#1

Licensing of Chain Pharmacy Warehouses

58-17b-102 (12)
"Class C pharmacy" means a pharmacy that engages in the manufacture, production, wholesale, or distribution of drugs or devices in Utah.

R156-17b- 302 (3)
A Class C pharmacy includes a pharmacy that is involved in:
(a) manufacturing;
(b) producing;
(c) wholesaling;
(d) distributing; or
(e) reverse distributing.

58-17b-102 (47)
(a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility engaged in the business of wholesale vending or selling of a prescription drug or device to other than a consumer or user of the prescription drug or device that the pharmaceutical facility has not produced, manufactured, compounded, or dispensed.
(b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical facility carrying out the following business activities:
(i) intracompany sales;
(ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, if the activity is carried out between one or more of the following entities under common ownership or common administrative control, as defined by division rule:
(A) hospitals;
(B) pharmacies;
(C) chain pharmacy warehouses, as defined by division rule; or
(D) other health care entities, as defined by division rule;

R156-17b-102 (9)
"Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the prescription drugs to a group of chain pharmacies that have the same common ownership and control.

R156-17b-102- (59)
"Wholesale distribution" means the distribution of drugs to persons other than consumers or patients, but does not include:
(a) intracompany sales or transfers;
(b) the sale, purchase, distribution, trade, or other transfer of a prescription drug for emergency medical reasons, as defined under 21 CFR 203.3(m), including any amendments thereto;
(c) the sale, purchase, or trade of a drug pursuant to a prescription;
(d) the distribution of drug samples;

NAPB model act language

"Chain Pharmacy Warehouse" means a permanent physical location for Drugs and/or Devices that acts as a central warehouse and performs intracompany sales and transfers of Prescription Drugs or Devices to chain Pharmacies, which are members of the same affiliated group, under common ownership and control. Chain Pharmacy Warehouses must be licensed as Wholesale Distributors.

Supply Chain and inter-company transfers

We would like to discuss the process of having Intermountain supply chain pharmacy (class B) or a few selected Intermountain community (class A) pharmacies compound non sterile and sterile products and transferring them to our Intermountain Class B pharmaceutical administration pharmacies for use. These would be inter company transfers and would be signed out on a per patient basis from the Class B administration pharmacy medication room upon order of the LIP and recorded in the Intermountain medical record. We believe this process would be legal under current compounding regulations and state law and would like to discuss it with the board to see if there are any concerns before we implement this process.

Recycling Programs Add item #1

The second topic is a business arrangement we are looking at with a non profit organization called "Dispensary of Hope'. They are able to secure drugs that are unused and provide them to us under a contract that would allow us to provide them to patients that are indigent free of charge. Much like forth street clinic pharmacy. We feel this would be a great resource for many of patients. Their eligibility will be determine by our social workers and our pharmacies would be able to provide them with medications they may not otherwise be able to secure. We would start in our community pharmacies associated with out hospitals and possibly expand. We would like to discuss the process with the board to see if there are any concerns from the board members. Please let me know if you have additional questions. If we are allowed on the agenda I can provide you with documents for talking points with the Board.

Old item #2

R156-17b-610.5. Dispensing in emergency department – Patient's immediate need.

In accordance with Subsection 58-17b-610.5, the guidelines for medical practitioners to dispense drugs to a patient in a hospital emergency department are established in this section.

(1) To meet a patient's immediate needs the prescribing practitioner may provide up to a three day emergency supply, which is properly labeled, to a patient.

(2) Notwithstanding, Subsection R156-17b-610.5 (1) STI prophylaxis can be provided in an emergency supply of seven days.

(3) Labeling of an emergency supply shall at minimum include:

(a) prescribing practitioner's name, facility name and telephone number;
(b) patient's name;
(c) name of medication and strength;
(d) date given;
(e) instructions for use; and
(f) beyond use date.

(4) Records of controlled substances dispensed by the prescribing practitioner must be provided to the appropriate pharmacy so that the applicable prescription data can be reported to the CSD.

~~**R156-17b-614c. Class B - Dispensing Drugs from an Emergency Department and Upon Discharge from a Rural Hospital Pharmacy.**~~

~~The "Guidelines for Hospital Pharmacies and Emergency Department Treatment" document, adopted May 21, 2012, by the Division in collaboration with the Utah State Board of Pharmacy, as posted on the Division website, is the guideline or standard to be utilized by rural hospital emergency departments dispensing a short course of necessary medications to patients when a pharmacy is not open to fill their prescriptions.~~

Unfunded Mon 41

R156-17b-304. Temporary Licensure.

(1) In accordance with Subsection 58-1-303(1), the Division may issue a temporary pharmacist license to a person who meets all qualifications for licensure as a pharmacist except for the passing of the required examination, if the applicant:

(a) is a graduate of an ACPE accredited pharmacy school within two months immediately preceding application for licensure or enrolled in [~~the second year of~~] a pharmacy graduate residency or fellowship program;

(b) submit a complete application for licensure as a pharmacist except the passing of the NAPLEX and MJPE examinations;

(c) submits evidence of having secured employment conditioned upon issuance of the temporary license, and the employment is under the direct, on-site supervision of a pharmacist with an active, non-temporary license that may or may not include a controlled substance license; and

(d) has registered to take the required licensure examinations.

(2) A temporary pharmacist license issued under Subsection (1) expires the earlier of:

(a) six months from the date of issuance;

(b) the date upon which the Division receives notice from the examination agency that the individual has failed either examination twice; or

(c) the date upon which the Division issues the individual full licensure.

(3) An individual who has failed either examination twice shall meet with the Board to request an additional authorization to test. The Division, in collaboration with the Board, may require additional training as a condition for approval of an authorization to retest.

(4) A pharmacist temporary license issued in accordance with this section cannot be renewed or extended.

Utah

Central Processing Relevant Law and Rule

58-17b-102 (9)

"Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

R156-17b-102

~~(7) "Centralized Prescription Filling" means the filling by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order.~~

~~(8) "Centralized Prescription Processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.~~

R156-17b-614f. Operating Standards - Class A, B, and D[~~, and E~~] - Central Prescription Processing and Filling.

In accordance with Subsection 58-17b-601 (1), the following operating standards apply to Class A, Class B, and Class D [~~and Class E~~] pharmacies that engage in central prescription processing [~~or central prescription filling~~]. The operating standards include:

(1) A pharmacy may perform centralized prescription processing or centralized prescription filling services for a dispensing pharmacy if the parties:

(a) have common ownership or common administrative control; or

(b) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations; and

(c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(2) The parties performing or contracting for centralized prescription processing or filling services shall maintain a policy and procedures manual, and documentation of implementation, which shall be made available to the Division upon inspection and which includes the following:

(a) a description of how the parties will comply with federal and state laws and regulations;

(b) appropriate records to identify the responsible pharmacists and the dispensing and counseling process;

(c) a mechanism for tracking the prescription drug order during each step in the dispensing process;

(d) a description of adequate security to protect the integrity and prevent the illegal use or disclosure of protected health information; and

(e) 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.

Unfinished item #3

R156-17b-614a. Operating Standards - General Operating Standards, Class A and B Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), the following operating standards apply to all Class A and Class B pharmacies, which may be supplemented by additional standards defined in this rule applicable to specific types of Class A and B pharmacies. The general operating standards include:

(a) shall be well lighted, well ventilated, clean and sanitary;

(b) if transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer. All required equipment shall be clean and in good operating condition;

(c) be equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity ~~of~~ the product inventory;

(d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;

(e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare; and

(f) if dispensing controlled substances, be equipped with a security system to:

(i) permit detection of entry at all times when the facility is closed; and

(ii) provide notice of unauthorized entry to an individual; and

(g) be equipped with a lock on any entrances to the facility where drugs are stored.

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. If a refrigerator or freezer is necessary to properly store drugs at the pharmacy, the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain each log entry for at least three years.

(3) Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:

(a) shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations;

(b) may compound in anticipation of receiving prescriptions in limited amounts;

(c) bulk active ingredients shall:

(i) be procured from a facility registered with the federal Food and Drug Administration; and

(ii) not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness;

(d) All facilities who dispense prescriptions must comply with the record keeping requirements of their State Boards of Pharmacy. When a facility compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section.

([~~d~~]e) a [~~master worksheet sheet~~] master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once

approved, a duplicate of the [~~master worksheet sheet~~] master formulation record shall be used as the [~~preparation worksheet sheet~~] compounding record from which each batch is prepared and on which all documentation for that batch occurs. The [~~master worksheet sheet~~] master formulation record may be stored electronically and shall contain at a minimum:

(i)[~~the formula~~] official or assigned name;

(ii) [~~the components~~] strength;

(iii) [~~the compounding directions~~] dosage form of the preparation;

(iv) [~~a sample label information~~] calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;

(v) [~~evaluation and testing requirements~~] description of all ingredients and their quantities;

(vi) [~~sterilization methods, if applicable~~] compatibility and stability information, including references when available;

(vii) [~~specific equipment used during preparation such as specific compounding device~~] equipment needed to prepare the preparation;

(viii) [~~storage requirements;~~] mixing instructions that should include:

a. order of mixing;

b. mixing temperatures or other environmental controls;

c. duration of mixing; and

d. other factors pertinent to the replication of the preparation as compounded.

(ix) sample labeling information, which shall contain, in addition to legally required information:

a. generic name and quantity or concentration of each active ingredient

b. assigned beyond use date

c. storage conditions

d. prescription or control number, whichever is applicable;

(x) container used in dispensing;

(xi) packaging and storage requirements;

(xii) description of final preparation; and

(xiii) quality control procedures and expected results.

([e] f) a [~~preparation worksheet sheet~~] compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the following:

(i) [~~identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes~~] official or assigned name;

(ii) [~~manufacturer lot number for each component~~] strength and dosage of the preparation;

(iii) [~~component manufacturer or suitable identifying number~~] Master Formulation Record reference for the preparation;

(iv) [~~container specifications (e.g. syringe, pump cassette)~~] names and quantities of all components;

(v) [~~unique lot or control number assigned to batch~~] sources, lot numbers, and expiration dates of components;

(vi) [~~beyond use date of batch prepared products~~] total quantity compounded;

(vii) [~~date of preparation~~] name of the person who prepared the preparation;

(viii) [~~name, initials or electronic signature of the person or persons involved in the preparation~~] name of the compounder who approved the preparation;

(ix) [~~names, initials or electronic signature of the responsible pharmacist or DMP~~] name of the person who performed the quality control procedures;

(x) [~~end-product evaluation and testing specifications, if applicable; and~~] date of preparation;

(xi) [~~comparison of actual yield to anticipated yield, when appropriate~~] assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable;

(xii) assigned beyond use date;

(xiii) duplicate label as described in the Master Formulation Record;

(xiv) description of final preparation;

(xv) results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids); and

(xvi) documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

(~~f~~g) the label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:

(i) the unique lot number assigned to the batch;

(ii) all active solution and ingredient names, amounts, strengths and concentrations, when applicable;

(iii) quantity;

(iv) beyond use date and time, when applicable;

(v) appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and

(vi) device-specific instructions, where appropriate;

(h) all prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in UCA 58-17b-602L the following.

(i) generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation.

(ii) assigned compounding record or lot number.

(iii)"this is a compounded preparation" or similar language shall be indicated.

(~~g~~i) the beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing;

(i) sources of drug stability information shall include the following:

(A) references can be found in Trissel's "Handbook on Injectable Drugs", 17th Edition, October 31, 2012;

(B) manufacturer recommendations; and

(C) reliable, published research;

(ii) when interpreting published drug stability information, the pharmacist or DMP shall consider all aspects of the final sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and

(iii) methods for establishing beyond use dates shall be documented; and

([~~h~~]j) there shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.

(4) The facility shall have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:

(a) Title 58, Chapter 1, Division of Occupational and Professional Licensing Act

(b) R156-1, General Rule of the Division of Occupational and Professional Licensing;

(c) Title 58, Chapter 17b, Pharmacy Practice Act;

(d) R156-17b, Utah Pharmacy Practice Act Rule;

(e) Title 58, Chapter 37, Utah Controlled Substances Act;

(f) R156-37, Utah Controlled Substances Act Rule;

(g) Title 58, Chapter 37f, Controlled Substance Database Act;

(h) R156-37f, Controlled Substance Database Act Rule;

(i) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USP DI Drug Reference Guides;

(j) current FDA Approved Drug Products (orange book); and

(k) any other general drug references necessary to permit practice dictated by the usual and ordinary scope of practice to be conducted within that facility.

(5) The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable for inspection by the Division and may be maintained in paper or electronic form.

(6) Facilities shall have a counseling area to allow for confidential patient counseling, where applicable.

(7) A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present and immediately available in the facility.

(8) Only a licensed Utah pharmacist, DMP or authorized pharmacy personnel shall have access to the pharmacy when the pharmacy is closed.

(9) The facility or parent company shall maintain a record for not less than 5 years of the initials or identification codes that identify each dispensing pharmacist or DMP by name. The initials or identification code shall be unique to ensure that each pharmacist or DMP can be identified; therefore identical initials or identification codes shall not be used.

(10) The pharmacy facility shall maintain copy 3 of DEA order form (Form 222) that has been properly dated, initialed and filed and all copies of each unaccepted or defective order form and any attached statements or other documents.

(11) If applicable, a hard copy of the power of attorney authorizing a pharmacist, DMP, or DMP designee to sign DEA order forms (Form 222) shall be available to the Division whenever necessary.

(12) A pharmacist, DMP or other responsible individual shall verify that controlled substances are listed on the suppliers' invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances.

(13) The pharmacy facility shall maintain a record of suppliers' credit memos for controlled substances.

(14) A copy of inventories required under Section R156-17b-605 shall be made available to the Division when requested.

(15) The pharmacy facility shall maintain hard copy reports of surrender or destruction of controlled substances and legend drugs submitted to appropriate state or federal agencies.

(16) If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling,

the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy.

Unfavorable item # 3

R156-17b-614a. Operating Standards - General Operating Standards, Class A and B Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), the following operating standards apply to all Class A and Class B pharmacies, which may be supplemented by additional standards defined in this rule applicable to specific types of Class A and B pharmacies. The general operating standards include:

(a) shall be well lighted, well ventilated, clean and sanitary;

(b) if transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer. All required equipment shall be clean and in good operating condition;

(c) be equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity ~~of~~ the product inventory;

(d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;

(e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare; and

(f) if dispensing controlled substances, be equipped with a security system to:

(i) permit detection of entry at all times when the facility is closed; and

(ii) provide notice of unauthorized entry to an individual; and

(g) be equipped with a lock on any entrances to the facility where drugs are stored.

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. If a refrigerator or freezer is necessary to properly store drugs at the pharmacy, the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain each log entry for at least three years.

(3) Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:

(a) shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations;

(b) may compound in anticipation of receiving prescriptions in limited amounts;

(c) bulk active ingredients shall:

(i) be procured from a facility registered with the federal Food and Drug Administration; and

(ii) not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness;

(d) All facilities who dispense prescriptions must comply with the record keeping requirements of their State Boards of Pharmacy. When a facility compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section.

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approved, a duplicate of the [~~master worksheet sheet~~] master formulation record shall be used as the [~~preparation worksheet sheet~~] compounding record from which each batch is prepared and on which all documentation for that batch occurs. The [~~master worksheet sheet~~] master formulation record may be stored electronically and shall contain at a minimum:

(i)[~~the formula~~] official or assigned name;

(ii) [~~the components~~] strength;

(iii) [~~the compounding directions~~] dosage form of the preparation;

(iv) [~~a sample label information~~] calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;

(v) [~~evaluation and testing requirements~~] description of all ingredients and their quantities;

(vi) [~~sterilization methods, if applicable~~] compatibility and stability information, including references when available;

(vii) [~~specific equipment used during preparation such as specific compounding device~~] equipment needed to prepare the preparation;

(viii) [~~storage requirements;~~] mixing instructions that should include:

a. order of mixing;

b. mixing temperatures or other environmental controls;

c. duration of mixing; and

d. other factors pertinent to the replication of the preparation as compounded.

(ix) sample labeling information, which shall contain, in addition to legally required information:

a. generic name and quantity or concentration of each active ingredient

b. assigned beyond use date

c. storage conditions

d. prescription or control number, whichever is applicable;

(x) container used in dispensing;

(xi) packaging and storage requirements;

(xii) description of final preparation; and

(xiii) quality control procedures and expected results.

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(i) [~~identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes~~] official or assigned name;

(ii) [~~manufacturer lot number for each component~~] strength and dosage of the preparation;

(iii) [~~component manufacturer or suitable identifying number~~] Master Formulation Record reference for the preparation;

(iv) [~~container specifications (e.g. syringe, pump cassette)~~] names and quantities of all components;

(v) [~~unique lot or control number assigned to batch~~] sources, lot numbers, and expiration dates of components;

(vi) [~~beyond use date of batch prepared products~~] total quantity compounded;

(vii) [~~date of preparation~~] name of the person who prepared the preparation;

(viii) [~~name, initials or electronic signature of the person or persons involved in the preparation~~] name of the compounder who approved the preparation;

(ix) [~~names, initials or electronic signature of the responsible pharmacist or DMP~~] name of the person who performed the quality control procedures;

(x) [~~end product evaluation and testing specifications, if applicable; and~~] date of preparation;

(xi) [~~comparison of actual yield to anticipated yield, when appropriate~~] assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable;

(xii) assigned beyond use date;

(xiii) duplicate label as described in the Master Formulation Record;

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(xv) results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids); and

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(i) the unique lot number assigned to the batch;

(ii) all active solution and ingredient names, amounts, strengths and concentrations, when applicable;

(iii) quantity;

(iv) beyond use date and time, when applicable;

(v) appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and

(vi) device-specific instructions, where appropriate;

(h) all prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in UCA 58-17b-602L the following.

(i) generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation.

(ii) assigned compounding record or lot number.

(iii)"this is a compounded preparation" or similar language shall be indicated.

(~~g~~i) the beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing;

(i) sources of drug stability information shall include the following:

(A) references can be found in Trissel's "Handbook on Injectable Drugs", 17th Edition, October 31, 2012;

(B) manufacturer recommendations; and

(C) reliable, published research;

(ii) when interpreting published drug stability information, the pharmacist or DMP shall consider all aspects of the final sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and

(iii) methods for establishing beyond use dates shall be documented; and

([~~h~~]j) there shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.

(4) The facility shall have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:

(a) Title 58, Chapter 1, Division of Occupational and Professional Licensing Act

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(e) Title 58, Chapter 37, Utah Controlled Substances Act;

(f) R156-37, Utah Controlled Substances Act Rule;

(g) Title 58, Chapter 37f, Controlled Substance Database Act;

(h) R156-37f, Controlled Substance Database Act Rule;

(i) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USP DI Drug Reference Guides;

(j) current FDA Approved Drug Products (orange book); and

(k) any other general drug references necessary to permit practice dictated by the usual and ordinary scope of practice to be conducted within that facility.

(5) The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable for inspection by the Division and may be maintained in paper or electronic form.

(6) Facilities shall have a counseling area to allow for confidential patient counseling, where applicable.

(7) A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present and immediately available in the facility.

(8) Only a licensed Utah pharmacist, DMP or authorized pharmacy personnel shall have access to the pharmacy when the pharmacy is closed.

(9) The facility or parent company shall maintain a record for not less than 5 years of the initials or identification codes that identify each dispensing pharmacist or DMP by name. The initials or identification code shall be unique to ensure that each pharmacist or DMP can be identified; therefore identical initials or identification codes shall not be used.

(10) The pharmacy facility shall maintain copy 3 of DEA order form (Form 222) that has been properly dated, initialed and filed and all copies of each unaccepted or defective order form and any attached statements or other documents.

(11) If applicable, a hard copy of the power of attorney authorizing a pharmacist, DMP, or DMP designee to sign DEA order forms (Form 222) shall be available to the Division whenever necessary.

(12) A pharmacist, DMP or other responsible individual shall verify that controlled substances are listed on the suppliers' invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances.

(13) The pharmacy facility shall maintain a record of suppliers' credit memos for controlled substances.

(14) A copy of inventories required under Section R156-17b-605 shall be made available to the Division when requested.

(15) The pharmacy facility shall maintain hard copy reports of surrender or destruction of controlled substances and legend drugs submitted to appropriate state or federal agencies.

(16) If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling,

the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy.