Pharmacy, Board of

Pharmacy, Board of

Chapter 2: General Practice of Pharmacy Regulations

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GENERAL PRACTICE OF PHARMACY REGULATIONS

CHAPTER 2

Section 1. Authority.

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

Section 2. 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 3. Definitions.

(a) "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 in collaboration to provide patient care services to achieve optimal medication use and desired patient outcomes.

(b) "Collaborative practice agreement" is a written and signed agreement between one or more pharmacists and one or more practitioners that defines a collaborative practice.

(c) "Compounding" means the preparation, mixing, assembling, altering, packaging, or labeling of a drug, drug-delivery device, or device, unless performed in a Food and Drug Administration (FDA)-registered outsourcing facility in conformance with Federal law, in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

(i) Preparation of drug dosage forms for both human and animal patients;

(ii) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns; and

(iii) Manipulation of commercial products for patient-specific needs beyond FDA-approved labeling.

(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.

(d) “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.

(e) “Dispense” or “Dispensing” means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation, final verification, and delivery of a drug or device to a patient or patient’s agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

(f) “Fill date” means the date that a new or refilled prescription was prepared, verified and labelled. It may or may not be the date the medication was received by the patient.

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

(h) “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.

(i) “Medication therapy management” (MTM) is a distinct service or group of services that optimize therapeutic outcomes for individual patients. 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.

(j) “Patient counseling” means the verbal communication by the pharmacist of information, to the patient or caregiver, in order to encourage proper use of drugs and devices. Patient counseling may be supplemented with printed materials. For medications provided by delivery, patient counseling may be provided in writing, and shall indicate the manner or method that the patient may use to contact a pharmacist for counseling or to answer questions.

(k) “Pharmacist care” are those patient care activities provided by a pharmacist, with or without the dispensing of drugs or devices, that are intended to achieve positive clinical outcomes and to optimize the patient’s health-related quality of life.

(l) “Pharmacist-in-Charge” (“PIC”) means a licensed pharmacist has the authority to direct the pharmacy’s operations and staff.

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

(n) “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.

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

(p) "Shared pharmacy services" means a pharmacy or pharmacist performing functions at the request of another pharmacy.

(q) "Supervise" means to direct the execution of pharmacy related functions or tasks.

Section 4. Responsibilities of the Pharmacist-in-Charge (PIC).

(a) Every resident pharmacy shall designate one pharmacist, who is licensed by the Board, as the PIC.

(b) Every non-resident pharmacy shall designate one registered pharmacist as the PIC.

(c) A pharmacist may not serve as PIC for more than one pharmacy at a time unless the pharmacist obtains a waiver from the Board.

(d) A PIC shall:

(i) Direct the pharmacy's operations and staff;

(ii) Ensure all pharmacy and professional staff licenses are current and on display;

(iii) Ensure all expired or recalled drug products are removed from active stock and placed in a designated quarantine area for return or destruction;

(iv) Ensure the proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug product(s) have been dispensed; and

(v) Maintain all pharmacy records required by state and federal law in a readily retrievable format.

(e) The PIC shall report to the Board, in writing, the following:

(i) Confirmed diversion, theft or significant loss of prescription drugs or controlled substances from the pharmacy within one business day of discovery. When a DEA Form 106 is submitted to the DEA in instances involving controlled substances, a copy of that completed DEA Form 106, along with a detailed explanation, shall be submitted to the Board within one business day of signing the form;

(ii) Security breaches within the pharmacy or pharmacy area within one business day of discovery;

Section 5. Responsibilities of the Pharmacy License Holder.

(a) The pharmacy license holder shall:

(i) Designate a PIC;

(ii) Notify the Board upon notice of the vacancy of the PIC for a period exceeding thirty (30) days.

(iii) Ensure the pharmacy operates in compliance with all state and federal laws, rules and regulations.

(iv) Ensure the pharmacy has at least one physically present licensed pharmacist on duty at all times the pharmacy is open;

(v) Ensure a sign stating "Pharmacy Closed – No Pharmacist on Duty" is conspicuously posted when there is no pharmacist present in the building;

(vi) Ensure a working environment is provided to staff that protects the health, safety and welfare of patients, which includes, but is not limited to:

(A) Sufficient staffing with pharmacists, pharmacy interns, pharmacy technicians, and/or pharmacy technicians in training as may be required to competently and safely provide pharmacy services.

(B) Appropriate opportunities for meal breaks.

(vii) Notify the Board of any of the following:

(A) Change in ownership of the pharmacy;

(B) Change in address of the pharmacy;

(C) Permanent closing of the pharmacy;

Section 6. Requirements for issuing valid prescriptions

(a) In order for a prescription drug to be valid it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing of the prescription drug is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

(b) All non-controlled substance prescriptions and refill authorizations shall contain the following:

(i) The patient's full name and date of birth;

(ii) Name and strength of the drug;

(iii) Quantity to be dispensed, including refills, if applicable;

(iv) Directions for use;

(v) Date issued by the practitioner;

(vi) The practitioner's full name, address, telephone number; and

(vii) If a written or faxed prescription, the recognizable signature of the issuing practitioner; or

(viii) If an electronically transmitted prescription, the prescribing practitioner's electronic or digital signature; or

(ix) If a verbal order, the name of the authorized agent providing information, if other than prescriber.

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

(d) A prescription may not be dispensed to a practitioner based on an order that is not issued for one specific patient. A prescription order for "office use" is not a valid order.

(e) 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 or her professional judgment may honor a patient's request for remaining medication refills, for a period not exceeding twelve (12) months.

(f) The pharmacist shall determine the accuracy and authenticity of all prescriptions received. Pharmacists shall request and document verification when necessary. If verification is refused, the prescription shall not be filled.

(g) All prescription medication shall be dispensed in child-resistant packaging, in accordance with the Poison Prevention Packaging Act.

(i) The patient may request a one-time or a blanket waiver from this requirement.

(ii) The practitioner, at the patient's request, may request a one-time waiver only.

(iii) The pharmacist shall document a one-time request on the prescription or in the patient profile record.

(h) 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 be able to reproduce the original prescription information and maintain it in a readily retrievable format;

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

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

(iv) Disposal of the hard copy must ensure privacy and confidentiality of the contents.

Section 7. Personal Responsibility and Accountability.

(a) Each pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician in training shall be responsible and accountable for their own actions performed in their practice of pharmacy.

(b) If any action of the supervising pharmacist is deemed to contribute to or cause a violation of the Wyoming Pharmacy Act, the Wyoming Controlled Substances Act, or the Board's Rules and Regulations, the supervising pharmacist may be held responsible.

(c) If any action of the pharmacy license holder is deemed to contribute to or cause a violation of the Wyoming Pharmacy Act, the Wyoming Controlled Substances Act, or the Board's Rules and Regulations, the pharmacy license holder may be held responsible.

Section 8. Unprofessional Conduct.

(a) It shall be unprofessional conduct for any licensed pharmacy staff member to practice pharmacy while under the influence of alcohol or drugs.

(b) It shall be unprofessional conduct for any licensed pharmacy staff member in the pharmacy to practice pharmacy with a mental or physical impairment affecting his or her ability to safely and competently practice pharmacy.

(c) It shall be unprofessional conduct for any licensed pharmacy staff member to sexually harass another licensee, employee of the pharmacy, or patient.

(d) It shall be unprofessional conduct for any licensed pharmacy staff member to not report another pharmacy staff member suspected of engaging in unprofessional conduct to the Board.

(e) It shall be unprofessional conduct for a licensed pharmacy or licensed pharmacy staff member to distribute or dispense prescription drug samples.

(f) 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 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 9. Refill Authorization.

(a) If a refill was not authorized on the original prescription or, if no refills remain, pharmacy staff may contact the prescriber to obtain refill authorization or a new prescription at the request of a patient.

(b) When refill 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.

(c) The following information shall be recorded in a readily retrievable manner when a prescription is refilled:

(i) Date refilled;

(ii) Quantity; and

(iii) Pharmacy staff's initials who are involved in dispensing the refill.

Section 10. Labeling Prescription Drug Containers.

(a) All original or refill prescription drug containers dispensed by a pharmacy shall be labeled with the following:

(i) The patient's full name; or

(ii) If the patient is an animal, the animal's name, species and the owner's last name;

(iii) Brand or generic name of the drug product dispensed, unless otherwise specified;

(iv) Drug strength and quantity;

(v) Directions for use;

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

(vii) The practitioner's name;

(viii) The serialized number of the prescription;

(ix) The date the prescription was filled or refilled;

(x) The product's physical description, including any identification code that may appear on the tablets and capsules, and;

(xi) Purpose for use where appropriate

(xii) Accessory cautionary labels for patient safety, where appropriate.

(b) All single unit dose or unit of use packaging shall include the following additional information on the label:

(i) Manufacturer's lot number; and

(ii) Expiration date; which shall be the lesser of the manufacturer's expiration date or twelve (12) months from the date of pre-packaging or repackaging.

Section 11. Patient Records.

(a) A patient profile record shall be maintained by pharmacies for patients for whom prescriptions are dispensed.

(b) The profile record shall provide for the immediate retrieval of information of previously dispensed drugs and devices.

(c) The pharmacy software shall be able to maintain the following patient information for each new prescription:

(i) Patient's full name;

(ii) Patient's address and telephone number;

(iii) Patient's date of birth;

(iv) Patient's sex; and

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

(d) Pharmacy staff shall make a reasonable effort to obtain, record, and maintain the following information in the patient profile record:

(i) Known allergies;

(ii) Adverse drug reactions; and

(iii) Pharmacist comments relevant to the patient or their drug therapy.

Section 12. Transfer of Non-Controlled Substance Prescription Orders Between Pharmacies.

(a) A pharmacy shall transfer prescription order information for non-controlled substances upon the request of the patient.

(b) Transfer of prescription order information for the purpose of filling or refilling a prescription is subject to the following requirements:

(i) 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.

(ii) Both the original and transferred prescription drug orders shall be maintained and readily retrievable for a period of two years from the date of last refill at the respective pharmacy;

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

(c) The individual transferring the prescription order information shall:

(i) Document that the prescription has been transferred in the data processing system;

(ii) Record his/her name;

(iii) Record the name of the receiving individual;

(iv) Record the name, store number if a chain pharmacy, telephone number, and whether the prescription is a controlled substance; and

(v) Record the date of the transfer.

(d) The individual receiving the transferred prescription order information shall:

(i) Document that the prescription was originated by transfer in the data processing system; and

(ii) Record the original prescription's issued date and prescription number;

(iii) Record the original number of refills authorized by the prescriber;

(iv) Record the date of original dispensing;

(v) Record the number of valid refills remaining;

(vi) Record the name, store number if a chain pharmacy, and whether the prescription is a controlled substance; and

(vii) Record the name of the individual transferring the prescription.

Section 13. 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.

(b) A prescription dispensed by a pharmacy for delivery but not delivered to the ultimate user may be returned to stock for redispensing provided:

(i) The prescription is returned to the original dispensing pharmacy;

(ii) Storage conditions during transport of the prescription to and from the pharmacy do not in any way compromise the integrity or stability of the drug;

(iii) No compounded or flavored prescription may be returned to stock;

(iv) The drugs did not require refrigeration, freezing, or special storage;

(v) The expiration date of the drug is not more than one year from the date it was dispensed, unless it was dispensed in the manufacturer's original sealed container and bears the manufacturer's original label and expiration date.

(c) A pharmacist may accept the return of a prescription for disposal or destruction if the prescription was dispensed by the pharmacy in error, was defective, adulterated, misbranded, expired, or subject to a recall.

Section 14. Therapeutic Equivalents.

(a) Therapeutic equivalents do not include therapeutic substitutions. Therapeutically 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 15. Shared Pharmacy Services

(a) Minimum requirements for shared pharmacy services:

(i) A resident or a non-resident pharmacy may participate in shared pharmacy services by another licensed pharmacy or pharmacist, provided involved parties:

(A) Have entered into a written agreement, specifying the services to be provided and the responsibilities and accountabilities of each party, or are of common ownership;

(B) Have a system in place to identify the parties responsible for each aspect of prescription preparation.

(b) A policy and procedure manual relating to shared pharmacy services shall be maintained by all involved parties and shall be available for inspection by the Board upon request. The manual shall:

(i) Outline the responsibilities of each of the involved parties;

(ii) Acknowledge the originating and sharing pharmacy shall be jointly responsible; and

(iii) Include policies and procedures for:

(A) Notifying patients that their prescription may be outsourced to another party for shared pharmacy services

(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) Operating a quality assurance 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; and

(E) Provide documentation of annual review of the written policies and procedures.

(c) The dispensing pharmacy, which shall be identified as such in the written agreement between pharmacies participating in shared pharmacy services shall ensure that:

(i) Drugs stored at the pharmacy shall be stored in an area secure from unauthorized personnel;

(ii) Access to the area where drugs are stored at the shared pharmacy services pharmacy must be limited to pharmacists, pharmacy interns, pharmacy technicians, or pharmacy technicians in training, who are employed by the shared pharmacy services pharmacy. Non-pharmacy staff may enter the drug storage area under the direct supervision of a pharmacist;

(iii) The pharmacy maintains and uses storage or shipment containers and shipping processes that ensure drug stability and potency;

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

(v) Records indicate the date the prescription was shipped to the originating retail pharmacy or patient; and

(vi) If the prescription is delivered directly to the patient, the patient shall receive written notice of available counseling. Such notice shall include:

(A) The days and hours when counseling is available,

(B) The location of pharmacy, and

(C) The manner or method that the patient may use to contact a pharmacist for counseling or to answer questions.

(d) A resident pharmacy requesting shared pharmacy services shall ensure that:

(i) Records are readily retrievable and include:

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

(B) The date and time the dispensed prescription was received from the central fill pharmacy or remote processing pharmacy or pharmacist by the originating pharmacy, including the method of delivery and the name of the person accepting delivery unless shipped directly to the patient.

(ii) The original prescription is maintained at the originating pharmacy for a time period not less than two (2) years from the date last filled or refilled.

(iii) Notification is provided to patients that their prescription may be outsourced to another pharmacy prior to outsourcing the prescription unless the prescription drug is delivered to patients in institutional facilities where a licensed healthcare professional is responsible for administering the prescription drug to the patient.

(iv) The prescription label clearly indicates a pharmacy that has access to the patient's records;

(v) The pharmacy has access to each pharmacy's prescription records and patient profiles and records, as needed to safely and properly perform the shared services activities.

(e) Shared pharmacy services pharmacies shall:

(i) Comply with federal and state laws and regulations; and

(ii) Protect the confidentiality and integrity of protected health information.

(f) Nothing in this Section shall prohibit an individual pharmacist, who is an employee of or under contract with a pharmacy, or a licensed certified pharmacy technician, certified pharmacy technician candidate, or pharmacy intern, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the prescription drug order processing functions permitted by the Pharmacy Act, if both of the following conditions:

(i) The pharmacy establishes controls to protect the confidentiality and integrity of protected health information; and

(ii) No part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

Section 16. Collaborative Pharmacy Practice

(a) Collaborative pharmacy practice is where one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and drug therapy management services not otherwise permitted to be performed by a pharmacist under specified conditions.

(b) A collaborative practice agreement must be in place prior to engaging in collaborative pharmacy practice.

(c) The collaborative practice agreement must explain the scope of the pharmacist's practices and shall be updated upon any changes in the scope or agreement of practices.

(d) A copy of the signed agreement and any additional information regarding the agreement must be readily retrievable upon request by the Board.

Section 17. Medication Therapy Management

Medication Therapy Management (MTM) services may be performed without a collaborative practice agreement. These services may include, but are not limited to:

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

(b) Ordering, or performing laboratory assessments; and

(c) Evaluating the response of the patient to therapy, as it directly relates to MTM, provided:

(i) 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

(ii) 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

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

Section 18. 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 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 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.