CHAPTER 2

GENERAL PRACTICE OF PHARMACY REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Purpose.

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

Section 3. Scope of Chapter.

This Chapter applies to any person, partnership, corporation, limited liability company, or other entity engaging in the practice of pharmacy within this 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~~A~~ practitioner (or by his or her authorized agent); or

(ii) t~~T~~he patient or research subject at the direction of the practitioner.

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

(d) "Collaborative pharmacy practice" means a practice in which a prescribing physician makes a diagnosis, maintains ongoing supervision of patient care, and refers the patient to a pharmacist under a protocol allowing the pharmacist to perform patient care functions authorized by the physician under specified conditions or limitations.

(e) "Collaborative practice agreement" means a voluntary agreement, written and signed, between a pharmacist and a prescribing physician that defines a collaborative practice ~~for the purpose of drug therapy management of patients.~~

(f) "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:

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STERILE COMPOUNDING

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STERILE COMPOUNDING

Section 1. Authority.

These rules are promulgated as authorized by the Act, and pursuant to the Wyoming Administrative Procedure Act, W.S. § 16-3-101, *et seq*. The effective date of this Chapter is January 1, 2012.

Section 2. Definitions.

(a) "Ante-Area" means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, compounded sterile preparation labeling, and other high-particulate generating activities are performed. It is also a transition area where pressure relationships are constantly maintained so that air flows from clean to dirty areas.

(b) "Aseptic Processing" means processing of pharmaceutical products that involves the separate sterilization of the product and of the package, and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.

(c) "Beyond-Use Date" (BUD) means a date after which a compounded sterile preparation shall not be used, stored, or transported. BUD is determined from the date or time the preparation is compounded.

(d) "Biological Safety Cabinet" means a ventilated cabinet for compounded sterile preparations, personnel, product, and environmental protection having:

(i) an open front with inward airflow for personnel protection;

(ii) downward High-Efficiency Particulate Air (HEPA)-filtered laminar airflow for product protection; and

(iii) HEPA-filtered exhausted air for environmental protection.

(e) "Buffer Area" means a Clean Room or area in which the Primary Engineering Control is physically located. In this area, activities include the preparation and staging of components and supplies used to compound sterile products.

(f) "Clean Room" means a room with a minimum of an ISO Class 7 environment **(ISO Class 8 environment for compounding radiopharmaceuticals)**:

(i) in which the concentration of airborne particles is controlled;

(ii) that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room;

(iii) in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary; and

(iv) in which microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear is not exceeded for a specified cleanliness class.

(g) "Closed System Transfer Device (CSTD)" is a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of Hazardous Drug or vapor concentrations outside the system.

(h) "Compounding Aseptic Containment Isolator" (CACI) means a closed system designed to provide personnel protection from exposure to undesirable levels of airborne drug throughout the compounding and transfer processes, and designed to provide an aseptic environment for compounding sterile preparations. Air is first passed through a microbial retentive filter (HEPA minimum) system. If volatile Hazardous Drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

(i) "Compounding Aseptic Isolator" (CAI) means a closed system specifically designed to maintain an aseptic compounding environment within the isolator. Air is first passed through a microbially retentive filter (HEPA minimum). Transfers are designed to minimize the entry of contamination and are accomplished through air locks, glove rings, or ports.

(j) "Critical Area" means any area in the Buffer Area where products or containers are exposed to the environment. It should be an ISO Class 5 environment.

(k) "CSP" means compounded sterile product.

(l) "Critical Site" means a location that includes any component or fluid pathway surfaces (such as injection ports) or openings (such as opened ampules or needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination.

(m) "Cytotoxic Drug" means a pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system, and the alteration of a host's inflammatory response system.

(n) "Disinfectant" means an agent applied to inanimate objects that frees from infection and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores.

(o) "FDA" means the United States Food and Drug Administration, Department of Health and Human Services.

(p) "Hazardous Drugs" means studies in animals or humans indicate that exposures to them have a potential for causing cancer, developmental or reproductive toxicity, or harm to organs.

(q) "HEPA Filter" means a filter where air is forced through in a uniform flow and 99.97% of all particles three-tenths (0.3) microns or larger are removed.

(r) "Immediate-Use" compounded sterile preparations means those products used in situations where there is a need for emergency or immediate patient administration. Examples are cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where delays caused by using conditions described for Low-Risk Level subjects the patient to additional risk. Batch compounding or storage is not appropriate for Immediate-Use compounded sterile preparations.

(i) The compounding process involves simple transfer of not more than three (3) commercially manufactured packages of sterile nonhazardous products from the manufacturers' original containers and not more than two (2) entries into any one container.

(ii) Unless required for the preparation, the compounding procedure is a continuous process not to exceed one (1) hour.

(iii) During preparation, aseptic technique is followed. If not immediately administered, the finished compounded sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter, or biological fluids, mix-ups with other products, and direct contact of outside surfaces.

(iv) Administration begins not later than one (1) hour following the START of the preparation of the compounded sterile preparation.

(v) Unless immediately and completely administered by the person who prepared it, or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one (1) hour BUD and time.

(vi) If administration has not begun within one (1) hour following the start of preparing the compounded sterile preparation, it shall be promptly, properly, and safely discarded.

(s) "ISO (International Organization for Standardization) Classification of Particulate Matter in Room Air" means limits in particles of 0.5 micrometer and larger per cubic meter.

Class Name and Particle Count:	
ISO Class 3	35.2 m3
ISO Class 4	352 m3
ISO Class 5	3,520 m3
ISO Class 6	35,200 m3
ISO Class 7	352,000 m3

ISO Class 8 3,520,000 m3

(t) "Media-Fill Test" means using a microbiological growth medium to substitute for the actual drug product to simulate admixture compounding in determining the quality of a person's technique.

(u) "Multiple-Dose Container" means more than one (1) dose is in the vial and it usually contains antimicrobial preservatives. The BUD for an opened or entered Multiple-Dose Container with antimicrobial preservatives is twenty-eight (28) days, unless otherwise specified by the manufacturer.

(v) "Negative Pressure Room" means a room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is *into* the room.

(w) "Parenteral" means a sterile preparation of drugs for injection through one (1) or more layers of skin.

(x) "Positive Pressure Room" means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out of* the room.

(y) "Primary Engineering Control" (PEC) means a device or room that provides an ISO Class 5 environment for the exposure of Critical Sites when compounding sterile products. Such devices include, but may not be limited to, Laminar Airflow Workbenches (LAFWs), Biological Safety Cabinets (BSCs), Compounding Aseptic Isolators (CAIs), and Compounding Aseptic Containment Isolators (CACIs).

(z) "Quality Assurance" means, for purposes of these regulations, the set of activities used to ensure that the processes used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.

(aa) "Quality Control" means, for the purposes of these regulations, the set of testing activities used to determine that the ingredients, components, and final sterile products meet predetermined requirements with respect to identity, purity, nonpyrogenicity, and sterility.

(bb) "Risk Levels" means, for the purposes of these regulations, the categories assigned according to the potential for microbial contaminations of compounded sterile preparations.

(i) Low-Risk Level means compounded sterile preparations under the following conditions:

(A) Compounded with aseptic manipulations entirely with ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices;

(B) The compounding involves only transfer, measuring, and mixing using not more than three (3) commercially manufactured packages of sterile

products and not more than two (2) entries into any one sterile container **(not applicable to compounding Low-Risk Level CSP radiopharmaceuticals)**;

(C) Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers with sterile needles and syringes, and transferring sterile liquids into sterile administration devices or containers for storage;

(D) In the absence of passing a sterility test, the storage periods cannot exceed forty-eight (48) hours at controlled room temperature, for not more than fourteen (14) days at a refrigerated temperature, and for forty-five (45) days in solid frozen state, minus twenty-five degrees Ce~~lsiusn~~**tigrade** (-25°C) or colder; minus ten degrees Fahrenheit (-10°F) or colder.

(E) Examples of Low-Risk Level compounding include single-volume transfers of sterile dosage forms from ampules, bottles, bags, and vials with sterile needles OR simple aseptic measuring and transferring with not more than three (3) packages of manufactured sterile products including an infusion or diluents solution. The solution content of ampules should be passed through a sterile filter to remove any particles.

(ii) Low-Risk Level with twelve (12) hour or less BUD means:

(A) PEC shall be certified and maintain ISO Class 5 for exposure of Critical Sites and shall be in a Segregated Compounding Area restricted to sterile compounding activities that minimize the risk of contamination;

(B) The location shall not have unsealed windows or doors that connect to the outdoors or in a location with high traffic flow, nor be adjacent to construction site, warehouse, or food preparation areas;

(C) Personnel shall follow the procedures in Sections 3 and 7 for personnel cleansing and garbing and additional requirements prior to compounding. Sinks shall not be located adjacent to the ISO Class 5;

(D) Specifications in Sections 3, 4, and 7 through 9 for cleaning and disinfecting, personnel training and competency evaluation, and environmental sampling shall be followed;

(E) Quality Assurance includes routine disinfection, air quality testing, visual confirmation that compounding personnel are properly gowned and garbed, review of all orders and packages of ingredients, and visual inspection of the compounded sterile preparation to ensure the absence of particulate matter or leakage, and thoroughness of labeling. **Visual inspection of Low-Risk Level CSP radiopharmaceuticals will be limited, in accordance with radiation safety practices**;

(F) Media-Fill Test procedure is performed annually by each person authorized to compound.

(iii) Medium-Risk Level means compounded sterile preparations are prepared aseptically under Low-Risk Level conditions and one or more the following conditions exists:

(A) Multiple small doses of sterile products are combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions;

(B) The compounding process includes complex aseptic manipulations other than the single-volume transfer;

(C) The compounding process requires unusually long duration such as that required to complete dissolution;

(D) In the absence of passing a sterility test, the storage periods cannot exceed thirty (30) hours at controlled room temperature, for not more than nine (9) days at refrigerated temperature, and for forty-five (45) days in solid frozen state, minus twenty-five degrees Ce~~lsius~~**ntigrade** (-25°C) or colder; minus ten degrees Fahrenheit (-1~~0~~**3**°F) or colder.

(E) Examples of Medium-Risk Level compounded sterile preparations include total parenteral nutrient fluids using manual or automated devices, filling of reservoirs of injection and infusion devices with more than three sterile drug products, transfer of volumes from multiple ampules or vials into one or more final sterile containers.

(F) Quality Assurance procedures include all elements of Low-Risk Level compounded sterile preparations as well as a more challenging Media-Fill Test passed annually or more frequently.

(G) Media-Fill Tests are performed at least annually under stressful conditions **encountered during compounding Medium-Risk Level CSPs.**

(H) If the pharmacy performs sterility testing, the pharmacy will document results of tests, as described in their policies and procedures. If sterility is documented, the compounded product may be retained and used up to the limits established by authoritative sources for potency and stability.

(iv) "High-Risk Level" compounded sterile preparations means the end product is either contaminated or at a high risk to become contaminated, for example:

(A) Nonsterile ingredients are incorporated or a nonsterile device is employed before terminal sterilization;

(B) Exposure to air quality worse than ISO Class 5 for more than one (1) hour by the sterile contents, a lack of effective antimicrobial preservatives, or sterile surfaces of devices and containers;

(C) Personnel are improperly garbed and gloved;

(D) Nonsterile water-containing preparations are stored for more than six (6) hours before being sterilized;

(E) It is assumed, not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendia specifications in unopened or in opened packages of bulk ingredients.

(F) The storage periods cannot exceed twenty-four (24) hours at controlled room temperature; cannot exceed three (3) days at refrigerated temperature; and cannot exceed forty-five (45) days in solid frozen state, minus twenty-five degrees Ce~~lsius~~**ntigrade** (-25°C) or colder; minus ten degrees Fahrenheit (-1~~0~~**3**°F) or colder.

(G) All nonsterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile pyrogen free water, then thoroughly drained or dried immediately before use for High-Risk Level compounding. All High-Risk Level solutions subjected to terminal sterilization are prefiltered by passing through a filter not larger than 1.2 microns. Sterilization of High-Risk Level solutions by filtration shall be performed with a sterile 0.2 micron or 0.22 micron nominal pore size filter entirely within an ISO Class 5 or superior air quality environment.

(H) Examples of High-Risk Level Conditions include: dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized; exposing the ingredients or components to air quality worse than ISO Class 5 for more than one (1) hour; measuring and mixing in nonsterile devices; assuming, without appropriate evidence, that packages contain at least ninety-five percent (95%) by weight of their active chemical and have not been contaminated between uses.

(I) Quality Assurance procedures include all those for Low-Risk Level compounded sterile preparations and, in addition, a Media-Fill Test that represents High-Risk Level compounding semiannually by each person authorized to compound High-Risk Level compounded sterile preparations.

(cc) "Segregated Compounding Area" means a designated space, either a demarcated area or room, which is restricted to preparing Low-Risk Level compounded sterile preparations with twelve (12) hour or less BUD. The area must contain a device that provides Unidirectional Flow of ISO Class 5 air quality and shall be void of activities and materials that are extraneous to sterile compounding.

(dd) "Single-Dose Container" means a vial intended for a single parenteral use and is labeled as such. Opened or needle-punctured Single-Dose Containers such as bags, bottles, syringes, and vials shall be used within one (1) hour, if opened in worse than ISO Class 5 **air quality**, and any remaining contents must be discarded. Opened single-dose ampules shall not be stored for any time period. Single-dose vials exposed to ISO Class 5 or cleaner air may be used up to six (6) hours after initial needle puncture.

(ee) "Temperature" means, for the purposes of these regulations:

(ii) **"Frozen" means temperatures of minus** twenty-five degrees Ce**ntigrade** (−25°C to −10°C) or colder, minus 13 to plus 14 degrees Fahrenheit (-13 F to 14 F)~~;~~

(ii) "Refrigerated" means temperatures **of** two **to** eight degrees Ce**ntigrade** (2°C to 8°C), thirty-six to forty-six degrees Fahrenheit (36°F to 46°F).

(iii) "Room Temperature" means temperatures **of twenty to twenty-five** degrees Ce**ntigrade** (**20**°C to **25**°C), **sixty-eight** to s**eventy-seven** degrees Fahrenheit (**68**°F to **77**°F).

(ff) "Unidirectional Flow" means airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

(gg) "USP" means the United States Pharmacopeia, an official public standards setting authority for all prescription and over-the-counter medicines and other health care products manufactured or sold in the United States. USP sets standards for the quality, purity, strength, and consistency of these products. USP is a non-governmental, not-for-profit public health organization.

(hh) "USP 797" means Chapter 797 in the United States Pharmacopeia-National Formulary book of public pharmacopeial standards specifically for pharmaceutical compounding of sterile preparations.

Section 3. Physical Layout and Environment.

(a) Compounding environment description.

(i) The compounding environment shall be contained in an area that is segregated from other pharmacy activities and limits access and activities to personnel, materials, and processes that are directly related to production of sterile compounded products, therefore, minimizing risk of particulate or microbial contamination. The compounding area shall be of sufficient size, lighting, and physical conditions (such as maintenance of temperature of 70 degrees Fahrenheit (70°F) or lower) to maximize the compounding accuracy and potential of compounding personnel.

(ii) The compounding area shall be constructed of smooth, impervious, non-particulate shedding materials that optimize the ability to routinely clean and disinfect surfaces. Ventilation should occur in a manner that allows the maintenance of appropriate ISO Class designations of each separate working area and should avoid disruption and cross-room currents.

(iii) The compounding area shall have walls, floors, and ceilings, along with fixtures, counters, shelves, and cabinets, that are smooth, impervious, free of cracks or crevices, non-shedding, and resistant to damage that could occur from routine disinfection with cleaning agents. Junctions between surfaces should be caulked or formed in a manner to avoid deep corners that cannot be reached and disinfected. Additional equipment/features, such as pass-throughs, refrigerators, lights, and vents shall be constructed to not become a vector for contamination of the work area.

(iv) The compounding area will not contain supplies other than those that are necessary for compounding and will not be considered a bulk storage area. All particle shedding packing will be removed and products cleaned before being brought into the compounding area.

(b) Low-Risk Level and Medium-Risk Level compounding areas.

(i) Ante-Area.

(A) The compounding work room shall contain an Ante-Area that conforms to ISO Class 8 conditions.

(B) The Ante-Area may contain a hands-free sink and closed soap system that allows use and movement to the next compounding area without recontamination of hands on extrinsic surfaces.

(C) The Ante-Area shall have area to support the gowning of compounding personnel.

(ii) Buffer Area.

(A) The compounding work room shall contain a Buffer Area that conforms to ISO Class 7 conditions. **When compounding Low-Risk Level radiopharmaceutical CSPs, the compounding work room shall contain a Buffer Area that conforms to ISO Class 8 conditions.**

(B) The Buffer Area shall be physically separated or have designated boundaries that separate it from the Ante-Area. The Buffer Area shall not be in a location with high traffic. The Buffer Area shall not be in a location with unsealed windows or doors that connect to the outdoors.

(C) Ventilation shall assure that contamination from the Ante-Area does not enter the Buffer Area through utilization of filtered Unidirectional Flow and principles of air displacement.

(D) The Buffer Area shall not contain sinks or drains and shall be void of all materials, equipment, and fixtures that are not directly involved in the current processing of compounded sterile preparations.

(E) The construction, arrangement, and ventilation of the Buffer Area shall not allow conditions that could adversely affect compounding, such as aberrant heating, cooling, door-drafts, and personnel traffic air currents.

(iii) Primary Engineering Control (PEC).

(A) The Buffer Area shall contain a Primary Engineering Control that conforms to ISO Class 5 conditions. This may be accomplished through utilization

of a laminar flow hood, Compounding Aseptic Isolator, Compounding Aseptic Containment Isolator, or an entire clean room that is filtered, ventilated, and constructed to maintain ISO Class 5 conditions during dynamic operating conditions.

(iv) Compounding Aseptic Isolators (CAIs).

(A) Compounding Aseptic Isolators shall be contained inside of an ISO Class 7 Buffer Area, unless the manufacturer of the unit can certify that its engineering controls will maintain ISO Class 5 conditions during dynamic operating conditions, such as personnel and product entry or transfer and throughout typical compounding duties.

(B) The compounding pharmacy that employs a Compounding Aseptic Isolator as a Buffer Area and Primary Engineering Control shall maintain documentation from the manufacturer.

(c) High-Risk Level additions.

(i) All conditions of Low-Risk Level and Medium-Risk Level compounding shall be maintained, and shall include the additional requirement that the Buffer Area shall have physical separation from the Ante-Area.

(d) Immediate Use and twelve (12) hour Beyond-Use Date (BUD).

(i) Compounding pharmacies may utilize a Primary Engineering Control in conditions that are less than ISO Class 7 quality, as long as the Primary Engineering Control is appropriately maintained, is segregated from other activities, personnel comply with all gowning and garbing procedures, and the compounded sterile preparation will be used immediately or within twelve (12) hours of compounding.

(ii) Personnel utilizing this form of compounding must be appropriately trained, with documentation in:

(A) Personnel;
(B) Equipment;
(C) Product cleansing;
(D) Gowning and garbing;
(E) Utilization of the Primary Engineering Control;
(F) Aseptic practices;

and be subject to all quality requirements of normal sterile compounding staff.

Section 4. Responsibility of Compounding Personnel.

(a) Professional compounding personnel are responsible for ensuring that, at a minimum:

(i) Proper aseptic technique is practiced at all times during sterile product compounding;

(ii) Compounded sterile preparations are appropriately and accurately prepared, identified, purified, sterilized, packaged, labeled, stored, dispensed, and distributed;

(iii) The compounding area is appropriately cleaned and maintained.

(b) Compounding supervisors (persons who supervise the compounding and dispensing of compounded sterile preparations) are responsible for ensuring that:

(i) Compounding personnel are appropriately educated to correctly perform compounding duties and ensure that correct compounding procedures and processes are used;

(ii) Compounding equipment is clean, accurate, appropriate and properly inspected and the compounding environment is properly maintained, isolated and inspected;

(iii) Ingredients have their correct identity, quality, and purity and opened or partially used containers are properly stored and inspected;

(iv) Proper and adequate sterilization methods are used;

(v) Completed compounded sterile preparations are appropriately packaged, labeled, and assigned an appropriate BUD, and evaluated for safety;

(vi) Deficiencies in compounding can be rapidly identified and corrected;

(vii) A written Quality Assurance program is established for monitoring, evaluating, correcting, and improving the activities, systems, and processes that support the preparation of compounded sterile preparations;

(viii) Policies and procedures are prepared and updated for the compounding, dispensing, delivery, administration, storage, and use of sterile pharmaceutical products appropriate for their facility.

Section 5. Personnel Training and Evaluation in Aseptic Manipulation Skills.

(a) Personnel who prepare compounded sterile preparations shall be trained in the theoretical principals and practical skills of Aseptic Processing and in achieving and maintaining ISO Class 5 environmental conditions before they begin to prepare compounded sterile preparations.

(i) This can be through any combination of written, audio, or video sources.

(ii) Personnel shall also pass written and Media-Fill Testing of aseptic technique before they begin to prepare compounded sterile preparations.

(iii) Results of all testing shall be recorded.

(b) Personnel shall also perform a didactic review and pass written and Media-Fill Testing of aseptic technique:

(i) annually for Low- and Medium-Risk Level compounding;

(ii) semiannually for High-Risk Level compounding.

(c) There shall be a process to retest and evaluate for personnel who fail testing processes.

(d) Results of all testing shall be recorded.

Section 6. Hazardous Drugs as CSPs.

(a) Physical Requirements.

(i) If the pharmacy practice site is engaged in the compounding of hazardous sterile products, they must ensure the safety of the personnel during the compounding and storage of the Hazardous Drugs.

(ii) Appropriate garbing must be used during receiving, distribution, stocking, inventorying, preparation for administration, and disposal of Hazardous Drugs.

(iii) Personnel shall be appropriately trained prior to initial handling and annually thereafter in the storage, handling, preparing, and disposing of Hazardous Drugs.

(iv) Such pharmacy will be designed and equipped for appropriate storage.

(A) Hazardous Drugs must be stored separately from other inventory and storage areas so identified.

(B) Access should be limited to appropriate personnel.

(v) Such pharmacy will have an appropriate area to prepare sterile Hazardous Drugs.

(A) All Hazardous Drugs shall be prepared in a CACI or in a BSC that is located in a negative pressure room. If a compounding facility prepares hazardous drugs in a sufficiently low volume (five [5] or less products per week), the use of two tiers of containment (e.g, a Closed System Transfer Device within a BSC) is acceptable.

(vi) Such pharmacy will have a procedure for disposal of materials containing hazardous residues in accordance with state and federal laws.

Section 7. Radiopharmaceuticals as CSPs.

(a). Standards for the production of Positron Emission Tomography (PET) drugs are addressed in USP Chapter <823> *Radiopharmaceuticals for Positron Emission Tomography - Compounding*, while USP Chapter <797> applies to the further handling, manipulation, or use of the product once it is released as a finished drug product from a production facility.

(i) For the purpose of this Section, the following shall be designated low-risk level radiopharmaceutical CSPs:

(A) Radiopharmaceuticals compounded from sterile components in closed sterile containers, using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment.

(B) Compounded Radiopharmaceuticals with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container.

(ii) Radiopharmaceuticals prepared as Low-Risk Level CSPs with 12-Hour or Less BUD shall be prepared in a properly designated and segregated compounding area.

(iii) Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturer recommendations **or as established by stability testing**.

(iv) Technetium-99m/molybdenum-99 generator systems shall be stored and operated under conditions recommended by the manufacturer and applicable state and federal regulations in an ISO Class 8 or cleaner air environment.

Section 8. Gowning and Garbing.

(a)Personal cleansing and gowning/garbing shall be as follows:

(i) Personnel shall not compound if they have open sores or infected wounds;

ii) Personnel shall not compound if they have an upper respiratory infection;

(iii) Upon entering a compounding area, personnel must remove outer garments (such as coats, hats, sweaters, bandanas, vests, and scarves), hand and other exposed jewelry, and any other unnecessary and potentially contaminated or particle shedding articles. If hand jewelry cannot be removed, then it must be thoroughly cleaned and covered with a sterile glove;

(iv) Hand cleansing and donning of personal protective equipment should proceed in a manner that goes from the dirtiest to the cleanest area: shoe covers, hair covers, facial hair covers, and face mask or eye shields (if working with caustic or irritant agents). Cleansing should be done in a no-touch sink using appropriate antibacterial detergent, starting at the hands and nails and progressing to the elbows. The process should take at least thirty (30) seconds. Hand and forearm drying should be done with non-shedding paper towels.

(A) At this point, personnel should don a non-shedding gown with sleeves that fit snuggly around wrists. Lastly, sterile gloves should be donned. The gloves should form a continuous surface with the gown sleeves. Care should be exercised when progressing through the Ante-Area and Clean Room to not re-contaminate the gloves.

(B) Re-sanitizing of the gloves with sterile 70% IPA should occur routinely throughout the compounding process, or at any point that the gloves may have touched a non-sterile surface.

(v) If it is necessary to leave the compounding area, hand cleansing and replacement of all personal protective equipment except for the non-shedding gown shall occur. The gown must be left in the Ante-Area if it is to be reused during a shift (not to exceed twenty-four (24) hours).

(vi) If a Compounding Aseptic Isolator is used, gowning and garbing should occur in a manner consistent with the manufacturer's documented procedures. If no studies have been done and the manufacturer cannot assure maintenance of sterility and ISO Class 5 conditions outside of an ISO Class 7 space, the compounder must follow gowning and garbing procedures discussed above.

Section 9. Policy and Procedure.

(a) Pharmacies that engage in the practice of sterile compounding shall have a Policies and Procedures (P&P) manual that describes the common practices of the pharmacy. The P&P manual will be reviewed and updated as necessary, at least annually. The Pharmacist-in-Charge (PIC) is responsible for the completeness, accuracy, and enforcement of compliance with the procedures by all pharmacy personnel. This P&P manual will be available at all times to staff and at the request of a Board of Pharmacy Inspector. All staff will review the P&P manual before engaging in sterile compounding and annually thereafter. If the PIC changes, the new PIC must review, date, and initial the P&P manual within thirty (30) days.

(b) The Policies and Procedures manual will contain procedures detailing at least the following:

(i) Responsibilities of compounding personnel;

(ii) Personnel training and testing;

(iii) Competency practices and assessment of compounding personnel;

(iv) Quality Assessment and Quality Improvement activities;

(v) Proper use and deployment of environmental controls;

(vi) Gowning and garbing practices;

(vii) Inspection of finished products, labeling, storage, and transfer to final use areas for storage or use;

(viii) Introduction of supplies and products into the compounding area;

(ix) The formulation, process for compounding, BUD, and storage requirements of each routinely compounded CSP.

Section 10. Elements of Quality Control.

(a) Compounding facility.

(i) All pharmacies engaging in sterile compounding shall have a Quality Assurance Program that is in written format with documentation that illustrates that the Program is being followed. Documentation of compliance with the Quality Assurance Program will be available for evaluation by Inspectors of the Wyoming Board of Pharmacy and other pertinent regulatory agencies. The Quality Assurance Program shall include, though not be limited to:

(A) Adequacy of training and evaluation of personnel;

(B) Verification, monitoring, and review of the adequacy of the compounding process;

(C) Maintenance of an appropriate environment for compounding sterile preparations;

(D) Review of the final product for accuracy of preparation, quality, and purity and, where appropriate, sterility and bacterial endotoxin content;

(E) Monitoring for adverse or negative patient outcomes due to utilization of a compounded sterile preparation or other quality related issue, and that identified issues are included in the facility's overall Quality Assurance Program.

(F) Addressing problems or issues identified by the Quality Assurance Program, including follow-up and assurance of correction.

(b) Personnel.

(i) All personnel engaged in preparation of sterile products will be adequately trained before they begin compounding.

(ii) Training shall include didactic learning and experiential components with results validated by testing of aseptic skills and knowledge including, but not limited to:

(A) Gowning and garbing assessment;

(B) Media-Fill Testing that is representative of compounding performed;

(C) Gloved fingertip testing done three (3) times prior to initial compounding and annually thereafter;

(D) Knowledge of sterile compounding processes; facility policies, procedures and quality programs; and legal requirements of state, federal, and pertinent regulating agencies.

(iii) All documentation of results will be available for review by pertinent individuals or agencies.

(c) Compounding Risk Levels.

(i) The Quality Assurance Program will correspond to the level of compounding risk that is undertaken at the individual facility. The facility's Quality Assurance Program shall include the following for each level:

(A) Low-Risk Level Compounding.

(I) Routine disinfection and air quality testing conducted to minimize microbial surface contamination and maintenance of ISO Class 5 conditions;

(II) Visual confirmation of personnel practices and garbing;

(III) Review of all orders and materials to ensure that the correct identity and quantity of ingredients were compounded;

(IV) Visual inspection of the sterile product to ensure the absence of particulate matter in the solution; appropriateness of color, clarity, and volume; the adequacy and competence of the container; and appropriateness of labeling. **Visual inspection of Low-Risk Level radiopharmaceutical CSPs will be limited, in accordance with radiation safety practices.**

(V) Annual basic Media-Fill Testing that is conducted in conditions of equal stress to the actual compounding process.

(B) Medium-Risk Level Compounding.

(I) All elements of the Low-Risk Level compounding quality requirements plus a more challenging Media-Fill Test performed at least annually.

(C) High-Risk Level Compounding.

(I) All elements of the Low-Risk Level compounding quality requirements plus a Media-Fill Test that represents High-Risk Level compounding completed semiannually by all compounding personnel.

(d) Verification of accuracy and sterility in High-Risk Level compounding.

(i) The compounding facility will have policies and procedures detailing standard practices that assure compounded sterile products are accurately produced and that the quality procedures in place achieve and maintain sterility.

(ii) High-Risk Level compounding shall have additional procedures and quality assurance to ensure accurate and sterile products.

(iii) Sterility and depyrogenation shall be achieved when necessary by the appropriate application of dry-heat, steam-heat, or filtration. Appropriate resources shall be used to determine the appropriate method for sterilization while maintaining strength, purity, quality, and package integrity.

(iv) Sterility and Bacterial Endotoxin testing shall be done when there are batches of more than twenty-five (25) identical individual single-dose packages; when in multiple-dose vials for administration to multiple patients; or when exposed longer than twelve (12) hours at two-to-eight degrees Ce**ntigrade** (2°C to 8°C), or longer than six (6) hours at above eight degrees Cen**tigrade** (8°C).

(v) If dispensed before results are obtained, daily monitoring of the testing will occur and, if positive results come back, the product will be immediately recalled and notification of results will be forwarded to the end patient and physician.

(e) Environmental quality and control.

(i) The facility producing compounded sterile preparations will have policies and procedures sufficient to ensure preparation of products that are sterile and of accurate strength, purity, quality, and package integrity. A Quality Assurance Program will be present that illustrates the adequacy of the processes used. The Quality Assurance Program will include, but not be limited to:

(A) Viable and nonviable environmental air sampling performed:

(I) As part of commissioning and certification of facilities or equipment;

(II) Following servicing of facilities or equipment;

(III) As part of re-certification (every six (6) months);

(IV) In response to identified problems with end products, staff technique or work practices, or patient-related infections that could be due to the compounded sterile preparation.

(B) Primary Engineering Controls and equipment will be monitored as part of the comprehensive Quality Assurance Program that assures maintenance of appropriate air quality and the ability to produce sterile and stable compounded products.

(f) Patient monitoring.

(i) The compounding facility will have policies and procedures detailing its Quality Assurance Program that monitor for adverse effects, negative outcomes, and medication errors.

(ii) The compounding facility will have a process that allows patients and other recipients to address their questions and to report any concerns they may have with the compounded sterile preparation or administrative device.

(iii) Reports of adverse events will be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences.

(iv) Compounding personnel are encouraged to participate in the adverse event reporting and product defects programs of the FDA and USP.

Section 11. Verification of Automated Compounding Devices for Parenteral Nutrition Compounding.

(a) Wherever possible, Parenteral nutritional solutions should be compounded using an automated compounder or repeater pump to ensure accuracy and sterility of these compounded products.

(b) Written procedures outlining use of equipment, calibration, appropriate maintenance, monitoring for proper function, and specified time frames for these activities shall be established and followed. Results and logs of calibration and maintenance reports shall be kept on file at the pharmacy for at least two (2) years and shall be available for inspection.

(c) Manufacturer recommendations regarding calibration and maintenance shall be made part of each facility's policies and procedures.

(d) The automated compounder shall be cleaned prior to each set-up and as necessary according to the manufacturer's guidelines.

(e) Accuracy assessments of automated compounding devices shall be conducted and daily or on each day used. At routine intervals, the pharmacist in charge or his/her designee will review these assessments to avoid potentially clinically significant cumulative errors over time.

CHAPTER 16

IMMUNIZATION REGULATIONS

Section 1. Authority.

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

Section 2. Definitions.

(a) "Healthy Adults" means, for the purpose of this Cchapter, those individuals who are nineteen (19) years of age or older and have no absolute contraindications to receive immunizations allowed in this Cchapter.

(b) "High--Risk Adults" means, for the purpose of this Cchapter, those adults nineteen (19) years of age or older who may have an absolute or relative contraindication to receive immunizations as allowed by in this Cchapter for whom a physician has issued a prescription authorizing a pharmacist to dispense and administer an immunization. Only those pharmacists that who meet the qualifications of this Cchapter may administer an immunization to a Hhigh--Rrisk Aadult.

(c) "Immunizations" means, for the purpose of this Cchapter, those vaccines which a pharmacist may prescribe or administer to healthy adults or those vaccines which may be administered on a specific order of a physician for Hhigh--Rrisk Aadults and shall be restricted to the following vaccines:

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

(ii) Measles, mumps, rubella (MMR)

(iii) aricella

(iv) Influenza

(v) Pneumococcal (Polysaccharide)

(vi) Hepatitis A

(vii) Hepatitis B

(viii) Meningococcal

(ix) Human papillomavirus (HPV)

(x) Zoster

Section 3. Qualifications.

(a) A pharmacist licensed by the board may prescribe and administer immunizations to healthy adults or administer immunizations to Hhigh--Rrisk Aadults authorized by a physician, provided the pharmacist has:

(i) Registered with the board to prescribe and administer immunizations;

(ii) Successfully completed the American Pharmaceutical Association's (APhA) immunization training certification program entitled, "*Pharmacy-Based Immunization Delivery*", or the Washington State Pharmacy Association's immunization training certification program entitled, "*Vaccinating Adults and Adolescents: An Immunization Program Practicum Session*, or an equivalent program approved by the board";

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

(iv) Completed a minimum of one (1) contact hour (0.1 CEU) of continuing education related to immunizations annually. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (A.C.P.E.).

(b) It is unprofessional conduct for a pharmacist, to prescribe or administer an immunization, who is not in compliance with this Chapter.

Section 4. Registration.

(a) Prior to prescribing or administering immunizations, a pharmacist shall submit an application supplied by the board and a $10.00 fee. Provided all requirements of Section 3(a) have been met, the board shall issue a registration. Registrations shall expire on December 31 of each year.

(b) Renewal applications will be mailed by the board annually on or about November 1st.

(c) A pharmacist may not prescribe or administer an immunization unless currently registered with the board under this Chapter.

Section 5. Immunizations.

(a) Immunizations authorized by this Chapter shall be prescribed in accordance with the latest notice from the U. S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). Specifically, CDC's "*Recommended Adult Immunization Schedule, by Vaccine and Age Group*" and "*Recommended Adult Immunization Schedule, by Vaccine and Medical and Other Indications*", including the footnotes provided for each schedule, shall be utilized by the pharmacist when considering the eligibility of a healthy adult to receive an immunization. The latest notice from CDC may be found at CDC's website (http://www.cdc.gov) or (http://www.cdc.gov/nip/recs/adult-schedule-bw.pdfvaccines/recs/schedules/downloads/adult/2009/adult-schedule.pdf).

(b) In addition to the requirements of Section 5(a) of this Cchapter, the pharmacist shall utilize the manufacturer's package insert for indications, contraindications, adverse reactions, adult dosing, route of administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this Cchapter.

Section 6. Vaccine Information Statement.

A current *Vaccine Information Statement*, as provided by the CDC, shall be provided to each person receiving an immunization for each immunization administered. The *Vaccine Information Statement* is available from the CDC's website (http://www.cdc.gov) or (http://www.cdc.gov/nip/publicationsvaccines/pubs/vis/VIS/default.htm).

Section 7. Record-keeping.

(a) An *Immunization Questionnaire and Consent Form*, as provided approved by the board, shall be completed for each person receiving an immunization. Two (2) copies shall be provided to the patient.

(b) The *Immunization Questionnaire and Consent Form* shall be filed in a manner that will allow timely retrieval. All records shall be maintained in the pharmacy where the pharmacist who administered the immunization is employed.

(c) The *Immunization Questionnaire and Consent Form* shall be kept on file for a time period not less than six (6) years from the date of the immunization.

Section 8. Emergencies.

(a) A pharmacist authorized to prescribe and administer immunizations under this Cchapter may administer auto-inject epinephrine in the management of an acute allergic reaction to an immunization, following guidelines issued by the American Pharmacy Association's (APhA) or the Washington State Pharmacy Association's immunization training certification program.

(b) A pharmacist shall post a protocol, as outlined in the APhA's or Washington State Pharmacy Association's immunization training certification program, and maintain an emergency kit which is readily retrievable to manage an acute allergic reaction to an immunization administered.

CHAPTER 13

COMPOUNDING

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

Section 2. Definitions.

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

(b) "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 their his/her professional practice.

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

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

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

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

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

Section 3. General Provisions.

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

(b) Pharmacists shall, when procuring active ingredients for compounding, obtain a Certificate of Analysis (C.O.A.) for each lot number procured, and shall retain each C.O.A. for a period of not less than two (2) years from the date the container is emptied. C.O.A.'s shall be

available for review by Board inspectors. Each C.O.A. must be issued by a firm located in the United States. If one is not available from the vendor, the pharmacist shall procure one from a laboratory located in the United States. C.O.A.'s are not required if the active ingredient utilized is designated U.S.P. or N.F.

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

(A) Product name;

(B) Lot number;

(C) Expiration date; and

(D) Assay.

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

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

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

Section 4. Organization and Personnel.

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

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

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

Section 5. Drug Compounding Facilities.

(a) Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. Sterile compounding shall be performed in a separate area in compliance with Section 10 of this ~~regulation~~Chapter.

(b) Bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature-controlled area or, if required, under proper refrigeration. The refrigerator shall provide a storage temperature of 36 to 46 degrees Fahrenheit (2 to 8 degrees Centigrade). If a freezer compartment is utilized, it must maintain a temperature of ~~–14~~ 13 to ~~+~~14 degrees Fahrenheit (~~20~~ 25 to –10 degrees Centigrade).

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

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

(e) If sterile products are being compounded, the pharmacist shall follow ~~Section 10~~Chapter 17 of this regulation.

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

Section 6. Equipment.

(a) Equipment and utensils used for compounding shall be of appropriate design and capacity, and shall be stored in a manner to protect from contamination. In addition, all equipment and utensils shall be cleaned prior to use to prevent contamination that would alter the safety or quality of the drug product beyond that desired. ~~The pharmacist is responsible for determining suitability for use. In the case of sterile compounding, follow Section 10 of this regulation as applicable to equipment and utensils.~~

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

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

(d) Any class 100 laminar flow cabinet or class II biological safety cabinet shall be certified by an independent contractor according to Federal Standard 209E for operational efficiency at least every 12 months or when it is relocated.

Section 7. Compounding Controls.

(a) There shall be recorded procedures for compounded products to include components, amount, order of procedure, and equipment to einsure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess.

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

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

(i) Capsule weight variation;

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

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

(d) Appropriate written procedures designed to prevent microbiological contamination of compounded sterile products shall be established and followed as outlined in Section 10 of this regulation. Such procedures shall include validation of any sterilization process.

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

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

The pharmacist shall label any excess or bulk compounded product to reference it to the formula used and the assigned control number and estimated beyond use date based on the

pharmacist's professional judgment, appropriate testing or published data. The product shall be stored appropriately.

Section 9. Records and Reports.

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

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

(i) Name of the product;

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

(iii) Lot number assigned by a pharmacist;

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

(v) Date of preparation;

(vi) Initials of compounding pharmacist/pharmacy technician;

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

(viii) Quantity prepared.

~~Section 10. Sterile Compounding.~~

~~(a) Sterile compounding includes the preparation of any parenteral, ophthalmic, inhalation, or any other prescription drug product, which requires compounding in a clean air environment.~~

~~(b) A policy and procedure manual for sterile product compounding shall be developed by the pharmacist in charge and reviewed annually. The manual shall include policies and procedures for:~~

~~(i) Oncology drugs, if applicable;~~

~~(ii) Disposal of unused supplies and medications;~~

~~(iii) Drug destruction and return;~~

~~(iv) Drug dispensing;~~

~~(v) Drug labeling;~~

~~(vi) Storage;~~

~~(vii) Duties and qualifications for staff;~~

(viii) Equipment;

(ix) Handling of hazardous wastes;

(x) Investigation drug protocol;

(xi) Safety of compounding procedures;

(xii) Record-keeping;

(xiii) Reference material;

(xiv) Maintenance of a sanitary environment;

(xv) Transportation, if applicable; and

(xvi) Quality assurance, as relates to:

(A) Recall procedures;

(B) Storage and dating;

(C) Educational procedures for staff and patient;

(D) Sterile procedures, to include routine maintenance and hood certification; and, if necessary, sterile testing of end products, operator procedures, and environment.

(c) The following physical requirements for sterile compounding are in addition to other requirements set forth in Chapter 2, Section 7 and Chapter 12, Section 8 of the Board's Rules:

(i) The licensed pharmacy shall have a designated area for sterile compounding. This area shall be designed to withstand routine disinfecting procedures and shall be kept free of particulate generators, e.g., corrugated cardboard containers. This area shall be designed to avoid unnecessary traffic and airflow disturbances. It shall be used only for the preparation of sterile products. It shall be of sufficient size to accommodate a class 100 laminar flow cabinet and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(ii) The minimum equipment shall be:

(A) Class 100 laminar flow cabinet or Class 100 clean room;

Sink with hot and cold running water which is convenient to the

compounding area;

(B) Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic and hazardous wastes from preparation of cytotoxic agents;

(C) A Class II biological safety cabinet, if cytotoxic agents are prepared;

(D) Refrigerator or freezer with a thermometer, which is convenient to the compounding area; and

(E) A temperature controlled delivery container (not required if delivered in the same facility).

(iii) The minimum supplies shall be:

(A) Disposable needles, syringes, and other supplies needed for sterile compounding;

(B) Disinfectant cleaning solutions;

(C) Hand-washing agent with bactericidal action;

(D) Disposable, lint-free towels or equivalent;

(E) Appropriate filters and filtration equipment;

(F) Oncology drug spill kit, if applicable; and

(G) Disposable personal protective gear.

(a) The sterile compounding area of the pharmacy shall not be accessible to the public and no one shall have access without authorization of the pharmacist-in-charge.

(e) Each pharmacy engaged in sterile compounding shall have current reference materials related to sterile products compounded therein.

(f) Each pharmacy engaged in sterile product compounding shall be managed by a pharmacist licensed in Wyoming who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance.

(g) A log, either manual or electronic shall be maintained for all sterile compounded products dispensed from the pharmacy. This log shall be maintained for a minimum of two years from the date that the sterile compounded product was dispensed. The log shall include the following:

(i) Date prepared;

(ii) Name or initial of pharmacist responsible for the preparation, and technician if applicable.

(iii) Name of patient;

(iv) Prescription number (if applicable); and

(v) Name of sterile compounded product including strength or concentration.

(h) All containers shall be labeled, as a minimum, with the following:

(i) Patient's Name and identifier, if applicable;

(ii) Prescribing practitioner's name, if applicable;

(iii) Name of drug, including concentration or amount;

(iv) Date prepared;

(v) Name or initials of pharmacist who prepared the product;

(vi) Directions, if applicable;

~~(vii) Route and rate of administration, if applicable; and~~

~~(viii) Expiration date.~~

~~(i) Any class 100 laminar flow cabinet or class II biological safety cabinet shall be certified by an independent contractor according to Federal Standard 209E for operational efficiency at least every 12 months or whenever it is relocated.~~

CHAPTER 13

COMPOUNDING

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

Section 2. Definitions.

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(b) "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 their his/her professional practice.

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

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

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

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

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

Section 3. General Provisions.

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

(b) Pharmacists shall, when procuring active ingredients for compounding, obtain a Certificate of Analysis (C.O.A.) for each lot number procured, and shall retain each C.O.A. for a period of not less than two (2) years from the date the container is emptied. C.O.A.'s shall be

available for review by Board inspectors. Each C.O.A. must be issued by a firm located in the United States. If one is not available from the vendor, the pharmacist shall procure one from a laboratory located in the United States. C.O.A.'s are not required if the active ingredient utilized is designated U.S.P. or N.F.

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

(A) Product name;

(B) Lot number;

(C) Expiration date; and

(D) Assay.

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

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

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

Section 4. Organization and Personnel.

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

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

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

Section 5. Drug Compounding Facilities.

(a) Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. Sterile compounding shall be performed in a separate area in compliance with Section 10 of this ~~regulation~~Chapter.

(b) Bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature-controlled area or, if required, under proper refrigeration. The refrigerator shall provide a storage temperature of 36 to 46 degrees Fahrenheit (2 to 8 degrees Centigrade). If a freezer compartment is utilized, it must maintain a temperature of ~~–14~~ 13 to ~~+~~14 degrees Fahrenheit (~~20~~ 25 to –10 degrees Centigrade).

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

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

(e) If sterile products are being compounded, the pharmacist shall follow ~~Section 10~~Chapter 17 of this regulation.

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

Section 6. Equipment.

(a) Equipment and utensils used for compounding shall be of appropriate design and capacity, and shall be stored in a manner to protect from contamination. In addition, all equipment and utensils shall be cleaned prior to use to prevent contamination that would alter the safety or quality of the drug product beyond that desired. ~~The pharmacist is responsible for determining suitability for use. In the case of sterile compounding, follow Section 10 of this regulation as applicable to equipment and utensils.~~

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

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

(d) Any class 100 laminar flow cabinet or class II biological safety cabinet shall be certified by an independent contractor according to Federal Standard 209E for operational efficiency at least every 12 months or when it is relocated.

Section 7. Compounding Controls.

(a) There shall be recorded procedures for compounded products to include components, amount, order of procedure, and equipment to einsure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess.

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

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

(i) Capsule weight variation;

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

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

(d) Appropriate written procedures designed to prevent microbiological contamination of compounded sterile products shall be established and followed as outlined in Section 10 of this regulation. Such procedures shall include validation of any sterilization process.

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

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

The pharmacist shall label any excess or bulk compounded product to reference it to the formula used and the assigned control number and estimated beyond use date based on the

pharmacist's professional judgment, appropriate testing or published data. The product shall be stored appropriately.

Section 9. Records and Reports.

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

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

(i) Name of the product;

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

(iii) Lot number assigned by a pharmacist;

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

(v) Date of preparation;

(vi) Initials of compounding pharmacist/pharmacy technician;

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

(viii) Quantity prepared.

~~Section 10. Sterile Compounding.~~

~~(a) Sterile compounding includes the preparation of any parenteral, ophthalmic, inhalation, or any other prescription drug product, which requires compounding in a clean air environment.~~

~~(b) A policy and procedure manual for sterile product compounding shall be developed by the pharmacist in charge and reviewed annually. The manual shall include policies and procedures for:~~

~~(i) Oncology drugs, if applicable;~~

~~(ii) Disposal of unused supplies and medications;~~

~~(iii) Drug destruction and return;~~

~~(iv) Drug dispensing;~~

~~(v) Drug labeling;~~

~~(vi) Storage;~~

~~(vii) Duties and qualifications for staff;~~

(viii) Equipment;

(ix) Handling of hazardous wastes;

(x) Investigation drug protocol;

(xi) Safety of compounding procedures;

(xii) Record-keeping;

(xiii) Reference material;

(xiv) Maintenance of a sanitary environment;

(xv) Transportation, if applicable; and

(xvi) Quality assurance, as relates to:

(A) Recall procedures;

(B) Storage and dating;

(C) Educational procedures for staff and patient;

(D) Sterile procedures, to include routine maintenance and hood certification; and, if necessary, sterile testing of end products, operator procedures, and environment.

(c) The following physical requirements for sterile compounding are in addition to other requirements set forth in Chapter 2, Section 7 and Chapter 12, Section 8 of the Board's Rules:

(i) The licensed pharmacy shall have a designated area for sterile compounding. This area shall be designed to withstand routine disinfecting procedures and shall be kept free of particulate generators, e.g., corrugated cardboard containers. This area shall be designed to avoid unnecessary traffic and airflow disturbances. It shall be used only for the preparation of sterile products. It shall be of sufficient size to accommodate a class 100 laminar flow cabinet and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(ii) The minimum equipment shall be:

(A) Class 100 laminar flow cabinet or Class 100 clean room;

Sink with hot and cold running water which is convenient to the

compounding area;

(B) Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic and hazardous wastes from preparation of cytotoxic agents;

(C) A Class II biological safety cabinet, if cytotoxic agents are prepared;

(D) Refrigerator or freezer with a thermometer, which is convenient to the compounding area; and

(E) A temperature controlled delivery container (not required if delivered in the same facility).

(iii) The minimum supplies shall be:

(A) Disposable needles, syringes, and other supplies needed for sterile compounding;

(B) Disinfectant cleaning solutions;

(C) Hand-washing agent with bactericidal action;

(D) Disposable, lint-free towels or equivalent;

(E) Appropriate filters and filtration equipment;

(F) Oncology drug spill kit, if applicable; and

(G) Disposable personal protective gear.

(a) The sterile compounding area of the pharmacy shall not be accessible to the public and no one shall have access without authorization of the pharmacist-in-charge.

(e) Each pharmacy engaged in sterile compounding shall have current reference materials related to sterile products compounded therein.

(f) Each pharmacy engaged in sterile product compounding shall be managed by a pharmacist licensed in Wyoming who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance.

(g) A log, either manual or electronic shall be maintained for all sterile compounded products dispensed from the pharmacy. This log shall be maintained for a minimum of two years from the date that the sterile compounded product was dispensed. The log shall include the following:

(i) Date prepared;

(ii) Name or initial of pharmacist responsible for the preparation, and technician if applicable.

(iii) Name of patient;

(iv) Prescription number (if applicable); and

(v) Name of sterile compounded product including strength or concentration.

(h) All containers shall be labeled, as a minimum, with the following:

(i) Patient's Name and identifier, if applicable;

(ii) Prescribing practitioner's name, if applicable;

(iii) Name of drug, including concentration or amount;

(iv) Date prepared;

(v) Name or initials of pharmacist who prepared the product;

(vi) Directions, if applicable;

~~(vii) Route and rate of administration, if applicable; and~~

~~(viii) Expiration date.~~

~~(i) Any class 100 laminar flow cabinet or class II biological safety cabinet shall be certified by an independent contractor according to Federal Standard 209E for operational efficiency at least every 12 months or whenever it is relocated.~~

CHAPTER 12

INSTITUTIONAL PHARMACY PRACTICE REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Purpose.

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

Section 3. Scope of Chapter.

This C~~c~~hapter applies to any person, partnership, corporation, l~~L~~imited l~~L~~iability c~~C~~ompany, or other entity engaging in the practice of pharmacy in an I~~i~~nstitutional F~~f~~acility, as defined below, within this state.

Section 4. Definitions.

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

(b) "Institutional P~~p~~harmacy" means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an I~~i~~nstitutional F~~f~~acility, and which is:

(i) Located within the ~~i~~Institutional F~~f~~acility, or

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

(c) "Drug Room" means a secure and lockable location within an inpatient care facility that does not have an I~~i~~nstitutional P~~p~~harmacy.

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

(e) "Formulary" means a continually revised compilation of pharmaceuticals that reflects the current clinical judgment of the medical staff of the Institutional ~~f~~Facility.

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

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

(h) "Clean Room" means a room with a minimum of an ISO Class 7 environment:

(i) in which the concentration of airborne particles is controlled; ~~and there are one or more clean zones according to Federal Standard 209E.~~

(ii) that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room;

(iii) in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary; and

(iv) in which microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear is not exceeded for a specific cleanliness class.

(i) "Investigational Drug" means:

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

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

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

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

(ii) Entering or transferring medication order data;

(iii) Performing prospective drug use review;

(iv) Obtaining substitution authorizations;

(v) Interpreting and acting on clinical data;

(vi) Performing therapeutic interventions;

(vii) Providing drug information;

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

Section 5. Licensing.

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

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

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

Section 6. Change of Ownership.

(a) If an Iinstitutional Ppharmacy changes ownership, it must obtain a new and separate registration from the Board. In the case of a corporation, limited liability company, or partnership holding an Iinstitutional pPharmacy license, the Board shall be notified and a new license applied for any time the majority of stock in the corporation is sold or a majority of the partners of the partnership or members of the limited liability company change.

Section 7. Personnel.

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

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

(i) ~~Hospitals with 50 or more acute care beds.~~ In hospitals Institutional Facilities with fifty (50) or more acute care beds ~~or more~~, a pharmacist shall be in the hospital Institutional Facility during the time the Institutional Ppharmacy is

open for pharmacy services, except in case of emergencies. Pharmacy services shall be provided for a minimum of forty (40) hours per week, unless an exception is made upon written request by the hospital Institutional Facility and with express permission of the Board.

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

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

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

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

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

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

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

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

(iii) Developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile pharmaceuticals compounded within the I~~i~~nstitutional P~~p~~harmacy;

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

(v) Providing ~~written~~ guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing,

sterilizing, and labeling of sterile pharmaceuticals is not performed under direct Institutional pPharmacy supervision;

(vi) Participating in the development of a Fformulary for the Institutional fFacility, which is approved by the appropriate committee, including the medical staff of the Institutional Facility;

(vii) Developing a system to assure that drugs to be administered to inpatients are distributed pursuant to an original or direct copy of the practitioner's Mmedication Oorder;

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

(ix) Participating in those aspects of the Institutional fFacility's patient care evaluation program, which that relate to pharmaceutical utilization and effectiveness;

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

(xi) Assuring the legal operation of the Institutional pPharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy;. and

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

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

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

(g) The PIC may be assisted by secretarial and clerical assistance as required to assist with record-~~-~~keeping, report submission, and other administrative duties.

Section 8. Environment.

(a) The I~~i~~nstitutional P~~p~~harmacy shall be enclosed and lockable.

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

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

(d) The I~~i~~nstitutional P~~p~~harmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(e) The I~~i~~nstitutional P~~p~~harmacy shall be properly lighted and ventilated.

(f) The temperature of the I~~i~~nstitutional P~~p~~harmacy shall be maintained within a range of 59 to 86 degrees Fahrenheit (15 to 30 degrees Centigrade). The temperature of the refrigerator shall be maintained within a range of 36 to 46 degrees Fahrenheit (2 to 8 degrees Centigrade) and the freezer shall be maintained within a range of –14~~3~~ to ~~–4~~+14 degrees Fahrenheit (-2~~0~~5 to –10 degrees Centigrade).

(g) The I~~i~~nstitutional P~~p~~harmacy shall store antiseptics, other drugs for external use, and disinfectants separately from internal and injectable medications.

(h) If the I~~i~~nstitutional P~~p~~harmacy compounds sterile pharmaceuticals, they shall be prepared in accordance ~~–~~with Wyoming Pharmacy Act, Rules and Regulations, Chapter ~~13, Section 10~~17 ~~of the Board's rules~~.

Section 9. References.

Each I~~i~~nstitutional ~~p~~Pharmacy shall maintain in its library at least one current reference ~~book~~ (text or electronic format, including online access or PDA) from each category listed below. The Board reserves the right to accept new references in lieu of the following:~~.~~

(a) Drug Monograph Reference:

(i) American Hospital Formulary Service® (ISBN: 978-1-58528-227-2);~~AHFS – Drug Information~~

(ii) Drug Facts and Comparisons® (ISBN: 978:0-032686-00-1);~~Drug Facts & Comparison~~

(iii) Thomson's Micromedex®;~~Micromedex or equivalent~~

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

(v) Drug Information Handbook (Lexi-Comp) (978-1-59195-254-1).

(b) Stability and Incompatibility Reference:

(i) Handbook on Injectable Drugs, Lawrence A. Trissel (ISBN: 978-1-58528-213-5);~~Handbook on Injectable Drugs (Trissel)~~

(ii) King Guide to Parenteral Admixtures (ISBN: 0970190220)~~Guide of Parenteral Admixtures (King/Cutter)~~; or

(iii) Thomson's Micromedex®.~~Micromedex or equivalent~~

(c) Reference on Drug Availability and Identification:

(i) American Hospital Formulary Service® (ISBN: 978-1-58528-227-2);~~AHFS- Drug Information~~

(ii) Drug Facts and Comparisons® (ISBN: 978:0-032686-00-1);~~Drug Facts and Comparisons~~

(iii) American Drug Index (ISBN-10: 1-57439-289-1);~~American Drug Index~~ or

(iv) Drug Information Handbook (Lexi-Comp) (978-1-59195-254-1).

(d) Drug Interactions:

(i) American Hospital Formulary Service® (ISBN: 978-1-58528-227-2)~~AHFS – Drug Information~~;

(ii) Thomson's Micromedex®~~Micromedex or equivalent~~;

(iii) Drug Interactions Facts (ISBN: 978: 1-57439-015-5)~~Drug Interactions Facts~~;

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

(v) Drug Information Handbook (Lexi-Comp) (978-1-59195-254-1).

(vi) Drug Interactions Analysis and Management (DIAM) (ISBN: 00-1092-048X).~~Hansten's Drug Interactions Analysis and Management~~

(e) Reference on Pharmacology and Therapeutics:

(i) Conn's Current Therapy (Rakel and Bope) (ISBN-13: 978-1-4160-5974-5)~~Conn's Current Therapy~~;

(ii) Drug Information Handbook (Lexi-Comp) (978-1-59195-254-1).

8125-1)~~Manual of Medical Therapeutics~~;

(iii) Applied Therapeutics: The Clinical Use of Drugs (Koda-Kimble) (ISBN: 978-0-7817-6555-8)~~Applied Therapeutics (Koda-Kimble);~~

(iv) Pharmacotherapy (DiPiro) (ISBN: 978-0-0714-7899-1)~~Pharmacotherapy (DiPiro);~~ or

(v) Textbook of Therapeutics (Herfindal and Gourley) (ISBN: 0-7817-5734-7)~~Textbook of Therapeutics (Herfindal).~~

(f) Current copies of the Wyoming Pharmacy Act and R~~r~~ules and Regulations, and Wyoming Controlled Substance Act and R~~r~~ules and Regulations, text or electronic format, and including internet access to the Board website.

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

Section 10. Equipment.

(a) Institutional pharmacies distributing M~~m~~edication O~~o~~rders shall have the following equipment:

~~(i) Typewriter or comparable equipment;~~

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

(ii~~i~~) Computer and software appropriate for the I~~i~~nstitutional F~~f~~acility; and~~.~~

(iii~~v~~) ~~Fax machine~~Facsimile capability located in the Institutional ~~p~~Pharmacy.

(b) If the I~~i~~nstitutional P~~p~~harmacy compounds M~~m~~edication O~~o~~rders~~, which~~ that require the use of a balance, a Class A prescription balance or electronic scale with 10 mg sensitivity shall be available. Such balance or electronic scale shall be properly maintained by the PIC and may be inspected at least every three (3) years by the Board of Pharmacy.

(c) If the Iinstitutional Ppharmacy compounds sterile pharmaceuticals, the Institutional pPharmacy shall have equipment and supplies listed in Wyoming Pharmacy Act, Rules and Regulations Chapter 13, Section 1017 of the Board's rules.

Section 11. Security.

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

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

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

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

(e) The pharmacist-in-chargePIC shall be responsible for policies and procedures for the safe distribution and control of prescription blanks bearing identification of the hospitalInstitutional Facility.

Section 12. Absence of Pharmacist.

(a) General. During such times as Iinstitutional Ppharmacy services are not available on-site, arrangements shall be made in advance by the Ppharmacist-in-Ccharge (PIC) for provision of drugs to the medical staff and other authorized personnel of the hospital Institutional Facility by use of Ffloor Sstock and/or access to the Institutional pPharmacy under the standing order of the pharmacist-in-chargePIC.

(b) If Ffloor sStock is used, the following shall prevail:

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

(ii) The ~~pharmacist-in-charge~~PIC shall, in conjunction with the appropriate committee, if any, of the I~~i~~nstitutional F~~f~~acility, develop inventory listings of those drugs to be included in such F~~f~~loor S~~s~~tock, and shall e~~i~~nsure that:

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

(B) Such drugs are prepackaged in appropriate small amounts~~, not to exceed thirty dosage units;~~ unless commercially prepared package ~~creates difficulty~~, e.g. ophthalmics, otics, topicals, etc.

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

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

(~~1~~I) The date and time of removal of a drug;

(II~~2~~) The patient's name and location;~~,~~

(III~~3~~) The name, strength, dosage form, and quantity of drug removed; and

(IV~~4~~) The signature of the nurse removing the drug.

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

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

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

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

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

(B) The patient's name and location;

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

(D) The signature of the nurse.

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

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

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

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

(i) The I~~i~~nstitutional ~~p~~Pharmacy shall have a pharmacist on duty at the I~~i~~nstitutional F~~f~~acility the minimum number of hours required in this C~~c~~hapter ~~12~~, Section 7 ~~of the Board's rules~~.

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

(iii) The Board shall be notified in writing by the I~~i~~nstitutional P~~p~~harmacy of any arrangement whereby pharmaceutical care is provided off-site. This notification shall include the following:

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

(B) The name, address, and Wyoming license number of each pharmacy exchanging information with the I~~i~~nstitutional F~~f~~acility.

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

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

(E) Description of patient information that is to be shared between the Institutional ~~f~~Facility and the off-site pharmacist. A~~t~~s ~~a~~ minimum, the off-site pharmacist shall have access to the patient's medical record.

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

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

(A) Review of any new Mmedication Oorder or change in existing Mmedication Oorder prior to administration by the nursing staff at the Iinstitutional Ffacility.

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

(C) The off-site pharmacist shall communicate with the Iinstitutional Ppharmacy staff on a daily basis or, if the Iinstitutional Ppharmacy is not opened on a daily basis, then communication shall occur whenever the Iinstitutional Ppharmacy is open for business.

Section 13. Emergency Outpatient Medication.

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

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

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

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

(C) The quantity of medication administered and distributed is limited to a seventy-two hour (72-hour) supply. Exceptions to the 72-hour supply include: pediatric antibiotic preparations (PO), otitics, ophthalmics, topicals, or metered dose inhalers; and

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

(I1) Name, address, and telephone number of the hospital Institutional Facility;

(II2) Name of patient;

(III3) Name of drug, strength, and quantity;

(IV4) Directions for use;

(V5) Date;

(VI~~6~~) Accessory cautionary information, as required for patient safety;

(VII~~7~~) Name of practitioner; and

(VIII~~8~~) Initials of the nurse administering and distributing the medication.

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

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

(i) Name of patient;

(ii) Date of issuance;

(iii) Name of d~~D~~rug;

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

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

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

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

Section 14. Emergency Drug Carts (c~~C~~rash c~~C~~arts).

Emergency D~~d~~rug C~~c~~arts may be used by ~~hospitals~~ Institutional Facilities if:

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

(b) A committee composed of the P~~p~~harmacist-in-C~~c~~harge, nursing staff, and medical staff of the ~~hospital~~ Institutional Facility develops a standard drug inventory, including kind and quantity of each drug;

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

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

(e) All drugs are properly labeled;

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

(g) The pharmacist, nursing staff, and medical staff develop and implement written policies and procedures for using Eemergency Ddrug Ccarts ~~(crash carts).~~

Section 15. Automated Dispensing Devices.

(a) No drug shall be distributed or issued by the use of any automated dispensing device unless the device and method of operation have been found by the Board to ei~~i~~nsure the purity, potency, and integrity of the drug, and to protect the drug from diversion~~,~~; and provided that:

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

(ii) The device shall be used only for the furnishing of drugs for administration to patients of that Ii~~i~~nstitutional Ff~~f~~acility; and

(iii) At the time of removal of any drug from the device, it shall automatically make a written or electronic record to be retained by the pharmacist for at least one (1) year, indicating:

(A) The date of removal of the drug;

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

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

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

Section 16. Parenteral Medications.

(a) The Pp~~p~~harmacist-in-Cc~~c~~harge (PIC) shall be responsible for the preparation, sterilization, labeling, and dispensing of parenteral medications prepared within the Ii~~i~~nstitutional Ff~~f~~acility~~;~~ and shall participate in the education and training,

including the provision of appropriate incompatibility information, of all personnel involved in the preparation of parenteral medications.

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

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

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

Section 17. Practitioner's Orders.

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

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

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

Section 18. Dispensing.

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

Section 19. Investigational Drugs and Protocols.

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

(b) A copy of all Iinvestigational Ddrug protocols shall be on file in the Institutional pPharmacy.

Section 20. Inspections.

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

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

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

(c) Thermolabile drugs are stored at the proper temperature;

(d) There are no outdated or deteriorated drugs;

(e) All drugs are properly labeled;

(f) Emergency Ddrug Ccarts (crash carts) are adequate and in proper supply;

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

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

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

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

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

Section 21. Medications brought into the institution by patients.

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

Section 22. Controlled Drugs.

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

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

(ii) The date and time of administration;

(iii) The quantity administered;

(iv) Name of patient;

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

(vi) The signature of the practitioner who administered the medication and a witness, when issued to surgery.

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

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

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

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

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

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

CHAPTER 12

INSTITUTIONAL PHARMACY PRACTICE REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Purpose.

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

Section 3. Scope of Chapter.

This C~~c~~hapter applies to any person, partnership, corporation, l~~L~~imited l~~L~~iability c~~C~~ompany, or other entity engaging in the practice of pharmacy in an I~~i~~nstitutional F~~f~~acility, as defined below, within this state.

Section 4. Definitions.

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

(b) "Institutional P~~p~~harmacy" means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an I~~i~~nstitutional F~~f~~acility, and which is:

(i) Located within the ~~i~~Institutional F~~f~~acility, or

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

(c) "Drug Room" means a secure and lockable location within an inpatient care facility that does not have an I~~i~~nstitutional P~~p~~harmacy.

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

(e) "Formulary" means a continually revised compilation of pharmaceuticals that reflects the current clinical judgment of the medical staff of the Institutional ~~f~~Facility.

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

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

(h) "Clean Room" means a room with a minimum of an ISO Class 7 environment:

(i) in which the concentration of airborne particles is controlled; ~~and there are one or more clean zones according to Federal Standard 209E.~~

(ii) that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room;

(iii) in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary; and

(iv) in which microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear is not exceeded for a specific cleanliness class.

(i) "Investigational Drug" means:

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

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

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

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

(ii) Entering or transferring medication order data;

(iii) Performing prospective drug use review;

(iv) Obtaining substitution authorizations;

(v) Interpreting and acting on clinical data;

(vi) Performing therapeutic interventions;

(vii) Providing drug information;

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

Section 5. Licensing.

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

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

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

Section 6. Change of Ownership.

(a) If an Iinstitutional Ppharmacy changes ownership, it must obtain a new and separate registration from the Board. In the case of a corporation, limited liability company, or partnership holding an Iinstitutional pPharmacy license, the Board shall be notified and a new license applied for any time the majority of stock in the corporation is sold or a majority of the partners of the partnership or members of the limited liability company change.

Section 7. Personnel.

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

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

(i) ~~Hospitals with 50 or more acute care beds.~~ In hospitals Institutional Facilities with fifty (50) or more acute care beds ~~or more~~, a pharmacist shall be in the hospital Institutional Facility during the time the Institutional Ppharmacy is

open for pharmacy services, except in case of emergencies. Pharmacy services shall be provided for a minimum of forty (40) hours per week, unless an exception is made upon written request by the hospital Institutional Facility and with express permission of the Board.

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

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

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

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

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

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

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

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

(iii) Developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile pharmaceuticals compounded within the I~~i~~nstitutional P~~p~~harmacy;

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

(v) Providing ~~written~~ guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing,

sterilizing, and labeling of sterile pharmaceuticals is not performed under direct Institutional pPharmacy supervision;

(vi) Participating in the development of a Fformulary for the Institutional fFacility, which is approved by the appropriate committee, including the medical staff of the Institutional Facility;

(vii) Developing a system to assure that drugs to be administered to inpatients are distributed pursuant to an original or direct copy of the practitioner's Mmedication Oorder;

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

(ix) Participating in those aspects of the Institutional fFacility's patient care evaluation program, which that relate to pharmaceutical utilization and effectiveness;

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

(xi) Assuring the legal operation of the Institutional pPharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy;. and

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

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

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

(g) The PIC may be assisted by secretarial and clerical assistance as required to assist with record-~~-~~keeping, report submission, and other administrative duties.

Section 8. Environment.

(a) The I~~i~~nstitutional P~~p~~harmacy shall be enclosed and lockable.

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

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

(d) The I~~i~~nstitutional P~~p~~harmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(e) The I~~i~~nstitutional P~~p~~harmacy shall be properly lighted and ventilated.

(f) The temperature of the I~~i~~nstitutional P~~p~~harmacy shall be maintained within a range of 59 to 86 degrees Fahrenheit (15 to 30 degrees Centigrade). The temperature of the refrigerator shall be maintained within a range of 36 to 46 degrees Fahrenheit (2 to 8 degrees Centigrade) and the freezer shall be maintained within a range of –14~~3~~ to ~~–4~~+14 degrees Fahrenheit (-2~~0~~5 to –10 degrees Centigrade).

(g) The I~~i~~nstitutional P~~p~~harmacy shall store antiseptics, other drugs for external use, and disinfectants separately from internal and injectable medications.

(h) If the I~~i~~nstitutional P~~p~~harmacy compounds sterile pharmaceuticals, they shall be prepared in accordance ~~–~~with Wyoming Pharmacy Act, Rules and Regulations, Chapter ~~13, Section 10~~17 ~~of the Board's rules~~.

Section 9. References.

Each I~~i~~nstitutional ~~p~~Pharmacy shall maintain in its library at least one current reference ~~book~~ (text or electronic format, including online access or PDA) from each category listed below. The Board reserves the right to accept new references in lieu of the following:~~.~~

(a) Drug Monograph Reference:

(i) American Hospital Formulary Service® (ISBN: 978-1-58528-227-2);~~AHFS – Drug Information~~

(ii) Drug Facts and Comparisons® (ISBN: 978:0-032686-00-1);~~Drug Facts & Comparison~~

(iii) Thomson's Micromedex®;~~Micromedex or equivalent~~

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

(v) Drug Information Handbook (Lexi-Comp) (978-1-59195-254-1).

(b) Stability and Incompatibility Reference:

(i) Handbook on Injectable Drugs, Lawrence A. Trissel (ISBN: 978-1-58528-213-5);~~Handbook on Injectable Drugs (Trissel)~~

(ii) King Guide to Parenteral Admixtures (ISBN: 0970190220)~~Guide of Parenteral Admixtures (King/Cutter)~~; or

(iii) Thomson's Micromedex®.~~Micromedex or equivalent~~

(c) Reference on Drug Availability and Identification:

(i) American Hospital Formulary Service® (ISBN: 978-1-58528-227-2);~~AHFS- Drug Information~~

(ii) Drug Facts and Comparisons® (ISBN: 978:0-032686-00-1);~~Drug Facts and Comparisons~~

(iii) American Drug Index (ISBN-10: 1-57439-289-1);~~American Drug Index~~ or

(iv) Drug Information Handbook (Lexi-Comp) (978-1-59195-254-1).

(d) Drug Interactions:

(i) American Hospital Formulary Service® (ISBN: 978-1-58528-227-2)~~AHFS – Drug Information~~;

(ii) Thomson's Micromedex®~~Micromedex or equivalent~~;

(iii) Drug Interactions Facts (ISBN: 978: 1-57439-015-5)~~Drug Interactions Facts~~;

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

(v) Drug Information Handbook (Lexi-Comp) (978-1-59195-254-1).

(vi) Drug Interactions Analysis and Management (DIAM) (ISBN: 00-1092-048X).~~Hansten's Drug Interactions Analysis and Management~~

(e) Reference on Pharmacology and Therapeutics:

(i) Conn's Current Therapy (Rakel and Bope) (ISBN-13: 978-1-4160-5974-5)~~Conn's Current Therapy~~;

(ii) Drug Information Handbook (Lexi-Comp) (978-1-59195-254-1).

8125-1)~~Manual of Medical Therapeutics~~;

(iii) Applied Therapeutics: The Clinical Use of Drugs (Koda-Kimble) (ISBN: 978-0-7817-6555-8)~~Applied Therapeutics (Koda-Kimble);~~

(iv) Pharmacotherapy (DiPiro) (ISBN: 978-0-0714-7899-1)~~Pharmacotherapy (DiPiro);~~ or

(v) Textbook of Therapeutics (Herfindal and Gourley) (ISBN: 0-7817-5734-7)~~Textbook of Therapeutics (Herfindal).~~

(f) Current copies of the Wyoming Pharmacy Act and R~~r~~ules and Regulations, and Wyoming Controlled Substance Act and R~~r~~ules and Regulations, text or electronic format, and including internet access to the Board website.

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

Section 10. Equipment.

(a) Institutional pharmacies distributing M~~m~~edication O~~o~~rders shall have the following equipment:

~~(i) Typewriter or comparable equipment;~~

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

(ii~~i~~) Computer and software appropriate for the I~~i~~nstitutional F~~f~~acility; and~~.~~

(iii~~v~~) ~~Fax machine~~Facsimile capability located in the Institutional ~~p~~Pharmacy.

(b) If the I~~i~~nstitutional P~~p~~harmacy compounds M~~m~~edication O~~o~~rders~~, which~~ that require the use of a balance, a Class A prescription balance or electronic scale with 10 mg sensitivity shall be available. Such balance or electronic scale shall be properly maintained by the PIC and may be inspected at least every three (3) years by the Board of Pharmacy.

(c) If the Iinstitutional Ppharmacy compounds sterile pharmaceuticals, the Institutional pPharmacy shall have equipment and supplies listed in Wyoming Pharmacy Act, Rules and Regulations Chapter 13, Section 1017 of the Board's rules.

Section 11. Security.

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

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

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

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

(e) The pharmacist-in-chargePIC shall be responsible for policies and procedures for the safe distribution and control of prescription blanks bearing identification of the hospitalInstitutional Facility.

Section 12. Absence of Pharmacist.

(a) General. During such times as Iinstitutional Ppharmacy services are not available on-site, arrangements shall be made in advance by the Ppharmacist-in-Ccharge (PIC) for provision of drugs to the medical staff and other authorized personnel of the hospital Institutional Facility by use of Ffloor Sstock and/or access to the Institutional pPharmacy under the standing order of the pharmacist-in-chargePIC.

(b) If Ffloor sStock is used, the following shall prevail:

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

(ii) The ~~pharmacist-in-charge~~PIC shall, in conjunction with the appropriate committee, if any, of the I~~i~~nstitutional F~~f~~acility, develop inventory listings of those drugs to be included in such F~~f~~loor S~~s~~tock, and shall e~~i~~nsure that:

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

(B) Such drugs are prepackaged in appropriate small amounts~~, not to exceed thirty dosage units;~~ unless commercially prepared package ~~creates difficulty~~, e.g. ophthalmics, otics, topicals, etc.

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

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

(~~1~~I) The date and time of removal of a drug;

(II~~2~~) The patient's name and location;~~,~~

(III~~3~~) The name, strength, dosage form, and quantity of drug removed; and

(IV~~4~~) The signature of the nurse removing the drug.

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

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

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

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

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

(B) The patient's name and location;

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

(D) The signature of the nurse.

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

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

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

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

(i) The I~~i~~nstitutional ~~p~~Pharmacy shall have a pharmacist on duty at the I~~i~~nstitutional F~~f~~acility the minimum number of hours required in this C~~c~~hapter ~~12~~, Section 7 ~~of the Board's rules~~.

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

(iii) The Board shall be notified in writing by the I~~i~~nstitutional P~~p~~harmacy of any arrangement whereby pharmaceutical care is provided off-site. This notification shall include the following:

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

(B) The name, address, and Wyoming license number of each pharmacy exchanging information with the I~~i~~nstitutional F~~f~~acility.

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

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

(E) Description of patient information that is to be shared between the Institutional ~~f~~Facility and the off-site pharmacist. A~~t~~s ~~a~~ minimum, the off-site pharmacist shall have access to the patient's medical record.

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

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

(A) Review of any new Mmedication Oorder or change in existing Mmedication Oorder prior to administration by the nursing staff at the Iinstitutional Ffacility.

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

(C) The off-site pharmacist shall communicate with the Iinstitutional Ppharmacy staff on a daily basis or, if the Iinstitutional Ppharmacy is not opened on a daily basis, then communication shall occur whenever the Iinstitutional Ppharmacy is open for business.

Section 13. Emergency Outpatient Medication.

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

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

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

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

(C) The quantity of medication administered and distributed is limited to a seventy-two hour (72-hour) supply. Exceptions to the 72-hour supply include: pediatric antibiotic preparations (PO), otitics, ophthalmics, topicals, or metered dose inhalers; and

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

(I1) Name, address, and telephone number of the hospital Institutional Facility;

(II2) Name of patient;

(III3) Name of drug, strength, and quantity;

(IV4) Directions for use;

(V5) Date;

(VI~~6~~) Accessory cautionary information, as required for patient safety;

(VII~~7~~) Name of practitioner; and

(VIII~~8~~) Initials of the nurse administering and distributing the medication.

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

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

(i) Name of patient;

(ii) Date of issuance;

(iii) Name of d~~D~~rug;

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

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

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

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

Section 14. Emergency Drug Carts (c~~C~~rash c~~C~~arts).

Emergency D~~d~~rug C~~c~~arts may be used by ~~hospitals~~ Institutional Facilities if:

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

(b) A committee composed of the P~~p~~harmacist-in-C~~c~~harge, nursing staff, and medical staff of the ~~hospital~~ Institutional Facility develops a standard drug inventory, including kind and quantity of each drug;

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

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

(e) All drugs are properly labeled;

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

(g) The pharmacist, nursing staff, and medical staff develop and implement written policies and procedures for using Eemergency Ddrug Ccarts ~~(crash carts).~~

Section 15. Automated Dispensing Devices.

(a) No drug shall be distributed or issued by the use of any automated dispensing device unless the device and method of operation have been found by the Board to ei~~i~~nsure the purity, potency, and integrity of the drug, and to protect the drug from diversion~~,~~; and provided that:

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

(ii) The device shall be used only for the furnishing of drugs for administration to patients of that Ii~~i~~nstitutional Ff~~f~~acility; and

(iii) At the time of removal of any drug from the device, it shall automatically make a written or electronic record to be retained by the pharmacist for at least one (1) year, indicating:

(A) The date of removal of the drug;

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

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

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

Section 16. Parenteral Medications.

(a) The Pp~~p~~harmacist-in-Cc~~c~~harge (PIC) shall be responsible for the preparation, sterilization, labeling, and dispensing of parenteral medications prepared within the Ii~~i~~nstitutional Ff~~f~~acility~~;~~ and shall participate in the education and training,

including the provision of appropriate incompatibility information, of all personnel involved in the preparation of parenteral medications.

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

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

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

Section 17. Practitioner's Orders.

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

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

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

Section 18. Dispensing.

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

Section 19. Investigational Drugs and Protocols.

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

(b) A copy of all Iinvestigational Ddrug protocols shall be on file in the Institutional pPharmacy.

Section 20. Inspections.

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

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

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

(c) Thermolabile drugs are stored at the proper temperature;

(d) There are no outdated or deteriorated drugs;

(e) All drugs are properly labeled;

(f) Emergency Ddrug Ccarts (crash carts) are adequate and in proper supply;

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

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

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

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

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

Section 21. Medications brought into the institution by patients.

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

Section 22. Controlled Drugs.

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

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

(ii) The date and time of administration;

(iii) The quantity administered;

(iv) Name of patient;

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

(vi) The signature of the practitioner who administered the medication and a witness, when issued to surgery.

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

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

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

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

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

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

Chapter 8, WY Pharmacy Act, Rules and Regulations

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Purpose.

The purpose of this regulation is to provide for the minimum licensing standards necessary to ensure the safety and efficacy of prescription drugs offered for sale by manufacturers and wholesale distributors.

Section 3. Scope.

This Chapter applies to any person, partnership, corporation or business engaging in the wholesale distribution of human prescription drugs either into, out of, or within this State.

Section 4. Definitions.

(a) "Adulterated" means a drug shall be deemed adulterated if:

(i) It consists in whole or in part of any filthy, putrid, or decomposed substance; or

(ii) It has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to assure that the drug meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or

(iii) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(iv) It bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of the Federal Food, Drug and Cosmetic Act (Federal Act); or it is a color additive, the intended use of which is for purposes of coloring only, and is unsafe with the meaning of the Federal Act.

(b) "Authenticate" means to affirmatively verify before any wholesale distribution of a prescription drug takes place that each transaction listed on the Pedigree has occurred, in accordance with this Chapter.

(c) "Authorized Distributor of Record" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

(i) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and

(ii) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which must be updated by the manufacturer on no less than a monthly basis.

(d) "Chain Pharmacy Warehouse" means a permanent physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs to chain pharmacies under common ownership and control. Chain pharmacy warehouses must be licensed as wholesale distributors.

(e) "Co-licensee" means an instance where two or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with the FDA's implementation of the Prescription Drug Marketing Act.

(f) "Counterfeit Drug" means a drug, the container, shipping container, seal, or product labeling which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, distributed, or wholesale distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed, distributed, or wholesale distributed by such other manufacturer, processor, packer, or distributor.

(g) "Drop Shipment" means the sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third-party logistics provider, that manufacturer's exclusive distributor, or an authorized distributor of record that purchased the product directly from the manufacturer to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug. That wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer a drug to a patient. The pharmacy, chain pharmacy warehouse, or other authorized person may receive delivery of the prescription drug directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third-party logistics provider, that manufacturer's exclusive distributor, or an authorized distributor of record. Drop shipments shall be part of the "Normal Distribution Channel".

(h) "Drug sample" means a unit of a prescription drug that is not intended to be sold but is intended to promote the sale of the drug.

(i) "Manufacturer" means a person licensed or approved by the FDA to

engage in the manufacture of prescription drugs consistent with the FDA definition of "manufacturer" under the FDA's regulations and interpretive guidances implementing the Prescription Drug Marketing Act, including any amendments thereto.

(j) "Manufacturer's Exclusive Distributor" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have a general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor must be licensed as a wholesale distributor under this Chapter, and to be considered part of the "normal distribution channel" must also be an "authorized distributor of record".

(k) "Normal Distribution Channel" means a chain of custody for a prescription drug that goes, directly or by drop shipment, from a manufacturer, the manufacturer's co-licensee, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

(i) an authorized distributor of record and, subsequently, to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(ii) an authorized distributor of record, then to a chain pharmacy warehouse and, subsequently, to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(iii) a chain pharmacy warehouse and, subsequently, to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(iv) an authorized distributor of record and, subsequently, to other authorized distributors of record who subsequently distribute to an office-based healthcare practitioner authorized by law to dispense or administer such drug to a patient; or

(v) a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient.

(l) "Prescription drug" means any drug required to be dispensed only by a prescription, by State law or regulations or by Federal law or regulations, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act.

(m) "Third Party Logistics Provider" means an entity that:

(i) Provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition; and

(ii) Is licensed as a wholesale distributor under this Chapter.

(iii) To be considered part of the “normal distribution channel” must also be an “authorized distributor of record”.

(n) "Wholesale Distribution" means the distribution of prescription drugs by wholesale distributors to persons other than consumers or patients, and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the value of the goods transferred exceeds five percent (5%) of total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve (12) month period. Wholesale distribution does not include:

(i) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug pursuant to a prescription;

(ii) The sale, purchase, or trade of a prescription drug or the offer to sell, purchase, or trade a prescription drug by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(iii) The lawful distribution of drug samples by manufacturers’ representatives or distributors' representatives;

(iv) The sale, purchase, or trade of blood and blood components intended for transfusion;

(v) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between co-licensees of a co-licensed product;

(vi) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use;

(vii) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals, chain pharmacy warehouses, pharmacies, or other health care entities that are under common control;

(viii) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with board regulations;

(ix) The return of recalled, expired, damaged, or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, chain pharmacy warehouses or charitable institution in accordance with board regulations;

(x) The transfer of prescription drugs between pharmacies pursuant to a centralized prescription processing agreement;

(xi) Sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons, as defined under 21 CFR 203.3(m), including any

amendment thereto. For purposes of this section “emergency medical reasons” includes transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;

(xii) Sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record during a time period for which there is documentation from the manufacturer that the manufacturer is unable to supply a prescription drug;

(xiii) Delivery of a prescription drug by a common carrier; or

(xiv) The sale or transfer from a pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, original wholesale distributor, or to a third party returns processor or reverse distributor.

(o) "Wholesale Distributor" means anyone engaged in wholesale distribution of prescription drugs in or into the State, including but not limited to, manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy warehouses and wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distributions.

Section 5. Wholesale Distributor Licensing Requirement.

Every wholesale distributor, wherever located, who engages in wholesale distribution into or within this State shall be licensed by the board in accordance with the laws and regulations of this State before engaging in wholesale distribution of prescription drugs.

(a) The board shall require the following minimum information from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

(i) All trade or business names used by the licensee (includes “is doing business as” and “formerly known as”), which cannot be identical to the name used by another unrelated wholesale distributor licensed to purchase/distribute prescription drugs in the State;

(ii) Name(s) of the owner and operator of the licensee (if not the same person), including:

(A) If a person: the name, business address, social security number, and date of birth;

(B) If a partnership: the name, business address, and social security number and date of birth of each partner, and the name of the partnership and federal employer identification number;

(C) If a corporation: the name, business address, social security number, date of birth, and title of each corporate officer and director; the corporate names, state of incorporation, federal employer identification number, and name of the parent company, if any; the name, business address, and social security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC;

(D) If a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity; and

(E) If a limited liability company: the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized.

(iii) Name(s), business address(es), and telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the wholesale distributor that engages in the wholesale distribution of prescription drugs. The board shall be notified of each change in designated representative within 30 days of the change. Effective January 1, 2009 fingerprints and a fifty dollar ($50.00) fee must be submitted for each designated representative for a criminal background history and with each change in designated representative;

(iv) A list of all state and federal licenses, registrations, or permits, including the license, registration, or permit numbers issued to the wholesale distributor by any other state and federal authority that authorizes the wholesale distributor to purchase, possess, and wholesale distribute prescription drugs;

(v) A list of all disciplinary actions by state and federal agencies against the wholesale distributor as well as any such actions against principals, owners, directors, or officers;

(vi) A full description of each facility and warehouse, including all locations utilized for prescription drug storage and/or wholesale distribution. The description shall include the following:

(A) Square footage;

(B) A general description of security and alarm systems;

(C) Terms of lease or ownership;

(D) Address; and

(E) Temperature and humidity controls in accordance with Section 11 below.

(vii) A copy of the deed for the property on which the wholesale distributor's establishment is located, if the property is owned by the wholesale

distributor; or a copy of the wholesale distributor's lease for the property on which the establishment is located which has an original term of not less than one (1) calendar year (if the establishment is not owned by the wholesale distributor);

(viii) Information regarding general and product liability insurance, including copies of relevant policies;

(ix) A description of the wholesale distributor's drug import and export activities;

(x) An electronic copy of the wholesale distributor's written policies and procedures as required by this Chapter. (See Section 15(a) through (h).)

(xi) The applicant shall provide, and attest to, a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding prescription drugs or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

(xii) The information collected pursuant to Section 5(a)(vi) and (x) shall be made available only to the board, a third party recognized by the board, and to state and federal law enforcement officials. The board shall make provisions for protecting the confidentiality of the information collected under this section.

(b) Effective January 1, 2009 all current wholesale distributor licensees and all applicants for licensure as a wholesale distributor must submit security in the amount of $100,000 to the board. Acceptable forms of security include:

(i) "Surety" bond naming the board as the payee; or

(ii) Irrevocable letter of credit naming the board as the payee; or

(iii) Funds deposited in a trust account or financial institution naming the board as the payee.

The purpose of these funds will be to secure payment for any administrative penalty assessed by the board, which remains unpaid thirty days after the liability for the payment is final. A separate bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their wholesale distributor license with the board. The board will waive the security requirement, if the wholesale distributor:

(i) has previously obtained a comparable bond or other comparable security for the purpose of licensure in another state provided the board is named as a payee; or

(ii) is a publicly held company.

(c) Effective January 1, 2010, all wholesale distributors licensed by the board and all applicants for licensure must provide evidence of VAWD® accreditation from the National Association of Boards of Pharmacy or from another third party recognized by

the board to inspect and accredit wholesalers and must undergo the re-accreditation process no less than every three (3) years after initial accreditation. Manufacturing facilities are exempt from this requirement provided the manufacturing facilities are currently registered with the FDA in accordance with Section 510 of the Federal Act.

(i) Any applicant that is denied accreditation described under this section shall have the right of review of the accreditation body's decision, by:

(A) The accreditation body; and

(B) The board.

(ii) The recognized accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.

(iii) Individual or third party inspectors must demonstrate to the board that they have received training or demonstrate familiarity with the inspection standards. A letter of certification from a training program, a notice from the inspector's employing third party organization, or other means recognized by the board shall be accepted as meeting the requirement.

(d) The board may license by reciprocity a wholesale distributor that is licensed under laws of another state, if:

(i) The requirements of that state are deemed by the board to be substantially equivalent; or

(ii) The applicant is accredited by a third party recognized by the board. An applicant that is accredited by a third party recognized and approved by the board shall not be subject to duplicative requirements set by the board.

(e) Where operations are conducted at more than one location by a single wholesale distributor, each location shall be licensed by the board.

(f) Changes in any information required by this Section shall be submitted to the board within thirty (30) days after the change.

(g) Any applicant denied licensure by the board shall have the right of timely review and appeal as authorized by the Wyoming Administrative Procedure Act.

Section 6. Minimum Qualifications.

(a) The board shall consider the following factors in determining eligibility for licensure of persons or firms who engage in the wholesale distribution of prescription drugs:

(i) Any criminal convictions, except minor traffic violations, or civil penalties of the applicant under any federal, state or local laws;

(ii) Any findings by the board that the applicant has violated, or been

disciplined by a regulatory agency in any state for violating, any federal, state, or local laws relating to wholesale drug distribution;

(iii) The applicant's past experience in the manufacture or distribution of prescription drugs;

(iv) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(v) Suspension, sanction, or revocation by federal, state or local government against any license currently or previously held by the applicant or any of its owners for violations of state or federal laws regarding prescription drugs;

(vi) Compliance with previously granted licenses related to wholesale distribution of prescription drugs;

(vii) Compliance with the requirements to maintain or make available to the board or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors; and

(viii) Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

Section 7. Personnel.

(a) Each person that is issued an initial or renewal license as a wholesale distributor, whether in state or out of state, must designate in writing on a form required by the board, a person for each facility to serve as the designated representative.

(b) To be certified as a designated representative, a person must:

(i) Submit an application on a form furnished by the board and provide information that includes:

(A) Fingerprint cards and fee for a criminal background history;

(B) Date and place of birth;

(C) Occupations, positions of employment, and offices held during the past seven (7) years;

(D) Principal business and address of any business corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;

(E) Whether the person, during the past seven (7) years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or wholesale distribution of prescription drugs, together with details of such events;

(F) Description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly

traded company or mutual fund, during the past seven (7) years, which manufactured, administered, prescribed, wholesale distributed, or stored prescription drugs in which such businesses were named as a party in a lawsuit;

(G) Description of any felony criminal offense, or any offense (misdemeanor or felony) involving moral turpitude, or any offense related to the qualifications, functions or duties of that person in connection with the operation of the wholesaler, of which the person, as an adult, was found guilty, regardless of whether adjudication of guilty was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 30 days after the disposition of the appeal, submit a copy of the final written order of disposition to the board;

(H) Passport type and size of photograph of the person taken within the previous year;

(ii) Have a minimum of two years of verifiable full-time managerial or supervisory experience in a pharmacy or wholesale distributor license in this State or another state, where the person's responsibilities included but were not limited to recordkeeping, storage, and shipment of prescriptions drugs;

(iii) May serve as the designated representative for only one wholesale distributor at any one time, except where more than one licensed wholesale distributor is co-located in the facility and such wholesale distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code;

(iv) Be actively involved in and aware of the actual daily operations of the wholesale distributor:

(A) Employed full-time in a managerial position by the wholesale distributor;

(B) Physically present at the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and

(C) Aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor.

Section 8. General Minimum Requirements for Facilities Storing and Handling of Prescription Drugs.

The following are required for the storage, handling, transport, and shipment of prescription drugs.

(a) All facilities at which prescription drugs are received, stored, warehoused, handled, held, offered, marketed, transported from or displayed shall:

(i) Be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

(ii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

(iii) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution or wholesale distribution, or that are in immediate or sealed secondary containers that have been opened prior to receipt by the wholesale distributor in accordance with Section 12 below;

(iv) Be maintained in a clean and orderly condition;

(v) Be free from infestation of any kind;

(vi) Be a commercial location and not a personal dwelling or residence;

(vii) Provide for the secure storage of information with restricted access and policies and procedures to protect the integrity of the information;

(viii) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs; and

(ix) Provide to another wholesale distributor or pharmacy, written or electronic pedigrees for prescription drugs that leave the normal distribution channel in accordance with Section 10 below.

Section 9. Security and Anti-Counterfeiting.

(a) Facility Security. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be adequately controlled;

(ii) The outside perimeter of the premises shall be adequately lighted;

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel;

(iv) All facilities shall be equipped with an alarm system to detect unauthorized entry after hours; and

(v) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(b) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting.

(c) Wholesale distributors engaged in wholesale distribution shall be equipped with security measures to protect the integrity of data and documents and make such data and documents readily available to the board and other state and federal law enforcement officials.

Section 10. Pedigrees.

(a) Pedigrees shall be required for wholesale distribution of prescription drugs that leave or have ever left the normal distribution channel. Each person who is engaged in wholesale distribution of prescription drugs that leave, or have ever left, the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug. A retail pharmacy or pharmacy intracompany warehouse shall comply with the requirements of this section only if the pharmacy engages in wholesale distribution of prescription drugs.

(b) The contents of each pedigree shall:

(i) Include all necessary identifying information concerning each sale in the chain of ownership of product from the manufacturer (or the manufacturer's third-party logistics provider/co-licensed product partner/manufacturer's exclusive distributor) through acquisition and sale by any wholesale distributor or repackager until final sale to a pharmacy or other person furnishing, dispensing, or administering drug. At a minimum, the necessary chain of ownership information shall include:

(A) Name, address, telephone number, and, if available, the email address of each owner of the prescription drug, and each wholesale distributor of the prescription drug;

(B) Name and address of each location from which the product was shipped, if different from the owner's;

(C) Transaction dates; and

(D) Certification from the designated representative that each recipient has authenticated the pedigree.

(E) A certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate (under penalty of perjury).

(ii) At a minimum, the pedigree shall also include the

(A) Name of the prescription drug;

(B) Dosage form and strength of the prescription drug;

(C) Size of the container;

(D) Number of containers;

(E) Lot number and the National Drug Code of the prescription

drug; and

(F) Name of the manufacturer of the finished dosage form.

(iii) Each pedigree or electronic file shall be maintained consistent with 21 CFR 203.60, including any amendments thereto.

(c) Wholesale distributors engaged in wholesale distribution and manufacturers from whom wholesale distributors have acquired prescription drugs shall cooperate with pedigree authentication efforts and provide the requested information in a timely manner.

(d) Each wholesale distributor engaged in wholesale distribution that has distributed a prescription drug for which an acquiring wholesale distributor is conducting a pedigree authentication, shall provide to the acquiring wholesale distributor, upon request, detailed information regarding its acquisition of the prescription drug.

(e) If the wholesale distributor attempting to authenticate the pedigree of the prescription drug is unable to authenticate the pedigree, the wholesale distributor shall quarantine the prescription drug and file a report, as defined by the board, with the board within three (3) business days after completing the attempted prescription drug pedigree authentication;

(f) If the wholesale distributor attempting to authenticate the pedigree of the prescription drug is able to authenticate the pedigree, the wholesale distributor shall maintain records of the authentication for two (2) years, and shall produce them to the board upon request.

(g) Wholesale distributors and manufacturers shall maintain an ongoing list of persons with whom they purchase or sell prescription drug products.

Section 11. Storage of Prescription Drugs.

(a) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the product labeling of such prescription drugs, or with requirements in the current edition of an official compendium such as the USP-NF.

(b) If no storage requirements are established for a prescription drug, the prescription drug may be held at "controlled" room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(c) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of prescription drugs.

Section 12. Examination of Materials.

(a) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit or contraband, or damaged prescription drugs or prescription drugs that are otherwise unfit for wholesale distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, contraband, suspected of being counterfeit or contraband, or other damage to the contents.

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

(c) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

Section 13. Returned, Damaged, and Outdated Prescription Drugs.

(a) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or other persons authorized to administer or dispense drugs or for a pharmacy's intracompany warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy. Returns of expired, damaged, recalled, or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesale distributor only to either the original manufacturer or a third party returns processor. The returns or exchanges of prescription drugs (saleable or otherwise), including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of this Chapter, so long as they are exempt from the pedigree requirement of the FDA's currently applicable Prescription Drug Marketing Act. Both licensees under this Chapter and pharmacies for other persons authorized by law to administer or dispense drugs shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit products into the marketplace.

(b) Appropriate documentation shall be made to the pedigree if any prescription drug that was ordered in excess of need by the wholesale distributor from a source outside the normal distribution channel, if identified as such, and which the integrity has been maintained, that is returned to the manufacturer or wholesale distributor from which it was acquired after which the wholesale distributor shall abide by the provisions of these regulations that govern returned, damaged and outdated prescription drugs.

(c) Any prescription drug that is ~~outdated,~~ damaged, deteriorated, misbranded, counterfeit, contraband, suspected of being counterfeit or contraband, adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically

separated from other prescription drugs until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired or to a third party returns processor. Notice of prescription drugs identified under this paragraph shall be given to the board and manufacturer or wholesale distributor from which they were acquired within three (3) business days of identification.

(d) Any prescription drug whose immediate or sealed outer or secondary containers or product labeling are adulterated, misbranded, counterfeited, contraband, or suspect of being counterfeit or contraband shall be quarantined and physically separated from other prescription drugs until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired. Notice of prescription drugs identified under this paragraph shall be given to the board and manufacturer or wholesale distributor from which they were acquired or to a third party returns processor within three (3) business days of identification.

(e) If the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality, or purity, then the prescription drug shall be destroyed or returned to the supplier unless examination, testing, or other investigation proves that the prescription drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a prescription drug has been returned cast doubt on the prescription drug safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the prescription drug has been held, stored, or shipped before or during its return and the condition of the prescription drug and its container, carton, or product labeling as a result of storage or shipping.

(f) Contraband, counterfeit, or suspected to be counterfeit or contraband drugs, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the board and the FDA.

(g) The shipping, immediate, or sealed outer or secondary container or product labeling, and accompanying documentation, suspected of or determined to be counterfeit, contraband, or otherwise fraudulent shall not be destroyed until its disposition is authorized by the board and the FDA.

(h) The recordkeeping requirements of this Chapter shall be followed for all outdated, damaged, deteriorated, counterfeit, contraband, misbranded, or adulterated prescription drugs.

Section 14. Electronic Track and Trace Requirements.

(a) Electronic track and trace requirements shall not be considered as a requirement until such time as the FDA implements a uniform electronic track and trace system utilizing widely accepted standard technology that is universally available to manufacturers, wholesalers, and pharmacies and is technically and operationally feasible and reliable for manufacturers, wholesale distributors and pharmacies.

(b) After the FDA has implemented a uniform and universally available standard for an electronic track and trace system to initiate, provide, receive, or maintain pedigrees, the board shall consult with manufacturers, wholesales distributors, and pharmacies and prepare a report before adopting any rules to implement such electronic track and trace system and imposing such requirements on all manufacturers, wholesaled distributors and pharmacies. Implementation of the FDA's standards shall satisfy the requirements under section 10 of this Chapter.

Section 15. Policies and Procedures.

Wholesale distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, shipping, and wholesale distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors shall include in their written policies and procedures the following:

(a) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the FDA or any other federal, state, or local law enforcement or other governmental agency, including the board of pharmacy; or

(ii) Any volunteer action by the manufacturer to remove defective or potentially defective prescription drugs from the market.

(b) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, natural disaster, or other situations of local, state, or national emergency.

(c) A procedure to ensure that any outdated prescription drugs shall be segregated from other prescription drugs and either returned to the manufacturer or third party return processor or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs.

(d) A procedure for the destruction of outdated prescription drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of two (2) years, and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements.

(e) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of two (2) years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(f) A procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within ten (10) business days to the board and/or appropriate federal or state agency upon discovery of such discrepancies.

(g) A procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drugs to the board, FDA, and, if applicable, DEA, within three (3) business days.

(h) A procedure for conducting authentication of pedigrees in accordance with this Chapter.

CHAPTER 3

PHARMACY INTERNSHIP REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by t~~T~~he Act.

Section 2. Interns in Pharmacy.

(a) "Intern" means any person who:

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

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

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

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

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

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

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

(d) ~~A license issued to an~~ Intern registration shall expire ~~one year from the date of its issuance~~annually on September 30. However, ~~the license~~registration may be renewed on or before

~~the date of expiration~~September 30, ~~or the date of expiration of any renewal~~ for a period of one (1) year. Registrants may not renew for multiple years. The fee for renewal of Intern registration shall be fifteen dollars ($15.00). An I~~i~~ntern ~~license~~ registration may not be renewed beyond twenty-four (24) months from the date of graduation from an approved school or college of pharmacy where the initial degree in pharmacy was obtained, unless a waiver is obtained from the B~~b~~oard. ~~The fee for renewal of Intern license shall be $15.00. The place of employment and the name of the registered pharmacist serving as the preceptor of the Intern shall be supplied to the Board.~~

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

(f) Internship credit hours shall not be approved by the Board unless all requirements of this Chapter are ~~adhered to~~met by the~~an~~ Intern.

Section 3. Internship Training Requirements.

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

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

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

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

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

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

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

Section 4. Intern Training.

(a) Interns shall, under the direct supervision of the preceptor pharmacist:

(i) Fill prescriptions, including I.V. orders, and comment on any unusual

prescriptions. ~~The~~ Interns shall evaluate prescriptions as to drug, dose, and therapeutic effect. This evaluation may be submitted in written form or discussed orally with the preceptor pharmacist.

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

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

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

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

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

(vii) Make the offer to counsel and provide counseling to patients regarding prescription drugs and over-~~-~~the-~~-~~counter drug products.

(viii) Accept verbal medication orders from a prescribing practitioner.

(ix) Transfer prescriptions, as provided in Board Rules and Regulations Chapter 2, Section 10 ~~of the Board's rules~~.

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

(xi) Become familiar with drug therapy management, including communicating with health care providers and patients regarding drug therapy management.

(xii) Become familiar with pharmacy record-keeping requirements.

Section 5. Preceptor Pharmacist Rules.

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

(b~~a~~) ~~Any~~ A preceptor pharmacist ~~serving as a preceptor for pharmacy interns in Wyoming~~ shall register with the Board by application provided by the Board. The initial registration fee and renewal fee shall be ten dollars ($10.00). Preceptor pharmacist registrations shall expire ~~every two years from the date issued~~annually on December 31. ~~Renewal notices will be mailed by the Board the month preceding the date of expiration.~~

(c~~b~~) Upon application to the Board and fee payment ~~of fee~~, a certificate shall be issued to the preceptor pharmacist identifying the preceptor pharmacist and pharmacy.

~~(c) A preceptor pharmacist shall be licensed in this State and active in the profession for a minimum of two years.~~

(d) The preceptor pharmacist shall instruct the Intern in the necessity of the strict

observance of the Code of Ethics of the pharmacy profession; shall assist the Intern in the performance of professional services so as to enhance the professional ability of the Intern; and shall train the Intern to become oriented in every phase of pharmacy practice, including those topics identified in Section 4 of this Chapter.

(e) A preceptor pharmacist shall not supervise more than two (2) pharmacy Ii~~i~~nterns at any one time.

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

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

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

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

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

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

(ii) f~~F~~or the purpose of research, teaching, or chemical analysis;~~,~~ or

(iii) i~~I~~n anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

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

(g) "Confidential information" means information maintained by the pharmacist in the patient's records, or ~~which is~~ 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.

(h) "Consultant pharmacist" ~~shall~~ means a pharmacist who establishes policies and procedures for the distribution and storage of drugs and visits the facility on a regularly scheduled basis, but is not physically present at the facility for a set number of hours on a daily basis.

(i) "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.

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

(k) "Digital signature" means an electronic identifier that:

(i) is intended by the party using it to have the same force and effect~~s~~ 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 ~~of Pharmacy laws, r~~Rules and Regulations.

(l) "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. ~~to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery~~

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

(n) "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.

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

(p) "Drug therapy management" means the review of drug therapy regimen(s) of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing physician regarding adjustment of the regimen. Decisions involving drug therapy management shall be made in the best interest of the patient. Drug therapy management may include:

(i) Implementing, modifying, and managing drug therapy according to the terms of the collaborative practice agreement and the specific written orders.~~;~~

(ii) Collecting and reviewing patient drug histories.~~;~~

(iii) Obtaining and checking vital signs including, but not limited to, pulse, temperature, blood pressure, and respiration.~~; and~~

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

(q) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a prescription and executed or adopted by a person with the intent to sign the prescription.

(r) "Electronic transmission" means 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 transmission of the electronic representation of

information from one computer or other similar electronic device to a fax machine, which is authenticated by an electronic signature.

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

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

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

(v) "Patient confidences", as used in W.S. § 33-24-101(c)(iii), means information transmitted by the prescribing practitioner or agent to the pharmacist or agent for purposes of treating the patient and information transmitted by the patient or agent to the pharmacist or agent for purposes of treatment, and includes the patient's name, address, medical condition, and drugs lawfully prescribed for ~~him~~the patient. ~~Provided however t~~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.

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

(x) "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure, ~~or~~ prevention, or management of an illness or injury.

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

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

~~**Note: Two definitions of pharmacy:**~~

(aa) ~~**(formerly definitions paragraph mm)**~~ "Pharmacy" means an area(s) where prescriptions are filled, counseling occurs, prescription drugs are stored, and patient records and other items required by law for the practice of pharmacy are maintained.

~~(aa) **(formerly definitions paragraph u)** "Pharmacy" means any place within this State where drugs are dispensed and pharmaceutical care is provided.~~

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

(cc) "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.

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

(ee) "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 prescription";

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

(iii) "Rx Only"; or

(iv) is a drug included on the Wyoming Dangerous Substance Listing, as referenced in Wyoming Pharmacy Act Rules and Regulations, Chapter 11, Section 2, and shall be dispensed pursuant to a prescription drug order.

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

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

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

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

(jj) "State Board", as used in W.S. § 33-24-136(b), shall mean the ~~state~~ 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 of the United States of America.

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

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

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

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

(oo) "Wholesale distributor" means any person or firm engaged in wholesale distribution of drugs ~~,~~ including, but not limited to, a manufacturer~~s~~; repackager~~s~~; own-label distributor~~s~~; private-label distributor~~rs~~; third-party logistics provider; jobber~~s~~; broker~~s~~; warehouse~~s~~, including manufacturers' and distributors' warehouses, chain drug warehouse~~s~~ and wholesale drug warehouses; independent wholesale drug trader~~;s~~ and any retail pharmac~~yies~~ that conducts wholesale distribution~~s~~.

Section 5. Pharmacist Licensure by Examination.

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

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

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

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

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

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

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

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

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

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

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

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

(v) Complete all requirements within two (2) years of the date of application to the Board's office; and,.

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

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

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

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

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

(iii) Pass the Multi--State Pharmacy Jurisprudence Examination (MPJE®™) for Wyoming with a minimum score of 75.;

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

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

(iv) Meet tThe required practical experience requirement of 1,2,000 internship hours is met, as specified in Chapter 3 of the Board's Rules and Regulations.;

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

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

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

(d) No candidate will be licensed until the required practical experience, as specified in Chapter 3, Section 3(a) of the Board's Rules and Regulations, has been met.

(e) Candidates failing to meet all requirements within the time period allowed in this Chapter 2, Section 5(b), (c), and (v), and Chapter 2, Section 5(c)(v) must file a new application, including payment of all fees or, if applicable, seek licensure by license transfer, as outlined in this Chapter 2, Section 6.

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

(g) The Board shall charge fees to cover administrative costs, which shall include one (1) wall certificate, a renewal certificate for current license year, and those costs associated in reviewing test questions for the jurisprudence examination (MPJE®™).

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

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

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

(iii) Obtaining a total score of 550 or higher on the paper-based Test of English as a Foreign Language (TOEFL®), or 213 or higher on the computer-based TOEFL®, and 50 or higher on the Test of Spoken English™ (TSE®); or

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

Section 6. Pharmacist Licensure by Reciprocal License Transfer.

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

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

(i) File all appropriate applications with the Board;

(ii) Pay the required **application** fee;

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

(iv) Pay the required criminal background check fee;

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

(~~iv~~**i**) Prove good moral character;

(vi**i**) Prove they have been in active pharmacy practice, as defined in this Chapter, ~~2,~~ Section 4(a~~oo~~), for the year preceding the date of their application for license transfer. Applicants failing to show proof must complete an internship in Wyoming approved by the Board of no less than four hundred (400) hours. ~~An applicant will be considered as successfully completing the internship if the overall score given by the preceptor, utilizing the Wyoming State Board of Pharmacy's "Intern Evaluation Report" is no less than a "C";~~

(vi) Meet all requirements under the Act and the Board~~'s~~ Rules and Regulations; ~~and~~

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

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

(~~c~~**d**) The Board shall not issue a pharmacist license by license transfer until all conditions under this Chapter ~~2~~, Section 6~~-~~(b), ~~-~~have been met.

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

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

(~~a~~**g**) In the event of rejecting an application, the fees paid to the Board will not be refunded.

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

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

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

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

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

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

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

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

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

(A) Current Wyoming pharmacy laws;

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

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

(D) Wyoming State Board of Pharmacy News, maintained in a binder; ~~and~~

(E) The current edition, with supplements, of the U.S. Food and Drug Administration (FDA) "orange book" or an alternate reference that provides the same information as the FDA "orange book".

(viii) Pharmacies must maintain adequate security to deter theft of drugs by personnel or public. Security requirements for new or remodeled pharmacies must meet the requirements of this Chapter ~~2~~, Section 7~~-~~(b)(ii)(D). No person other than the pharmacist, intern, or technician employed by the pharmacy shall be permitted in the pharmacy without the express consent of the Pharmacist-in-Charge.

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

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

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

(xi) ~~A sequential numbering machine or electronic data device for the~~Consecutive numbering of all prescriptions must be maintained, along with appropriate printing equipment to produce prescription drug labels.

(xii) In addition to the requirements identified in this Chapter ~~2~~, Section 7~~-~~(a) of these Rules and Regulations, all pharmacies involved in the preparation of sterile compounded products must meet the requirements of Chapter 17~~3, Section 10~~ of the Board~~'s~~ Rules and Regulations.

(b) In addition to the requirements of this Chapter ~~2~~, Section 7, except for a change of ownership of an existing pharmacy, an individual or business who opens a new pharmacy or remodels an existing pharmacy after July 1, ~~2001~~ 2010 shall meet the following requirements~~:~~.

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

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

(A) The pharmacy shall consist of no less than ~~2~~500 square feet.~~;~~

(B) The pharmacy shall include an identified counseling area, which is apart from the cash register, and offers sufficient privacy for counseling. Pharmacies~~, which~~ that do not provide prescription services to "walk-in" customers~~,~~ are not required to have a counseling area.~~;~~

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

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

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

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

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

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

(c) Upon written request, and for good cause, the Board may waive any of the requirements of this Chapter 2, Section 7. A waiver that is granted under this Section shall only be effective when issued by the Board in writing.

Section 8. Licensing of Facilities.

(a) Prior to the issuing of the registration to operate a pharmacy or prescription department in Wyoming, the Board will inspect the pharmacy for minimum standards including space, fixtures, sanitation, reference library, technical equipment, and security.

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

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

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

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

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

(f) The Board shall be notified in writing of a pharmacy change in address. The new location shall be inspected by the Board prior to issuance of an amended pharmacy license for the new location. The new location must meet all requirements for a new or remodeled pharmacy, as noted in this Chapter ~~2~~, Section 7 ~~of the board's rules.~~.

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

Section 9. Pharmacist-in-Charge.

Every licensed pharmacy must be in the continuous daily charge of a ~~registered~~ pharmacist. A pharmacist shall be designated as the Pharmacist-in-Charge and shall have direct control of the pharmaceutical affairs of said pharmacy. A pharmacist may not serve as the Pharmacist-in-Charge unless said pharmacist is physically present in the pharmacy a minimum of thirty-two (32) hours per week, every week, or eighty (80) percent of the time the ~~store~~ pharmacy is open, if opened less than forty (40) hours per week.

A pharmacist may not serve as Pharmacist-in-Charge (PIC) for more than one pharmacy at any one time. The name of the PIC~~harmacist-in-charge~~ shall be designated o~~i~~n the application of the pharmacy for license and in each renewal thereof. A pharmacist may seek a waiver from the Board to serve as a PIC~~pharmacist-in-charge~~ for more than one pharmacy, provided those requirements for number of hours physically present in the pharmacy are met.

It shall be the responsibility of the person, partnership, firm, or corporation holding a pharmacy license to notify the Board immediately of the disability for a period exceeding thirty (30) days of the Pharmacist-in-Charge and a new Pharmacist-in-Charge shall be designated.

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

(b) Responsibility as the Pharmacist-in-Charge (PIC) includes requiring that all federal and State pharmacy laws and regulations are complied with and enforced. It shall be the duty of the ~~pharmacist-in-charge~~PIC to report all pharmacy violations within their facility to the Board~~. Provided however~~, with the single exception that, whenever a ~~pharmacist-in-charge~~PIC or staff pharmacist reports a pharmacist or p~~h~~armacy technician to the Wyoming Professional Assistance Program (W~~.~~P~~.~~A~~.~~P~~.~~) 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 W~~.~~P~~.~~A~~.~~P shall be reported to the Board.

(c) Additional responsibilities of the Pharmacist-in-Charge shall be to:

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

(ii) Supervise the professional employees of the pharmacy.

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

(iv) Establish and supervise the record–keeping for and security of all pharmaceuticals.

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

(vi) Ensure that all staff, i.e.,~~:~~ registered pharmacists, interns, pharmacy technicians-in-training, and ~~certified~~ registered pharmacy technicians, have valid licenses or registrations in good standing, and that all certificates are on display.

(vii) Ensure that all pharmacy licenses, including State and federal controlled substances registrations, are valid and posted.

(viii) Develop and implement a procedure for drug recall.

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

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

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

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

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

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

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

(d) Every pharmacy shall have at least one registered pharmacist on duty and physically present in the pharmacy area at all times that the prescription department is open for the transaction of business.

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

(e) No pharmacy shall be permitted to operate without a Pharmacist-in-Charge (PIC). The Board shall be notified in writing of any newly designated ~~pharmacist-in-~~

~~charge~~PIC. The Board shall record the PIC change and issue an amended ~~corrected copy of the~~ license.

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

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

(a) A pharmacist will transfer prescription order information upon request of a patient. A pharmacist may transfer prescription order information for the purpose of refilling a prescription subject to the following requirements. The information is communicated directly by one pharmacist to another pharmacist, or the information may be electronically transferred between pharmacies. Pharmacies electronically transferring information must satisfy all information requirements of a transferred prescription ~~which~~ that is communicated directly by one pharmacist to another pharmacist, including those requirements as identified in W.S. § 33-24-136a.

(b) The transferring pharmacist shall:

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

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

(A) His/her name;

(B) The name of the receiving pharmacist;

(C) The name of the receiving pharmacy;

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

(E) The date of the transfer.

(c) The pharmacist receiving the transferred prescription order information shall reduce the transferred information to writing,~~;~~ write the word "transfer" or a word of similar import on the face of the transferred prescription order or electronically document that the prescription has been transferred, and provide all information required by law or regulation to be on the prescription order, including:

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

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

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

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

(v) The number of refills authorized;

(vi) The number of valid refills remaining;

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

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

(ix) The name of the transferring pharmacist;

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

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

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

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

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

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

(i) A prescription order for a controlled substance in Schedule III through V may be transferred only one time, that transfer being from the pharmacy where the prescription was originally filled. It shall not be further transferred by, or to, any other pharmacy.

(j) 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.

Section 11. Labeling Prescription Drug Containers.

(a) All original or refill prescription drug containers utilized in a traditional dispensing system shall be labeled as follows: name of the patient, brand or generic name of the drug product dispensed, unless otherwise specified; drug strength and quantity; the name, address, and telephone number of the pharmacy; the practitioner's name; the serialized number of the prescription; the date the prescription was filled or refilled; directions for use, including accessory cautionary information as required for patient safety; the identifying

initials of the dispensing pharmacist, and any other information required by federal or State law.

(b) Effective January 1, 2004, all original or refill prescription drug containers utilized in a traditional dispensing system shall be labeled with ~~its~~ the product's physical description, including any identification code that may appear on the tablets and capsules. A waiver will be granted for new drugs for the first one-hundred-twenty (120) days on the market and ninety (90) days on drugs for which the national reference file has no description on file.

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

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

(ii) Strength;

(iii) Manufacturer's lot number; and

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

(v) All unit of issue packaging dispensed shall include the following information on the label, in addition to that required by this Chapter ~~2~~, Section 11 (c) (i) through (iv) ~~of the Board's rules~~:

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

(B) Prescription number;

(C) Name of the patient;

(D) Name of the practitioner;

(E) Directions for use;

(F) Date dispensed;

(G) Initials of dispensing pharmacist;

(H) Accessory cautionary labels for patient safety; and

(I) Quantity of medication.

(vi) All unit of issue packaging dispensed by a retail pharmacy to residents of long-term care facilities, as defined in Chapter 15 ~~,Wyoming Pharmacy Act,~~of the Board Rules and Regulations, as well as prescription~~s~~ drugs dispensed from hospital emergency room departments, as described in Chapter 12, Section 13~~,~~ of the Board ~~Wyoming Pharmacy Act,~~ Rules and Regulations, shall be labeled with the product's physical description, including any identification code that may appear on the tablets and capsules.

Section 12. Child-Resistant Packaging.

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

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

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

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

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

Section 13. Record of Refills.

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

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

Section 14. Doctor-Patient Relationship as Affecting Prescriptions.

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

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

Section 15. Return or Exchange of Prescription Drugs.

(a) Pharmacies (institutional~~Hospital~~ or retail) are prohibited from accepting from patients or their agents any dispensed prescription drug for redispensing. However, prescription drugs may be accepted for redispensing, if all the following are met:~~;~~

(i) Pharmacies may accept previously dispensed drugs for return from locations that employ persons who are licensed to administer drugs, and the prescription drugs were maintained under the control of those persons licensed to administer drugs.~~;~~

(ii) Prescription drugs shall only be returned to the pharmacy from which originally dispensed.~~;~~

(iii) The Pharmacist-in-Charge of the pharmacy accepting the prescription drugs for redispensing shall ensure that conditions of transportation to the location, storage at the location, and during the return from the location, are such as to prevent deterioration and/or contamination by any means that would affect the efficacy and/or toxicity of the product to be redispensed.~~; and~~

(iv) Prescription drugs accepted for redispensing must have been initially dispensed as a unit dose package or unit of issue package.

(b) The following prescription drugs shall not under any circumstances be returned to the pharmacy for redispensing:~~;~~

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

(ii) Any prescription drug dispensed in other than a unit dose package or unit of issue package~~, and/or~~.

(iii) Any prescription drug not labeled in accordance with this Chapter ~~2~~, Section 11.

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

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

(ii) Prescription drug products ~~which~~ that have been prepackaged or repackaged into unit dose packages and unit of issue package in the pharmacy may be redispensed one time only, provided that the integrity of the product and package are maintained, and then only in the package in which originally dispensed, except as provided in (iii) below. Partially used unit of issue packages may not be emptied and the drugs removed and repackaged, nor may additional units of medication be added to partially used unit of issue packages.

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

(d) In hospitals~~, which~~ that have a licensed institutional pharmacy, the pharmacy may accept prescription drugs for redispensing or reissue from all areas of the hospital under the effective control of professionally qualified personnel. The labeling of such drugs shall meet the requirements of this Chapter ~~2~~, Section 11, and the packaging shall meet the requirements of this Chapter ~~2~~, Section 4.

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

Section 16. Scope of Practice.

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

Section 17. Identification of a Patient.

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

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

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

Section 18. Reinstatement of Registered Pharmacist License After Failure to Renew, Returning from Inactive Status, Issuance of Duplicate License.

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

(i) Write a letter requesting consideration of reinstatement.~~;~~

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

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

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

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

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

(vii) Provide a notarized employer affidavit attesting to the active practice of pharmacy in the year preceding the date of the application for reinstatement. Active practice requires that the pharmacist work a minimum of four hundred (400) hours during this time period.~~proof that pharmacist has been active in the practice of pharmacy and in good-standing in the state where practicing.~~

(b) Minimum Competency for an Inactive Pharmacist Shall be Established to the Satisfaction of the Board.

When a registered pharmacist has been out of the practice of pharmacy for an extended period of time and wishes to reactivate that license, the Board shall determine on an individual basis the requirements needed to reactivate that license.

The requirements will include all of the elements of Section 18(a) and (b) above and may include ~~some or all of~~ the following:

~~(i) Approved continuing education certificates for period in question up to a maximum of five years;~~

(i)Pass a jurisprudence examination.~~;~~

~~(iii)Any past license fees shall be paid including annual fines, up to a maximum of five (5) years.~~

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

(iii) Board ~~I~~interview ~~by the Board~~.

~~(v) Individual shall produce at least two (2) recent letters of character reference.~~

~~(c) Duplicate licenses may be issued upon request when licensee's name changes or the license become damaged or destroyed. There shall be a fee charged for the duplicate license.~~

Section 19. 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.

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

~~(vii) Recognizable signature of the practitioner;~~

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

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

(c) Prescriptions may be transmitted to the pharmacist in written form; orally, including by telephone; by ~~telephonic~~ facsimile (~~FAX~~fax); and by electronic transmission. Schedule II controlled substance prescriptions may be transmitted by ~~FAX~~ fax if they meet the conditions as outlined in this Chapter ~~2~~, Section 20 (c). Controlled substance prescriptions may be transmitted electronically only to the extent allowed by federal ~~law~~ and Wyoming 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.

The patient shall have the exclusive right to freedom of choice for any pharmacy to dispense ~~their~~ his/her prescription orders. No collaborative practice agreement between prescriber and pharmacy shall require that prescription orders be transmitted from the prescriber to only that pharmacy.

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

Section 20. Transmission of Prescriptions by ~~Telephonic~~ Facsimile (Fax) Machines ~~(FAX)~~.

Prescriptions transmitted by ~~FAX~~ fax shall include all of the features listed in this Chapter, Section 19 (a), including the practitioner's recognizable signature.

(a) Other requirements for ~~FAX~~ fax prescriptions include:

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

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

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

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

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

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

All ~~FAX~~ fax machines ~~which are to be~~ used in transmitting prescriptions shall be programmed with a ~~FAX~~ fax identification number, so that the document received will show the sender's ~~FAX~~ fax identification number.

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

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

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

(ii) A prescription written for a Schedule II substance for a resident of a l~~L~~ong-term care facility. ~~or;~~

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

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

(e) A ~~FAXed~~ faxed prescription may be dispensed only by the pharmacy receiving the ~~FAX~~fax.

Section 21. Prescription Refill Information.

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

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

Section 22. ~~Telephonic~~ Facsimile Machines (~~FAX~~Fax) in General.

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

Section 23. Therapeutic Equivalents.

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

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

Section 24. Specific Requirements for Licensure of Non-Resident Pharmacies to Ship Prescription Drugs into the State.

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

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

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

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

(iii) Submit a copy of the current D~~.~~E~~.~~A~~.~~ registration;

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

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

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

(d) The Board office shall be notified of any change in ownership or ~~the~~ Pharmacist-in-Charge.

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

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

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

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

(h) The Board may revoke, deny, or suspend the licensure and registration of any non-resident pharmacy for violations of ~~the Act~~ W.S. § 33-24-152 and ~~Board regulations,~~this Chapter ~~2~~, Section 24.

Section 25. Fees (including examination, re-examination, license, license renewal, registration, registration renewal, mailing list, and late fees).

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

(i) Pharmacist licensure by examination or reexamination shall be seventy five dollars ($75.00) plus t~~T~~he National Association of Boards of Pharmacy®~~'s~~ (NABP®) fee for the North American Pharmacist Licensure Examination (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination (MPJE®).

(ii) Pharmacist licensure by reciprocity shall be two hundred dollars ($200.00) plus NABP®~~'s~~ fee for licensure transfer application and the MPJE®.

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

(iv) Pharmacy intern licensure shall be fifteen dollars ($15.00) and shall be renewed every twelve (12) months. 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 fifty dollars ($250.00) per year. Oxygen manufacturer or distributor license and renewals shall be one hundred dollars ($100.00) per year.

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

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

(xiii) The Board shall charge a thirty-five dollar ($235.00) fee to verify the license of any non-resident pharmacy, manufacturer, distributor, wholesaler, or reverse distributor.

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

(xv) Pharmacists and interns must report any change of address or place of employment to the Board within fifteen (15) days of the change.

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

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

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

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

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

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

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

Section 26. Emergency Drug Supply for Nursing Homes, Hospices, Extended Care Facilities, or Intermediate Care Facilities.

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

(i) The pharmacy servicing the facility or facilities listed in Section 26(a) shall make application to the Board, on an application provided by the Board. The Board may issue a permit, if the conditions of this Section 26 are met, in the name of the facility and the pharmacy authorizing the storage and use of a emergency drug supply at the facility. This registration shall be valid until June 30 of each year. The permit must be renewed annually.

(ii) The fee for the permit shall be fifteen dollars ($15.00) annually.

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

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

(c) The facility and the pharmacy servicing the facility shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of the emergency drug supply. Copies of the most recent policy and procedure manual shall be on file at both the facility and the pharmacy servicing the facility.

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

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

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

(i) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or seventy-two (72) hours, whichever is less. The drugs shall be administered only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and patient's profile for potential contraindications and adverse drug reactions.

(ii) Drugs that a prescriber has ordered for a patient on an as -needed basis, if the utilization and administration of those drugs are subject to ongoing review by a pharmacist.

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

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

(h) Facilities described in Section 26(a) are exempt from the provisions of Section 26, provided that the pharmacy providing their emergency drug supply is physically located at the same site as the facility and this pharmacy possesses a DEA registration and is licensed by the Wyoming State Board of Pharmacy.

Section 27. Reinstatement of a Revoked or Suspended Pharmacist, Pharmacy Technician License.

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

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

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

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

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

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

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

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

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

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

(ii) If the application is complete, the Executive Director, in consultation with a ~~the~~ Board~~'s~~ I~~i~~nspector/Compliance Officer, a~~n ex officio~~ member of the Board, and legal counsel shall make a decision if the evidence submitted supports reinstatement or not. A hearing shall be scheduled by the Executive Director. The Executive Director will notify the applicant whether the Board~~'s~~ staff will support or oppose the request for reinstatement.

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

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

(i) ~~Complete t~~The North American Pharmacist Licensure Examination (NAPLEX®) with a minimum score of 75;

(ii) ~~Complete t~~The Multistate Pharmacy Jurisprudence Examination (MPJE®) with a minimum score of 75; and/or

(iii) ~~Complete a~~An internship, not to exceed ~~2000~~ 1,200 hours, as prescribed by the Board.

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

Section 28. Collaborative Pharmaceutical Care.

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

(b) The collaborative practice agreement shall include:

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

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

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

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

(C) The procedures the pharmacist is to follow in the course of conducting drug therapy management, including documentation of decisions ~~made~~ and a plan or appropriate mechanism for communication and reporting to the prescribing physician concerning specific decisions ~~made~~. Documentation **of decisions** shall occur in the prescribing physician's patient medical chart. ~~-~~If the medical chart is not available at the practice site, a copy of the documentation **of decisions** will be sent to the prescribing physician.~~and shall also occur in the pharmacist's patient medical chart located within the pharmacist practice site.~~

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

(iv) A provision that allows the prescribing physician to override the collaborative practice agreement whenever ~~he~~ deemed~~s~~ ~~it~~ necessary or appropriate.~~;~~

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

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

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

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

(ii) Allergies;

(iii) Medical diagnoses;

(iv) All current medication(s), including current dosages (and including over-the-counter (OTC) and prescription products);

(v) Pertinent lab values;

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

(vii) Method of communicating information between pharmacist and physician;

(viii) Frequency of physician follow-up;

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

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

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

(e) At a minimum, the written collaborative practice agreement shall be reviewed/renewed annually. If necessary, the collaborative practice agreement may be

revised. The Board of Pharmacy must approve all revisions, once signed by the pharmacist and the prescribing physician, prior to implementation.

(f) The Board shall review and approve all collaborative practice agreements, including revisions prior to implementation. This shall be accomplished as follows:

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

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

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

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

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

(h) Nothing in this Section shall be interpreted to permit a pharmacist to accept delegation of a physician's authority outside the limits included in W.S. § 33-26-202 of the Medical Practice Act and the Wyoming State Board of Medicine~~'s~~ regulations.

Section 29. Electronic Prescription Transmission.

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

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

(ii) Identify the transmitter's telephone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the

transmission, as well as any other information required by federal or Sstate laws and regulations.;

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

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

(v) Contain all other information as required by State or federal law.

(b) The pharmacist shall exercise professional judgement 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, which that are generated from electronic media utilizing an electronic signature shall be applied to paper that utilizes security features that will ensure that the prescription is not subject to any form of copying and/or alterations.

(e) However, prescriptions may be transmitted from fax to fax, as allowed in this Chapter 2, Section 20 of these regulations.

(f) Controlled substance prescriptions shall not be communicated by way of electronic transmission, except by fax, as allowed in this Chapter 2, Section 20(c). of the Board's rules.

Section 30. Resident Retail Pharmacy Closure or Change of Ownership.

(a) Resident Retail Pharmacy Closure.

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

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

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

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

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

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

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

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

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

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

(C) Patient signature logs.

(viii) The date the Drug Enforcement Administration (DEA) was contacted regarding the closure and that the DEA was notified that all invoices and DEA 222 forms referencing the sale of controlled substances at closure, blank DEA 222 forms, and the DEA registration certificate will be delivered to the Board for disposition.

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

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

(A~~i~~) A copy of the final controlled substance inventory.

(B~~ii~~) Documentation, as noted in this Chapter ~~2~~, Section 30 (a)(iv), regarding notification to the public of the closure of the retail pharmacy.

(Ciii) The Wyoming retail pharmacy license.

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

(Ev) Any changes to information previously provided to the Board as required in this Chapter, 2, Section 30(a).

(Fvi) The DEA registration certificate and blank DEA 222 forms.

(xid) It is unprofessional conduct for a retail pharmacy to close in a manner other than that prescribed in this Chapter 2, Section 30 (a)(b)(c), Wyoming Pharmacy Act, Rules and Regulations.

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

(b) Resident Retail Pharmacy Change of Ownership.

When a change in ownership necessitates a change of DEA registration number, the following is required:

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

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

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

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

(D) The proposed method of communicating to the public the change in ownership, no later than fourteen (14) days prior to the date the ownership will change.

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

1. Completed DEA 222 forms or retrievable electronic equivalent.

2. Invoices for purchases of Schedule III, IV, and V controlled substances.

3. Patient signature logs.

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

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

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

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

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

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

(C) Any changes to information previously provided to the Board, as required in this Chapter, Section 30(a).

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

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

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

Section 31. Institutional Pharmacy Closure.

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

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

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

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

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

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

(C) Patient-specific records.

(iv) The date the Drug Enforcement Administration (DEA) was contacted regarding the closure and that DEA was notified that all invoices and DEA 222 forms referencing the sale of controlled substances at closure, blank DEA 222 forms, and the DEA registration certificate will be delivered to the Board for disposition.

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

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

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

(ii) The Wyoming institutional pharmacy license.

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

(iv) Any changes to information previously provided to the Board, as required in this Chapter ~~2~~, Section 31~~-~~(a).

(v) The DEA registration certificate and blank DEA 222 forms.

(d) It is unprofessional conduct for an institutional pharmacy to close in a manner other than that prescribed in this Chapter ~~2~~, Section 31~~-~~(a)(b)(c)~~, Wyoming Pharmacy Act, Rules and Regulations~~.

Section 32. Drug Samples.

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

Section 33. Centralized Prescription Processing.

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

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

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

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

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

(f) Minimum Requirements:

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

(A) have the same owner; or

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

(C) share a real-time database; and

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

(ii) The Pharmacist-in-Charge of the central fill pharmacy shall ensure that:

(A) The pharmacy maintains and uses storage or shipment containers and shipping processes ~~which~~ that ensure drug stability and potency. Shipping processes shall include the use of appropriate packaging material~~;~~ and/or devices ~~which~~ that ensure the drug is maintained at a temperature range ~~which~~ 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 non-resident dispensing or central fill pharmacy shall comply with the provisions of W.S. § 33-24-152 and this Section.

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

(g) Notifications to patients.

(i) A pharmacy that out-sources prescription processing to another pharmacy shall:

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

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

(h) 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 Section 11 of this Chapter.

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

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

(ii) Include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription processing.~~;~~ ~~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 S~~s~~tate laws and regulations.~~;~~

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

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

(G) Identifying the pharmacist responsible for making the offer to counsel to the patient, as required by Chapter 9~~, Wyoming Pharmacy Act,~~ of the Board Rules and Regulations.~~; and~~

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

(j) Records.

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

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

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

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

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

(iv) The central fill pharmacy shall maintain records which indicate:

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

Section 34. Automated Storage and Distribution Systems.

(a) Before using an automated storage and distribution system, a pharmacy licensee or pharmacist in charge shall:

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

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

(b) A pharmacy licensee or Pharmacist-in-Charge 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 drugs 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 Substance Act.

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

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

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

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

(F) Provides a method for a patient to obtain consultation with a pharmacist, if requested by the patient.~~; 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) E~~I~~nsures 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) A pharmacy licensee or Pharmacist-in-Charge shall:

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

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

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

(d) The Board may prohibit a pharmacy licensee or Pharmacist-in-Charge 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.