Pharmacy, Board of

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

Section 2. Purpose.

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

Section 3. Scope.

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

Section 4. Definitions.

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

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

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

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

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

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

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

(f) "Automated Dispensing Device" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

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

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

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

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

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

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

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

(iv) Compounding does not include mixing, reconstituting, adding flavoring or other such acts that are performed in accordance with directions contained in approved labeling provided by the product’s manufacturer and other manufacturer directions consistent with the labeling.

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

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

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

(n) “Device” means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part of accessory, which is

required under federal law to bear the label, “Caution: Federal law restricts this device to sale by or on the order of a physician.”

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

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

(ii) Is unique to the authorized signer;

(iii) Is capable of verification;

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

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

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

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

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

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

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

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

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

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

(w) “Electronic transmission” means:

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

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

(x) "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 refill consolidation" means a component of medication therapy management that recognizes the authority of the pharmacist, at the patient's directions, to proactively adjust the medication quantity or refill schedule and to manage a patient's maintenance medications by coordinating the refill schedules, not to exceed the total quantity prescribed, to improve patient outcomes.

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

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

(ii) Formulating a medication treatment plan;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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 pharmacists and the collaborating practitioners (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 pertinent to the practice of pharmacy and the distribution of drugs.

(gg) “Pharmacy intern” is described in Chapter 3 of these rules.

(hh) “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.

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

(jj) “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.”

(kk) “Prescription drug order” means a lawful order of a practitioner for a drug or device for a specific patient.

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

(mm) “Repackage” means to prepare a single unit dose or unit of use package or traditional dispensing system package for dispensing pursuant to an existing order.

(nn) “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.

(oo) “Traditional dispensing system” means a drug package system in which individual doses are not packaged in single unit dose packages or unit of use packages.

(pp) “Unit dose dispensing system” means a drug distribution system that is in a pharmacy and uses single unit dose packages or unit of use packages that enable distribution of packaged doses in a manner that preserves the identity and the integrity of the drug.

(qq) “Single Unit Dose” means a package that contains one unit of medication.

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

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

Section 5. Pharmacist-in-Charge (PIC).

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

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

(ii) 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.

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

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

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

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

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

(B) Supervise the professional employees of the pharmacy;

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

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

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

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

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

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

(I) 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.

(II) 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.

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

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

(viii) No pharmacy shall be permitted to operate without a PIC for more than thirty (30) days.

Section 6. Transfer of Prescription Orders Between Prescription Drug Outlets.

(a) A prescription label or a written copy of a prescription order from another pharmacy may be issued for informational purposes only and shall not be considered to be a valid

prescription order. A pharmacist who receives such a label or prescription order copy shall either contact the prescribing practitioner for authorization to dispense the prescription or, alternatively, shall comply with this section.

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

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

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

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

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

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

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

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

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

(I) His/her name;

(II) The name of the receiving pharmacist;

(III) The name of the receiving pharmacy;

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

(V) The date of the transfer.

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

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

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

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

(D) The date of the dispensing of the original prescription order, if any;

(E) The number of refills authorized;

(F) The number of valid refills remaining;

(G) The date of the last refill of the original prescription order, if any;

(H) The prescription order number from which the prescription order information was transferred, if any;

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

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

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

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

(vi) 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.

(vii) 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.

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

(ix) 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.

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

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

(B) The transferring pharmacist must do the following:

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

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

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

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

(I) Date of issuance of original prescription;

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

(III) Date of original dispensing;

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

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

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

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

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

(I) The date of the original dispensing;

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

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

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

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

(E) 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.

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

(xii) 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.

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

(xiv) 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.

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

Section 7. Labeling Prescription Drug Containers.

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

(i) name of the patient;

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

(iii) drug strength and quantity;

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

(v) the practitioner's name;

(vi) the serialized number of the prescription;

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

(viii) purpose for use where appropriate;

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

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

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

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

(c) All single unit dose or unit of use packaging shall be labeled as follows:

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

(ii) Strength;

(iii) Manufacturer's lot number;

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

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

Section 8. Child-Resistant Packaging.

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

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

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

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

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

Section 9. Record of Refills.

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

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

Section 10. Practitioner/Patient Relationship as Affecting Prescriptions.

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

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

Section 11. Return of Unused Prescription Drugs.

(a) A pharmacist may:

(i) Accept and redistribute an unused prescription drug under the Wyoming Drug Donation Program Act, W.S. § 35-7-1601 et seq or its rules; or

(ii) Accept and redistribute any unused prescription drug, or a part of it, after it has left the premises of the pharmacy if:

(A) The drug was intended for inpatients of an institutional facility and has been maintained in the custody and control of the institutional facility or dispensing pharmacy;

(B) The drug was returned to the original dispensing pharmacy;

(C) The drug is in a single unit dose or unit of use package or in the manufacturer's sealed container;

(D) In the professional judgment of the PIC of the pharmacy, the safety and efficacy of the drug has not been compromised during transportation and storage;

(E) A system is in place to track the restocked drug for purposes of a recall; and

(F) Accepting and redistributing of the drug complies with state and federal law.

(iii) Accept those prescription drugs that were dispensed in a manner inconsistent with the prescriber's instructions for quarantine and destruction as allowed by state and federal law.

Section 12. Validity of Prescriptions.

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

Section 13. Prescriptions in General.

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

(i) Name of patient;

(ii) Name and strength of drug;

(iii) Quantity to be dispensed;

(iv) Directions for using the drug;

(v) Date of issuance by practitioner;

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

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

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

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

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

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

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

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

Section 14. Transmission of Prescription by Fax Machines.

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

(i) Practitioner's recognizable signature;

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

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

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

(v) Date and time of fax; and

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

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

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

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

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

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

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

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

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

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

Section 15. Prescription Refill Information.

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

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

Section 16. Fax Machines in General.

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

Section 17. Therapeutic Equivalents.

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

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

Section 18. Fees (including examination, re-examination, license, license renewal, registration, registration renewal, mailing list and late fees).

(a) The Board shall charge the following fees:

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

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

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

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

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

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

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

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

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

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

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

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

(xiii) Third party logistics provider license and renewals shall be two hundred seventy-five dollars ($275.00) per year;

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

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

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

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

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

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

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

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

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

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

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

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

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

(vi) A manufacturer, distributor, or wholesaler of prescription drug products (drugs or oxygen) whose license renewal application is postmarked or hand delivered to the Board office after June 30 shall be assessed a late fee of two hundred dollars ($200.00) in addition to the license renewal fee;

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

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

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

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

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

Section 19. Ancillary Drug Supply for Nursing Homes Hospices, Extended Care Facilities or Intermediate Care Facilities.

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

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

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

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

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

(i) An emergency situation;

(ii) To temporarily replace unavailable medications; or

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

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

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

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

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

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

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

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

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

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

Section 20. Electronic Prescription Transmission.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 21. Drug Samples.

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

Section 22. Centralized Prescription Processing.

(a) Definitions specific to this Section:

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

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

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

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

(b) Minimum requirements:

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

(A) Have the same owner;

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

(C) Share a real-time database; and

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

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

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

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

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

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

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

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

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

(d) Prescription labeling.

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

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

(e) Policies and Procedures. A policy and procedures manual relating to centralized processing shall be maintained at both pharmacies and shall be available for inspection. Each

pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operation. The manual shall:

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

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

(iii) Include policies and procedures for:

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

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

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

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

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

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

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

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

(f) Records.

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

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

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

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

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

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

Section 23. Automated Storage and Distribution Systems.

(a) Before using an automated storage and distribution system, a PIC shall ensure that the automated storage and distribution system and the policies and procedures comply with this chapter.

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

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

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

(A) Only allows patient access to prescriptions that:

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

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

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

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

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

from outside the pharmacy and is attached to the wall in such a manner that prevents unauthorized removal;

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

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

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

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

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

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

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

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

(c) The PIC shall:

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

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

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

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

Section 24. Electronic Records of Prescriptions.

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

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

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

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

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

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

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

Section 25. Drug Disposal Including Controlled Substances.

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

Section 26. Dangerous Substance List.

Pursuant to W.S. § 33-24-127, the Board adopts the most recent edition and its supplements of section 3.1 "Prescription Drug Product List" of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations,* as the official listing of Dangerous Substances for the State of Wyoming is hereby incorporated by reference.

Section 27. Incorporation by Reference.

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

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

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

The incorporated code, standard, rule or regulation is maintained at Board's office and is available for public inspection and copying at cost at the same location.

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

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

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

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

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