoming may prescribe that medication in Wyoming.
- (e) The patient shall have the exclusive right to freedom of choice for any pharmacy to dispense his/her prescription orders. No collaborative practice agreement between prescriber and pharmacy shall require that prescription orders be transmitted from the prescriber to only that pharmacy.
- (f) The pharmacist shall be required to determine the accuracy and authenticity of all prescriptions received. Practitioners or their agents shall provide voice verification, when requested by the pharmacist. If refused, the prescription shall not be filled.

Section 19. Transmission of Prescriptions by 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.
- (v) Name of the individual acting as the practitioner's agent, if other than the practitioner.

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

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

(d) The fax machine for any receiving pharmacy shall be in the prescription department to protect patient confidentiality and shall utilize non-fading paper. Alternatively, a non-fading photocopy of manually written copy of the faxed prescription shall be stapled to the fax.

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

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

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

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

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

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

Section 20. Prescription Refill Information.

(a) Prescription refill permission may be obtained in written, fax, or electronic form, or by oral 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 21. Fax Machines in General.

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

Section 22. Therapeutic Equivalents.

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

(b) Pharmaceuticals that are considered to be therapeutic substitution instead of generic substitution shall not be used for 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 23. 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 PIC.

(c) Pharmacy license and controlled substance registrations shall be renewed annually by July 1 to continue doing business in the State.

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

(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.

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

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

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

(a) The Board shall charge the following fees as indicated:

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

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

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

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

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

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

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

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

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

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

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

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

(xiii) 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.

(xiv) 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.

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

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

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

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

(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.

Section 25. 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 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 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 twenty five dollars (\$25.00) 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 Substances Act and/or Rules and Regulations promulgated under said Acts.

(b) 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 by the Consultant Pharmacist of the facility and the facility's director of nursing.

(c) 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 within seven (7) days of discovery.

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

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

(ii) Drugs that a practitioner had ordered for a patient on an as needed basis, if the utilization and administration of those drugs are subject to ongoing review by a pharmacist. The pharmacist must be notified within 48 hours of the removal of the medication.

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

(e) 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.

(f) Facilities described in this Section are exempt from the provisions of this Section, 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 State Board of Pharmacy.

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

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

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

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

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

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

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

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

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

(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 NAPLEX® with a minimum score of 75;

- (ii) The MPJE® with a minimum score of 75; and/or
- (iii) An internship, not to exceed 1,200 hours, as prescribed by the Board.

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

Section 27. Collaborative Pharmacist Care.

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

(b) The collaborative practice agreement shall include:

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

(ii) The specific types of 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 practitioner concerning specific decisions. Documentation of decisions shall occur in the prescribing practitioner patient medical record. If the medical record is not available at the practice site, a copy of the documentation of decisions will be sent to the prescribing practitioner.

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

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

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

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

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

- (i) Patient's name, gender, date of birth, height, and weight;
- (ii) Allergies;
- (iii) Medical diagnosis;
- (iv) All current medication(s), including current dosages (including any laboratory test);
- (v) Method of communicating information between pharmacist and practitioner;
- (vi) Frequency of practitioner follow-up;
- (vii) Date the order will be renewed (specific order must be renewed annually);
- (viii) Signatures of 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 must approve all revisions, once signed by the pharmacist and the prescribing 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. The Executive Director shall convene the Collaborative Practice Advisory Committee to review pending collaborative practice agreements. The Committee shall have authority to recommend approval or rejection of the collaborative practice agreement.

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

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

(g) A pharmacist and prescribing 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 28. Electronic Prescription Transmission.

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

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

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

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

(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 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 PIC. A copy shall be provided to the Board.

(x) An inspection of the pharmacy shall be conducted by the Board after the retail pharmacy has closed for business and all prescription drug stock has

been removed. At the time of inspection, the following documents shall be provided to the Board Inspector/Compliance Officer;

- (A) A copy of the final controlled substance inventory.
 - (B) Documentation, as noted in this Chapter, regarding notification to the public of the closure of the retail pharmacy.
 - (C) The Wyoming retail pharmacy license.
 - (D) Documentation of the transfer of all prescription drug inventory (controlled and non-controlled) to a third party authorized to have such possession of inventory. Under no circumstance may prescription drug inventory remain in the possession of a person or business not authorized by law to have possession.
 - (E) Any changes to information previously provided to the Board as required in this Chapter.
 - (F) The DEA registration certificate and blank DEA 222 forms.
- (xi) It is unprofessional conduct for a retail pharmacy to close in a manner other than that prescribed in this Chapter.
- (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.

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

controlled substances. (II) Invoices for purchases of Schedule III, IV and V

(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 PIC from the prior and the new ownership. A copy shall be provided to the Board.

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

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

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

(C) The DEA registration certificate and blank DEA 222 forms from the prior owner.

(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 PIC.

(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 30. Institutional Pharmacy Closure.

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

- (i) The last day the institutional pharmacy will be open for business.
- (ii) The proposed disposition of all prescription drug inventory, including controlled and non-controlled prescription drug products.
 - (iii) The name, address and telephone number of the custodian of records for the following documents, which must be maintained for two (2) years from the date of closure.
 - (A) Completed DEA 222 forms or retrievable electronic equivalent.
 - (B) Invoices for purchases of Schedule III, IV and V controlled substances.
 - (C) Patient specific records.
 - (iv) The date the 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 Schedule II, III, IV and V controlled substances shall be taken. This inventory shall be dated and signed by the PIC. A copy shall be provided to the Board.
- (c) An inspection of the pharmacy shall be conducted by the Board after the institutional pharmacy has closed for business and all prescription drug stock has been removed. At the time of inspection, the following documents shall be provided to the Board Inspector/Compliance Officer:
 - (i) A copy of the final controlled substance inventory.
 - (ii) The Wyoming institutional pharmacy license.
 - (iii) Documentation of the transfer of all prescription drug inventory (controlled and non-controlled) to a third party authorized to have such possession of inventory. Under no circumstances may prescription drug inventory remain in the possession of a person or business that is not authorized by law to have possession.
 - (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 31. Drug Samples.

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

Section 32. Centralized Prescription Processing.

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

(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 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 PIC of the central fill pharmacy shall ensure that:

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

(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. § 33-24-152 and this Section

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

(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 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 the patient, as required by Chapter 9.

(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 the date the prescription was shipped to the dispensing pharmacy.

Section 33. Automated Storage and Distribution Systems.

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

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

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

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

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

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

(A) Only allows patient Access to prescriptions that:

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

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

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

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

(C) Is located inside a building in a wall of a licensed pharmacy where the pharmacy staff has access to the device from within the pharmacy and patients have access from outside 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 or pharmacy technician.

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

(c) The PIC shall:

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

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

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

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

Section 34. 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.