AGENDA

Florida Board of Pharmacy
Rules Subcommittee Meeting
Class III Institutional Pharmacy Permit Discussion

April 19, 2018 – 9:00 a.m.

Best Western Gateway Grand Hotel and Conference Center
*4200 NW 97th Boulevard * Gainesville, FL 32606*
(352) 331-3336

Committee Members:
Richard Montgomery, BPharm, MBA – Chair

Board Staff
C. Erica White, MBA, JD – Executive Director

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Note: Participants in this public meeting should be aware that these proceedings are being recorded.

1.	**Introductions**	9:00 – 9:15 a.m.
2.	**Overview of Rule Drafting** (*Facilitator – Lawrence Harris*)	9:15 – 9:30 a.m.
3.	**Review of Legislation** (*Facilitator – Richard Montgomery*)	9:30 -10:00 a.m.
4.	**Drafting of Rules** (Break included) (*Facilitator – Richard Montgomery*)	10:00 – Noon
5.	**Lunch**	Noon - 1:00 p.m.
6.	**Drafting of Permit Application** (*Facilitator – Richard Montgomery*)	1:00 – 2:30 p.m.
7.	**Summary**	2:30 – 3:00 p.m.
8.	**Public Comment**	
9.	**Adjourn**	

TAB #1

An act relating to pharmacies; amending s. 465.003, F.S.; revising and providing definitions; amending s. 465.004, F.S.; revising the membership of the Board of Pharmacy; amending s. 465.019, F.S.; establishing Class III institutional pharmacies; providing requirements for such pharmacies; conforming provisions to changes made by the act; amending s. 465.0252, F.S.; revising notice requirements to conform to changes made by the act; amending s. 499.003, F.S.; providing and revising definitions; amending s. 499.01, F.S.; authorizing the distribution of medicinal drugs and prepackaged drug products without a specified permit under certain conditions; deleting a provision exempting certain drug repackagers from specified permit requirements; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (7) and (13) of section 465.003, Florida Statutes, are amended, and subsections (21) and (22) are added to that section, to read:

465.003 Definitions.—As used in this chapter, the term:

(7) "Institutional formulary system" means a method

whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II or Class III institutional pharmacy.

(13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic

medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189 and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.

(21) "Central distribution facility" means a facility under common control with a hospital holding a Class III institutional pharmacy permit that may dispense, distribute, compound, or fill prescriptions for medicinal drugs; prepare prepackaged drug products; and conduct other pharmaceutical services.

(22) "Common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

Section 2. Subsection (2) of section 465.004, Florida Statutes, is amended to read:

465.004 Board of Pharmacy.—

(2) Seven members of the board must be licensed pharmacists who are residents of this state and who have been engaged in the practice of the profession of pharmacy in this state for at least 4 years and, to the extent practicable, represent the various pharmacy practice settings. Of the pharmacist members, two must be currently engaged in the practice of pharmacy in a community pharmacy, two must be currently engaged in the practice of pharmacy in a Class II, ~~institutional pharmacy or a~~ Modified Class II, or Class III institutional pharmacy, and three must be pharmacists licensed in this state irrespective of practice setting. The remaining two members must be residents of the state who have never been licensed as pharmacists and who are in no way connected with the practice of the profession of pharmacy. No person may be appointed as a consumer member who is in any way connected with a drug manufacturer or wholesaler. At least one member of the board must be 60 years of age or older. The Governor shall appoint members to the board in accordance with this subsection as members' terms expire or as a vacancy occurs until the composition of the board complies with the requirements of this subsection.

Section 3. Subsections (4) and (6) of section 465.019, Florida Statutes, are amended, and paragraph (d) is added to subsection (2) of that section, to read:

465.019 Institutional pharmacies; permits.—

(2) The following classes of institutional pharmacies are established:

(d)1. "Class III institutional pharmacies" are those institutional pharmacies, including central distribution facilities, affiliated with a hospital that provide the same services that are authorized by a Class II institutional pharmacy permit. Class III institutional pharmacies may also:

a. Dispense, distribute, compound, and fill prescriptions for medicinal drugs.

b. Prepare prepackaged drug products.

c. Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are each permitted under this chapter to possess medicinal drugs.

d. Provide the services in sub-subparagraphs a.-c. to an entity under common control which holds an active health care clinic establishment permit as required under s. 499.01(2)(r).

2. A Class III institutional pharmacy shall maintain policies and procedures addressing:

a. The consultant pharmacist responsible for pharmaceutical services.

b. Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.

c. Recordkeeping to monitor the movement, distribution,

and transportation of medicinal drugs and prepackaged drug products.

d. Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.

e. Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III institutional pharmacies.

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II or Class III institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the

patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

(6) In a Class II or Class III institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs, proprietary preparations, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by the pharmacists employed in such institution. A facility with a Class II or Class III institutional pharmacy permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

Section 4. Subsection (3) of section 465.0252, Florida Statutes, is amended to read:

465.0252 Substitution of interchangeable biosimilar products.—

(3) A pharmacist who practices in a Class II, ~~or~~ Modified Class II, or Class III institutional pharmacy shall comply with the notification provisions of paragraph (2)(c) by entering the substitution in the institution's written medical record system or electronic medical record system.

Section 5. Subsection (39) of section 499.003, Florida Statutes, is amended, and paragraphs (w) and (x) are added to subsection (48) of that section, to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(39) "Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing or by a facility holding a Class III institutional pharmacy permit ~~in the establishment in which the prepackaging occurred~~.

(48) "Wholesale distribution" means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

(w) A hospital covered by s. 340B of the Public Health Service Act, 42 U.S.C. s. 256b, that arranges for a prescription drug wholesale distributor to distribute prescription drugs covered under that act directly to a contract pharmacy. Such hospital is exempt from obtaining a restricted prescription drug distributor permit under s. 499.01(2)(h).

(x) The dispensing or distribution of a medicinal drug by a Class III institutional pharmacy pursuant to s. 465.019.

Section 6. Paragraphs (b) and (h) of subsection (2) and

subsection (5) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(b) Prescription drug repackager permit.—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer.

2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

3. A prescription drug repackager permit is not required for distributing medicinal drugs or prepackaged drug products between entities under common control which each hold either an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (2)(r). For purposes of this subparagraph, the term "common control" has the same meaning as in s. 499.003(48)(a)3.

(h) Restricted prescription drug distributor permit.—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(48)(a).

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(48)(j) to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of

the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic

establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

5. A restricted prescription drug distributor permit is not required for distributions between pharmacies that each hold an active permit under chapter 465, have a common ownership, and are operating in a freestanding end-stage renal dialysis clinic, if such distributions are made to meet the immediate emergency medical needs of specifically identified patients and do not occur with such frequency as to amount to the regular and systematic supplying of that drug between the pharmacies. The department shall adopt rules establishing when the distribution

of a prescription drug under this subparagraph amounts to the regular and systematic supplying of that drug.

6. A restricted prescription drug distributor permit is not required for distributing medicinal drugs or prepackaged drug products between entities under common control that each hold either an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (2)(r). For purposes of this subparagraph, the term "common control" has the same meaning as in s. 499.003(48)(a)3.

~~(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(48)(a)3., if:~~

~~(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;~~

~~(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing~~

~~prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;~~

~~(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and~~

~~(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.~~

~~The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection. A prescription drug distributor that repackages and distributes prescription drugs under this subsection to a not-for-profit rural hospital, as defined in s. 395.602, is not required to comply with paragraph (c) or paragraph (d), but must provide to each health care entity for which it repackages, for each prescription drug that is repackaged and distributed, the information required by department rule for labeling prescription drugs. The department shall adopt rules to ensure the safety and integrity of prescription drugs repackaged and distributed under this subsection, including rules regarding prescription drug manufacturing and labeling requirements.~~

Section 7. This act shall take effect July 1, 2018.

TAB #2

CHAPTER 2018-95

Committee Substitute for House Bill No. 675

An act relating to pharmacies; amending s. 465.003, F.S.; revising and providing definitions; amending s. 465.004, F.S.; revising the membership of the Board of Pharmacy; amending s. 465.019, F.S.; establishing Class III institutional pharmacies; providing requirements for such pharmacies; conforming provisions to changes made by the act; amending s. 465.0252, F.S.; revising notice requirements to conform to changes made by the act; amending s. 499.003, F.S.; providing and revising definitions; amending s. 499.01, F.S.; authorizing the distribution of medicinal drugs and prepackaged drug products without a specified permit under certain conditions; deleting a provision exempting certain drug repackagers from specified permit requirements; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (7) and (13) of section 465.003, Florida Statutes, are amended, and subsections (21) and (22) are added to that section, to read:

465.003 Definitions.—As used in this chapter, the term:

(7) "Institutional formulary system" means a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II or Class III institutional pharmacy.

(13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of

any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189 and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.

(21) "Central distribution facility" means a facility under common control with a hospital holding a Class III institutional pharmacy permit that may dispense, distribute, compound, or fill prescriptions for medicinal drugs; prepare prepackaged drug products; and conduct other pharmaceutical services.

(22) "Common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

Section 2. Subsection (2) of section 465.004, Florida Statutes, is amended to read:

465.004 Board of Pharmacy.—

(2) Seven members of the board must be licensed pharmacists who are residents of this state and who have been engaged in the practice of the profession of pharmacy in this state for at least 4 years and, to the extent practicable, represent the various pharmacy practice settings. Of the pharmacist members, two must be currently engaged in the practice of pharmacy in a community pharmacy, two must be currently engaged in the practice of pharmacy in a Class II, ~~institutional pharmacy or a~~ Modified Class II, or Class III institutional pharmacy, and three must be pharmacists licensed in this state irrespective of practice setting. The remaining two members must be residents of the state who have never been licensed as pharmacists and who are in no way connected with the practice of the profession of pharmacy. No person may be appointed as a consumer member who is in any way connected with a drug manufacturer or wholesaler. At least one member of the board must be 60 years of age or older. The Governor shall appoint members to the board in accordance with this subsection as members' terms expire or as a vacancy occurs until the composition of the board complies with the requirements of this subsection.

Section 3. Subsections (4) and (6) of section 465.019, Florida Statutes, are amended, and paragraph (d) is added to subsection (2) of that section, to read:

465.019 Institutional pharmacies; permits.—

(2) The following classes of institutional pharmacies are established:

(d)1. "Class III institutional pharmacies" are those institutional pharmacies, including central distribution facilities, affiliated with a hospital

that provide the same services that are authorized by a Class II institutional pharmacy permit. Class III institutional pharmacies may also:

a. Dispense, distribute, compound, and fill prescriptions for medicinal drugs.

b. Prepare prepackaged drug products.

c. Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are each permitted under this chapter to possess medicinal drugs.

d. Provide the services in sub-subparagraphs a.-c. to an entity under common control which holds an active health care clinic establishment permit as required under s. 499.01(2)(r).

2. A Class III institutional pharmacy shall maintain policies and procedures addressing:

a. The consultant pharmacist responsible for pharmaceutical services.

b. Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.

c. Recordkeeping to monitor the movement, distribution, and transportation of medicinal drugs and prepackaged drug products.

d. Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.

e. Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III institutional pharmacies.

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II or Class III institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

(6) In a Class II or Class III institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs, proprietary preparations, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by the pharmacists employed in such institution. A facility with a Class II or Class III institutional pharmacy permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

Section 4. Subsection (3) of section 465.0252, Florida Statutes, is amended to read:

465.0252 Substitution of interchangeable biosimilar products.—

(3) A pharmacist who practices in a Class II, ~~or~~ Modified Class II, or Class III institutional pharmacy shall comply with the notification provisions of paragraph (2)(c) by entering the substitution in the institution's written medical record system or electronic medical record system.

Section 5. Subsection (39) of section 499.003, Florida Statutes, is amended, and paragraphs (w) and (x) are added to subsection (48) of that section, to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(39) "Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing or by a facility holding a Class III institutional pharmacy permit ~~in the establishment in which the prepackaging occurred~~.

(48) "Wholesale distribution" means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

(w) A hospital covered by s. 340B of the Public Health Service Act, 42 U.S.C. s. 256b, that arranges for a prescription drug wholesale distributor to distribute prescription drugs covered under that act directly to a contract pharmacy. Such hospital is exempt from obtaining a restricted prescription drug distributor permit under s. 499.01(2)(h).

(x) The dispensing or distribution of a medicinal drug by a Class III institutional pharmacy pursuant to s. 465.019.

Section 6. Paragraphs (b) and (h) of subsection (2) and subsection (5) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(b) Prescription drug repackager permit.—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer.

2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

3. A prescription drug repackager permit is not required for distributing medicinal drugs or prepackaged drug products between entities under common control which each hold either an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (2)(r). For purposes of this subparagraph, the term "common control" has the same meaning as in s. 499.003(48)(a)3.

(h) Restricted prescription drug distributor permit.—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(48)(a).

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(48)(j) to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment.

The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

5. A restricted prescription drug distributor permit is not required for distributions between pharmacies that each hold an active permit under chapter 465, have a common ownership, and are operating in a freestanding

end-stage renal dialysis clinic, if such distributions are made to meet the immediate emergency medical needs of specifically identified patients and do not occur with such frequency as to amount to the regular and systematic supplying of that drug between the pharmacies. The department shall adopt rules establishing when the distribution of a prescription drug under this subparagraph amounts to the regular and systematic supplying of that drug.

6. A restricted prescription drug distributor permit is not required for distributing medicinal drugs or prepackaged drug products between entities under common control that each hold either an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (2)(r). For purposes of this subparagraph, the term "common control" has the same meaning as in s. 499.003(48)(a)3.

~~(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(48)(a)3., if:~~

~~(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;~~

~~(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;~~

~~(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and~~

~~(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.~~

~~The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection. A prescription drug distributor that repackages and distributes prescription drugs under this subsection to a not-for-profit rural hospital, as defined in s. 395.602, is not required to comply with paragraph (c) or paragraph (d), but must provide to each health care entity for which it repackages, for each prescription drug that is repackaged and distributed, the information required by department rule for labeling prescription drugs. The department shall adopt rules to ensure the safety and integrity of prescription drugs repackaged and~~

~~distributed under this subsection, including rules regarding prescription drug manufacturing and labeling requirements.~~

Section 7. This act shall take effect July 1, 2018.

Approved by the Governor March 23, 2018.

Filed in Office Secretary of State March 23, 2018.

TAB #3

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

INSTITUTIONAL PHARMACY PERMIT APPLICATION AND INFORMATION

January 2018

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the board) staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting the application. You should keep a copy of the completed application and all other materials sent to the board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at info@floridaspharmacy.gov or you may at call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

INSTITUTIONAL PHARMACY PERMIT APPLICATION INFORMATION

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of $255.00. The application MUST have the original signatures of the owner or officer of the establishment and the Consultant Pharmacist of Record (COR). If compounding sterile preparations, submit an additional application on Form DH-MQA 1270, "Special Sterile Compounding Permit" and pay the additional permitting fee.

There are three types of Institutional Pharmacy Permit applicants. Please read the description below. Check which permit type you are applying for on the application.

1. **Institutional Class I Pharmacy** – An Institutional Class I pharmacy is an institutional pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises. No medicinal drugs may be dispensed in a Class I Institutional pharmacy. A Special- Closed System Pharmacy Permit, Special Parenteral and Enteral Pharmacy Permit, or Community Pharmacy Permit allow dispensing of individual patient prescriptions.

2. **Institutional Class II Pharmacy Permit** – An Institutional Class II pharmacy is an institutional pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. An Institutional Class II pharmacy is required be open sufficient hours to meet the needs of the hospital facility.

3. **Modified Institutional Class II Pharmacy Permits -** Modified Institutional Class II pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. Modified Class II Institutional pharmacies are designated as Type "A", Type "B" and Type "C" according to the type of specialized pharmaceutical delivery system utilized. Please review Rule 64B16-28.702, Florida Administrative Code for specific requirements.

Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

Application Processing

Please read all application instructions before completing your application.

1) Mail Application.

Please mail the application and the $255.00 application fee (cashier's check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Application & Fees:
Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

Express Mail ONLY
Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

Within 30 days of receipt of your application and fees, the Board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

2) Submit fingerprint results.

Failure to submit fingerprints will delay your application. All owners, officers, and Consultant Pharmacists of Record (CORs) are required to submit a set of fingerprints unless the corporation is exempt under Section 465.022, Florida Statutes, for corporations having more than $100 million of business taxable assets in this state. These corporations are only required to have the COR to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, or Consultant Pharmacist of Record has already been fingerprinted at the time you are completing this Institutional Pharmacy permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

How do I find a Livescan vendor in order to submit my fingerprints to the Department?
The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

What information must I provide to the Livescan vendor I choose?

- If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number.
- You must provide the correct ORI number.

Where do I get the ORI number to submit to the vendor?
The ORI number for the pharmacy profession is **EDOH4680Z**.

Attestation for Business Taxable Assets
If the applicant has more than $100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business affirming the corporation has more than $100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

Licensure Process

Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. **Please wait 7 - 14 days from your satisfactory inspection before checking on the status of your permit**.

You may look up your license number on our website at http://www.flhealthsource.com/ under "Verify a License."

Drug Enforcement Administration (DEA)

Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(e) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete.

INSTITUTIONAL PHARMACY PERMIT

_____ All Application Questions Answered?

_____ $255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)

_____ Articles of Incorporation paperwork from the Secretary of State provided?

_____ COR Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____ Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____ Answers to Policy and Procedure Questions provided for **Institutional Pharmacy** applicants (Application Item #3)?

_____ Answers to Policy and Procedure Questions provided for **Modified Class II Institutional Pharmacy** applicants (Application Item #4)?

_____ Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____ Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____ Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
850-245-4292
http://www.floridaspharmacy.gov

INSTITUTIONAL PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:

___New Establishment ($255.00 fee)
Complete: Section A only, along with Items #1 and 2.

___Change of Ownership ($255.00 fee)
Complete: Sections A and C only, along with Items #1 and 2.

___ Change of Location ($100.00 fee)
Complete: Sections A and B only.

___ Stock Transfer (no fee)
Complete: Section A, pages 2-3 and Section D only.

Pharmacy Permit Type – Please choose only one of the following:

____Institutional Class I

____Institutional Class II
Complete: Item #3 only,

Modified Institutional Class II A ___Class II B____ Class II C___
Complete: Item #4 only,

SECTION A. Please complete for all Application Types

Please list your Federal Employer Identification Number:

1. Corporate Name	**Telephone Number**
2. Doing Business As (d/b/a)	**E-Mail Address**** (see note below)

3. Mailing Address

City	**State**	**Zip**

4. Physical Address

City	**State**	**Zip**

5. Consultant Pharmacist of Record (COR) Information

Name	**License Number**
Email Address ** (see note below)	**Telephone Number**
6. Contact Person	**Title**
Email Address ** (see note below)	**Telephone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

7. Ownership Information

a Type of Ownership: _____Individual _____Corporation _____Partnership

NOTE: If the applicant is a corporation or limited partnership you must include with your application a copy of the Articles of Incorporation on file with the Florida Secretary of State's office.

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes _____ No_____

c. Does the corporation have more than $100 million of business taxable assets in this state? *If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).*

Yes _____ No_____

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 7c. If 7c. is "Yes", please list the owners below and only submit fingerprints for the Consultant Pharmacist of Record. If 7c. is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation. *Attach a separate sheet if necessary.*

Owner/Officer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

8. Has anyone listed in 7d. has an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes_____ No_____

8a. Has anyone listed in 7d. had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

Pursuant to Section 465.022(5), the questions 9 – 17 are being asked. If you answer "Yes" to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

9. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?

Yes _____ No_____

10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?

Yes _____ No _____

11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?

Yes _____ No_____

12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes_____ No_____

13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?

Yes _____ No_____

14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period?

Yes _____ No _____

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application?

Yes _____ No _____

16. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities? *(If yes, please submit proof.)*

Yes _____ No _____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466?

Yes _____ No _____

18. Are you currently registered or permitted in any other states? *(If yes, provide the state, permit type and permit number for each permit. Attach a separate sheet if necessary.)*

Yes_____ No _____

State	Permit Type	Permit Number

19. Has the applicant, affiliated persons, partners, officer, directors, or Consultant Pharmacist of Record ever owned a pharmacy? *(If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.*

Yes _____ No _____

Individual's Name	Pharmacy Name	State	Status

20. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or consultant pharmacist of record?

Yes _____ No _____

21. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction.

Yes _____ No _____

22. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? *(If yes, please answer question #22a,)*

Yes _____ No _____

22a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?

Yes _____ No _____

23. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?

Yes _____ No_____

24. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?

Yes _____ No_____

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address

City	**State**	**Zip**
E-Mail Address** (see note below)	**Telephone Number**	

2. New Practice Location Address

City	**State**	**Zip**
E-Mail Address** (see note below)	**Telephone Number**	

Please provide your existing Pharmacy Permit Number:

Please provide your existing federal DEA Number:

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

SECTION C. Please complete for Change of Ownership only.

1. Are you changing physical locations with this change of ownership?

Yes _____ No _____ *NOTE: If yes, please complete **Section B** above.*

2. Please provide date when business transaction for the change of ownership will be completed?

Date:

3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred? *NOTE: A copy of the signed letter should be provided with your application.*

Yes _____ No _____

SECTION D. Please complete for Stock Transfer of Ownership Interests only.

1. Please provide the date when the transfer of ownership interest took place?

Date:

2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, Question 1 above?

Yes_____ No _____ *NOTE: If yes, please complete **Section C** above and include necessary fee.*

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I swear and affirm that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, Board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.

Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- The ORI number for the Board of Pharmacy is **EDOH4680Z**.
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address: _____ Apt. Number: _____

City:_____ State: _____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____ Eye Color:_____ Hair Color: _____

Race: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown)

Sex: _____
(M=Male; F=Female)

Citizenship: _____

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Live Scan Service provider*.)

Keep this form for your records.

Item #1- Consultant Pharmacist of Record Designation and Privacy Statement Acknowledgement

To: **Florida Board of Pharmacy**
Post Office Box 6320
Tallahassee, FL 32314-6320
(850) 245-4292- phone
(850) 413-6982 - fax
MQAPharmPDMAffiliate@flhealth.gov

File #: (if known)**:**
License #: (if applicable)**:**

Section A. Consultant Pharmacist of Record (COR) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming COR Name:		**License#:**
		PU
Date Beginning as COR:	**Incoming COR Signature**	

Transaction Control Number (TCN) – related to Livescan Fingerprints *(optional, if known)***:**
** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**

****OPTIONAL: Only provide following information if there is an Outgoing COR at current pharmacy****

Outgoing COR Name:	**License#:**
	PU
Date Ending as COR:	**Outgoing COR Signature** *(optional)*

Section B. Incoming COR Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming COR.

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming COR Signature**

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

To be completed by EACH Affiliate/Owner listed in the application.

To: **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

From:

Affiliate / Owner Name:		**File # (required):**
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	**State**	**Zip**
Affiliate/Owner E-Mail ** (see note below)	**Affiliate/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.		

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

_____ _____

Affiliate/Owner Signature (Required) **Date (of signature)**

Item #3 - Policy and Procedure Questions

To be completed by Institutional Class II Pharmacy Permit Applicants

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Class II Institutional Pharmacy and shall be available for inspection by the Department of Health. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

1) List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number: Address:
Permit number (if already licensed as an institutional pharmacy):

2) Explain the practice setting of the proposed facility.

3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.

4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.

5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.

6) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient. If utilizing remote medication order processing and the pharmacist is not an employee of the institution, describe the pharmacist and institution's responsibility.

7) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.

8) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.

9) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.

10) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.

11) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

12) What is the procedure for the annual review and updating of the policy and procedure manual?

13) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.

14) Include a sample copy of a patient profile.

15) Address the use of aseptic techniques.

16) Describe the Quality Assurance Program.

17) Describe with detail the policy and procedure for patient education, including the personnel involved.

18) Address the policy and procedure for handling waste and returns.

19) Describe the type of certified laminar flow hood(s) used and the frequency of certification.

20) Describe the refrigerator/freezer to be used.

21) Describe appropriate waste containers for:

a. Used needles and syringes.

b. Cytotoxic waste including disposable apparel used in preparation.

22) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.

23) Address the following references to be used:

a. Chapters 465 and 893, F.S., and Rule Title 64B16,F.A.C.
b. Authoritative Therapeutic Reference.
c. Handbook of injectable drugs by American Society of Health-System Pharmacists.

24) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

Item #4 - Policy and Procedure Questions

To be completed by Modified Institutional Class II Pharmacy Permit Applicants

Modified Institutional Class II pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. Modified Class II Institutional pharmacies are designated as Type "A", Type "B" and Type "C" according to the type of specialized pharmaceutical delivery system utilized. Please review Rule 64B16-28.702, Florida Administrative Code for specific requirements.

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Modified Class II Institutional Pharmacy and shall be available for inspection by the Department of Health. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual

1) List the following:
   Firm Name:
   Doing business as (d/b/a):
   Telephone number:
   Address:
   Consultant pharmacist of record:

2) Describe the purpose of the establishment. What sector of the community are you serving?

3) Is this is an inpatient facility? If so, how many beds are housed in the facility?
   What is the average length of stay?

4) List the drug formulary to be used.

5) Include a diagram of pharmacy storage space and a description of drug security measures.

6) Describe the consultant pharmacist of record's responsibilities.

7) Under whose DEA registration will controlled substances be ordered?

8) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient.

9) Include a statement that perpetual inventory records will be maintained for controlled substances and injectable inventory.

10) Include a statement to the effect that no drugs will be dispensed from the facility.

If compounding sterile preparations, please answer the additional questions below.

11) If compounding sterile preparations, describe compliance with Rule 64B16- 27.797, F.A.C.

12) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.

13) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how this product is protected from extreme temperature conditions.

14) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.

15) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.

16) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

17) What is the procedure for the annual review and updating of the policy and procedure manual?

18) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.

19) Include a sample copy of a patient profile.

20) Address the use of aseptic techniques.

21) Describe the Quality Assurance Program.

22) Describe with detail the policy and procedure for patient education, including the personnel involved.

23) Address the policy and procedure for handling waste and returns.

24) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.

25) Describe the refrigerator/freezer to be used.

26) Describe appropriate waste containers for:
    a. Used needles and syringes.
    b. Cytotoxic waste including disposable apparel used in preparation.

27) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.

28) Address the following references to be used:
    a. Chapters 465 and 893, F.S., and Title 64B16, F.A.C.
    b. Authoritative Therapeutic Reference.
    c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
    d. Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

TAB #4

CHAPTER 64B16-28
GENERAL REQUIREMENTS – PERMITS

64B16-28.606	Remote Medication Order Processing for Class II Institutional Pharmacies or Special Pharmacy Permits Servicing Class I, Class II, Modified Class II, and Special ALF Permitted Facilities
64B16-28.607	Automated Pharmacy System – Long-Term Care, Hospice, and Prison
64B16-28.608	Automated Filling Systems within a Pharmacy
64B16-28.702	Modified Class II Institutional Pharmacies
64B16-28.800	Special Pharmacies
64B16-28.802	Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities
64B16-28.810	Special Pharmacy – Limited Community Permit
64B16-28.820	Sterile Products and Special Parenteral/Enteral Compounding
64B16-28.830	Special – Closed System Pharmacy
64B16-28.840	Special – Non Resident (Mail Service) (Repealed)
64B16-28.850	Special Pharmacy – ESRD
64B16-28.860	Special Pharmacy – Parenteral/Enteral Extended Scope Permit
64B16-28.870	Special-ALF
64B16-28.900	Definitions – Nuclear Pharmacy
64B16-28.901	Nuclear Pharmacy – General Requirements
64B16-28.902	Nuclear Pharmacy – Minimum Requirements
64B16-28.903	Training Qualifications (Repealed)
64B16-28.904	Nuclear Pharmacist – Continuing Education (Repealed)
64B16-28.905	Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities (Transferred)

64B16-28.100 Pharmacy Permits – Applications and Permitting.

This section addresses the application and permitting requirements of business establishments regulated under Chapter 465, F.S. Any establishment that is required to have a permit shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at http://www.doh.state.fl.us/mqa/pharmacy or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850)488-0595. Inquiries regarding the status of the application or license verification may be obtained at http://www.FLHealthsource.com. The application must be accompanied with a $250 initial permit fee, payable to the Board.

(1) All Permits: A permit is valid only for the name and address to which it is issued. The name in which the permit is issued must be the name in which the company is doing business, i.e., the name that appears on purchase and sales invoices.

(a) A permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:

1. A contiguous area under the control of the permit holder. For purposes of this rule, a public thoroughfare will be considered to have not broken the area of contiguity; and,

2. An area not more than one half (1/2) mile from the central location of the permit.

(b) The name in which a permit is issued may be changed upon notification to the board. To change the name in which a permit is issued the person or establishment must file with the board an original Form DH-MQA 1227 "Pharmacy Permit Name Change Form" effective December 2010, which is incorporated by reference herein, and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02297 or on the web at http://www.doh.state.fl.us/mqa/pharmacy.

(c) Each applicant must file with the board a legible set of fingerprint cards and a $48 fee for each person who submits an application meeting the requirements in Section 465.022(3), F.S. An applicant may register demographic information and purchase fingerprint cards (FD-258) at http://http://www.fldoh.sofn.net/. If an applicant chooses not to purchase a fingerprint card, the applicant must make sure the police or agency that rolls the fingerprints uses a FD-258 fingerprint card. A Non-Resident Pharmacy Registration applicant is not required to submit a legible set of fingerprints upon application.

(d) Passing an on-site inspection is a prerequisite to issuance of a new permit, whether based on an initial application, change of ownership, or change of address. At the time of the on-site inspection, the board inspector will document the applicant's compliance with all applicable rules and statutes.

(e) Each applicant must attach to the application the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships.

(2) Community Pharmacy Permit as authorized by Section 465.018, F.S., is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. Applicants for a community pharmacy permit must complete an application for a permit using an original Form DH-MQA 1214, "Community Pharmacy Permit Application and Information," effective August 2012 which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02298.

(a) Applicants for a Community Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1), of this rule; and,

2. Designate a prescription department manager as required by Section 465.018, F.S.

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02299.

(c) The policy and procedure manual for Community Pharmacies shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations. The policy and procedural manual shall provide the following:

1. Provisions to identify and guard against invalid practitioner-patient relationships.

2. Provisions to guard against filling fraudulent prescriptions for controlled substances.

3. Provisions to identify prescriptions that are communicated or transmitted legally.

4. Provisions to identify the characteristics of a forged or altered prescription.

(3) Institutional Pharmacy Permits as authorized by Section 465.019, F.S., is required for any location in any health care institution where medicinal drugs are compounded, dispensed, stored or sold. Applicants for a Institutional Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1215, "Institutional Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02300.

(a) Applicants for an Institutional Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1) of this rule; and,

2. Designate a consultant pharmacist of record as required by Section 465.019, F.S.

(b) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02301.

(4) Nuclear Pharmacy Permit as authorized by Section 465.0193, F.S., is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. Applicants for a Nuclear Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1218, "Nuclear Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02302.

(a) Applicants for a Nuclear Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1), of this rule; and,

2. Designate a nuclear pharmacist of record as required by Section 465.0193, F.S.

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(5) Special Pharmacy Permits as authorized in Section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which are not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special – Parenteral and Enteral, Special – Closed System Pharmacy, Special – End Stage Renal Disease (ESRD), Special – Parenteral/Enteral Extended Scope, and Special – Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit

Application and Information," effective August 2012, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02303.

(a) Applicants for a Special Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1), of this rule; and,

2. Designate a prescription department manager or consultant pharmacist of record as required by Section 465.0196, F.S.

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(c) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010.

(d) The Board recognized the following types of Special Pharmacy permits:

1. Special Limited Community Permit may be obtained by an Institutional Class II Pharmacy that dispenses medicinal drugs to employees, medical staff, emergency room patients, and other patients on continuation of a course of therapy.

2. Special Parenteral and Enteral Permit is required to provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special – Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special – Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.

3. Special Closed System Pharmacy Permit is not open to the public and prescriptions are individually prepared for dispensing utilizing closed delivery systems, for ultimate consumers in health care institutions including nursing homes, jails, ALF's, Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by AHCA rules which the Board may approve. This permit may not provide medications to in-patients in a hospital.

4. Special Pharmacy – End Stage Renal Disease (ESRD) Permit is a type of special pharmacy which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.

5. Special Pharmacy – Parenteral/Enteral Extended Scope Permit is required for pharmacies to compound patient specific parenteral/enteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.

6. Special – Assisted Living Facility (ALF) Permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

(6) Internet Pharmacy Permit as authorized by Section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Applicants for an Internet Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," effective August 2012.

(a) Applicants for an Internet Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1), of this rule; and,

2. Designate a prescription department manager or consultant pharmacist of record as required by Section 465.0197, F.S.

(b) As set forth in Section 465.0197, F.S., the permittee shall notify the board within 30 days of any change of location, corporate officers, and the pharmacist serving as the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(7) Special Sterile Compounding Permit: Except those pharmacies which already hold an active stand alone Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope Compounding permit, any pharmacy engaged in sterile compounding must obtain a special sterile compounding permit by filing an application on form DH-MQA 1270, "Special Sterile Compounding Permit Application and Information," effective May 2013, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-03142.

(a) All applicants that hold an active pharmacy permit that are currently engaged in sterile compounding have 180 days from the effective date of this amendment (eff. 9/23/13) to obtain a Special Sterile Compounding Permit. All pharmacies, which obtain the permit within the 180 days, on or before March 21, 2014, are exempt from paying an additional application or license fee.

(b) Applicants for a Special Sterile Compounding Permit must:

1. Comply with all permitting requirements in subsection (1), of this rule,

2. Designate a prescription department manager or consultant pharmacist of record.

(c) The permittee and the newly designated prescription department manager of record or consultant pharmacist of record shall notify the board within 10 days of any change in the prescription department manager or consultant pharmacists of record on FORM DH-MQA PH10, "Prescription Department Manager Change," effective December 2010 or FORM DH-MQA 1184, "Change of Consultant Pharmacist of Record."

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 456.0635, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History–New 2-21-13, Amended 9-23-13, 5-31-17.

64B16-28.101 Prescription Area Accessible to Inspection.

(1) The prescription department compounding room or any other place where prescriptions are compounded, filled, processed, accepted, dispensed, or stored in each pharmacy shall be so situated and located that authorized agents and employees of the Department or other persons authorized by law to enter and inspect, can observe and survey the confines of said department, room or area and can enter into said department, room or area after identifying themselves, for the purpose of inspection at a reasonable hour or when the practice of the profession of pharmacy is being carried on, as defined in Section 465.003, F.S., without having been previously detained or announced. Such inspection may be routinely conducted at any time by authorized agents of the Department to determine whether Chapter 465, F.S., or provisions of these rules have been violated or for other lawful purposes, and need not be in response to a complaint filed with the Department. There shall be a minimum of one (1) inspection per year except as otherwise provided herein or directed by the Board.

(a) A pharmacy shall be inspected twice during the first year of operation.

(b) A pharmacy which has had passing inspections for the most current three years, and no discipline during the most current three years shall be inspected every two years.

(c) A pharmacy which fails to obtain a passing inspection or which is disciplined during the two year inspection cycle will be inspected annually until it achieves passing inspections for the most current three years, and no discipline during the most current three years as set forth in this subsection.

(2) Authorized agents and employees of the Department or other persons authorized by law shall have the right to inspect invoices, shipping tickets, or any other document pertaining to the transfer of drugs or drug preparations, from or to all pharmacies and a reasonable amount of time shall be allowed for said information to be made available.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.017, 465.022 FS. History–New 5-19-72, 11-2-81, Formerly 21S-1.01, 21S-1.001, Amended 7-31-91, Formerly 21S-28.101, 61F10-28.101, 59X-28.101, Amended 5-4-05, 2-2-12.

64B16-28.102 Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment.

There shall be provided for the prescription department of each pharmacy:

(1) An adequate sink in workable condition and running water easily accessible to the prescription counter that shall be available during the hours when the prescription department is normally open for the business related to prescriptions.

(2) Sufficient shelf, drawer or cabinet space for the neat and orderly storage of pharmaceutical stock, prescription containers, prescription labels, the required equipment, and all other items, articles or equipment stored therein and there shall be sufficient walking space and sufficient work counter space within each prescription department of said establishment so as to allow employees or pharmacists employed therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(3) Adequate facilities for the proper storage of pharmaceuticals which require refrigeration, and such pharmaceuticals shall be stored therein, and in such manner as to preserve their therapeutic activity.

(4) Adequate sanitation to insure the prescription department is operating under clean, sanitary, uncrowded, and healthy conditions.

(5) The following items:

(a) A current pharmacy reference compendium such as the United States Pharmacopoeia/National Formulary, the U.S. Dispensatory, USP DI, (United States Pharmacopoeial Drug Information), the Remington Practice of Pharmacy, Facts and Comparisons or an equivalent thereof sufficient in scope to meet the professional practice needs of that pharmacy, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida. It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

(b) Such other equipment as is necessary to meet the needs of the professional practice of pharmacy.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.02, 21S-1.002, 21S-28.102, 61F10-28.102, 59X-28.102, Amended 5-4-05.

64B16-28.103 Sufficient Space in Prescription Department.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.03, 21S-1.003, 21S-28.103, 61F10-28.103, 59X-28.103, Repealed 5-4-05.

64B16-28.1035 Patient Consultation Area.

A community pharmacy shall provide a private consultation area so all patients of the pharmacy will be able to obtain counseling without being overheard by others in the prescription dispensing area of the pharmacy. The consultation area must be accessible by the patient from the outside of the prescription dispensing area of the pharmacy without having to traverse a stockroom or the prescription dispensing area. In determining whether the area is suitable, consideration shall be given to the proximity of the counseling area to the check-out or cash register area, the volume of pedestrian traffic in and around the consultation area, and the presence of walls or other barriers between the counseling area and the prescription dispensing area of the pharmacy. The consultation area may consist of designated private counter space. The area shall be designated with a sign bearing "Patient Consultation Area," or words that are substantially similar.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History-New 9-20-99, Amended 5-4-05.

64B16-28.104 Refrigeration.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.04, 21S-1.004, 21S-28.104, 61F10-28.104, 59X-28.104, Repealed 5-4-05.

64B16-28.105 Sanitation.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 5-19-72, Repromulgated 12-18-74, Amended 1-29-80, Formerly 21S-1.07, 21S-1.007, Amended 7-31-91, Formerly 21S-28.105, 61F10-28.105, 59X-28.105, Repealed 5-4-05.

64B16-28.106 Right to Inspect Invoices.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.017 FS. History–New 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, 4-30-85, Formerly 21S-1.008, 21S-28.106, 61F10-28.106, 59X-28.106, Repealed 5-4-05.

64B16-28.107 Pharmacy Equipment.

Rulemaking Authority 465.005, 465.022, 465.022(1)(h) FS. Law Implemented 465.022(1)(h) FS. History–New 5-19-72, Repromulgated 12-18-74, Amended 4-8-80, 4-26-84, Formerly 21S-1.10, Amended 4-4-88, Formerly 21S-1.010, Amended 7-31-91, Formerly 21S-28.107, 61F10-28.107, Amended 6-4-97, Formerly 59X-28.107, Amended 2-4-99, Repealed 5-4-05.

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.

Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.

(1) Definitions.

(a) "Controlled substance" means any substance named or described in Schedules II-V of Section 893.03, F.S.

(b) "Customized medication package" means a package that:

1. Is prepared by a pharmacist for a specific patient.

2. Is a series of containers.

3. Contains two (2) or more solid oral dosage forms.

(c) "Labeling" means a label or other written, printed, or graphic material upon an agent or product or any of its containers, wrappers, drug carts, or compartments thereof, as well as a medication administration record (MAR) if a medication administration record is an integral part of the unit dose system.

(d) “Radiopharmaceutical” means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(e) “Serial number” means a prescription number or other unique number by which a particular prescription or drug package can be identified.

(2) The label affixed to each container dispensed to a patient shall include:

(a) Name and address of the pharmacy.

(b) Date of dispensing.

(c) Serial number.

(d) Name of the patient or, if the patient is an animal, the name of the owner and the species of animal.

(e) Name of the prescriber.

(f) Name of the drug dispensed (except where the prescribing practitioner specifically requests that the name is to be withheld).

(g) Directions for use.

(h) An Expiration Date or Beyond-Use Date: The expiration date must be the date provided by the manufacturer, repackager, or other distributor. The beyond-use date must not exceed the expiration date and it shall not be a date greater than one year from the date the medicinal drug is filled. The board finds that the use of a “discard-after-date” or “do not use after date” to be equivalent of a beyond-use date.

(i) If the medicinal drug is a controlled substance, a warning that it is a crime to transfer the drug to another person.

(3) The label on the immediate container of a repackaged product or a multiple unit prepackaged drug product shall include:

(a) Brand or generic name.

(b) Strength.

(c) Dosage form.

(d) Name of the manufacturer.

(e) Expiration date.

(f) Lot number:

1. Manufacturer’s lot number, or

2. Number assigned by the dispenser or repackager which references the manufacturer’s lot number.

(4) A medicinal drug dispensed in a unit dose system by a pharmacist shall be accompanied by labeling. The requirement will be satisfied if, to the extent not included on the label, the unit dose system indicates clearly the name of the resident or patient, the prescription number or other means utilized for readily retrieving the medication order, the directions for use, and the prescriber’s name.

(5) A unit dose system shall provide a method for the separation and identification of drugs for the individual resident or patient.

(6) A customized patient medication package may be utilized if:

(a) The consent of the patient or the patient’s agent has been secured; and,

(b) The label includes:

1. Name, address and telephone number of the pharmacy.

2. Serial number for the customized medication package and a separate serial number for each medicinal drug dispensed.

3. Date of preparation of the customized patient medication package.

4. Patient’s name.

5. Name of each prescriber.

6. Directions for use and any cautionary statements required for each medicinal drug.

7. Storage instructions.

8. Name, strength, quantity and physical description of each drug product.

9. A beyond use date that is not more than 60 days from the date of preparation of the customized patient medication package but shall not be later than any appropriate beyond use date for any medicinal drug included in the customized patient medication package.

(c) The customized patient medication package can be separated into individual medicinal drug containers, then each container

shall identify the medicinal drug product contained.

(7) The label affixed to the immediate outer container shield of a radiopharmaceutical shall include:

(a) Name and address of the pharmacy.

(b) Name of the prescriber.

(c) Date of the original dispensing.

(d) The standard radiation symbol.

(e) The words "Caution Radioactive Material."

(f) Name of the procedure.

(g) Prescription order number.

(h) Radionuclide and chemical form.

(i) Amount of radioactivity and the calibration date and time.

(j) Expiration date and time.

(k) If a liquid, the volume.

(l) If a solid, the number of items or weight.

(m) If a gas, the number of ampules or vials.

(n) Molybdenum 99 content to the United States Pharmacopeia (UPS) limits.

(o) Name of the patient or the words "Physician's Use Only."

(8) The label affixed to the immediate inner container of a radiopharmaceutical to be distributed shall include:

(a) The standard radiation symbol.

(b) The words "Caution Radioactive Material."

(c) Radionuclide and chemical form.

(d) Name of the procedure.

(e) Prescription order number of the radiopharmaceutical.

(f) Name of the pharmacy.

(9) The labeling on a carton or package containing a medicinal drug or product dispensed from an Extended Scope Renal Dialysis (ESRD) pharmacy shall include:

(a) "Use as Directed" statement.

(b) The name and address of the person to whom the products will be delivered.

(c) Name of the prescriber.

(d) Name and address of the ESRD pharmacy location from which the products were shipped.

(e) Prescription number.

(f) Any special instructions regarding delivery dates or locations.

(g) Beyond use date or, if the medicinal drug or product is dispensed in an unopened sealed package, the manufacturer's expiration date.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1), 465.0255 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, 9-18-84, 1-20-85, Formerly 21S-1.13, Amended 10-2-88, Formerly 21S-1.013, Amended 7-31-91, 10-1-92, 4-19-93, 7-12-93, Formerly 21S-28.108, 61F10-28.108, 59X-28.108, Amended 3-31-05, 4-22-13.

64B16-28.1081 Regulation of Daily Operating Hours; Commencement of Operations.

(1) Any person who receives a community pharmacy permit pursuant to Section 465.018, F.S., and commences to operate such an establishment, shall keep the prescription department of the establishment open for a minimum of twenty (20) hours per week.

(a) "Commences to Operate" means the compounding, dispensing, storage, or sale of medicinal drugs or the filling or dispensing of prescriptions.

(b) The Board recognizes that a delay may exist between the time a pharmacy receives a Florida pharmacy permit and commences to operate. Accordingly, upon receipt of a Florida pharmacy permit, a community pharmacy may delay commencement of operations in compliance with the following:

1. Within fourteen (14) days of receipt of the Florida pharmacy permit, the permittee shall notify the Board office, in writing, of the permittee's election to delay commencement of operations and the reason(s) therefore,

2. The permittee shall display a sign in block letters not less than one inch in height at the main entrance of the establishment

stating that the pharmacy is not yet open for business and that medicinal drugs may not be dispensed or sold nor prescriptions filled or dispensed,

3. Within two (2) business days of commencement of operations, the permittee shall notify the Board office in writing that the permittee has commenced to operate and the date of commencement.

(c) Any pharmacy permittee that does not commence to operate within six (6) months of the date of receipt of the Florida pharmacy permit shall provide a written statement to the Board office, which shall include the reason(s) the pharmacy has not yet commenced operations, the efforts the pharmacy has made to commence to operate, and the date the pharmacy expects to commence to operate.

(2) At the time a pharmacy commences to operate, a sign in block letters not less than one inch in height stating the hours the prescription department is open each day shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. Any pharmacy that is not open 40 hours a week, must post the days and hours that the pharmacy is open and the information for after-hours access and shall also have a written policy and procedure for transferring a prescription pursuant to Section 465.026, F.S., or receiving an emergency dose pursuant to Section 465.0275, F.S.

Rulemaking Authority 465.005, 465.022(1) FS. Law Implemented 465.022(1)(b) FS. History–New 4-10-05, Amended 2-1-12, 8-23-16.

64B16-28.109 Prescription Department; Padlock; Sign: "Prescription Department Closed."

(1) The prescription department of any community pharmacy permittee shall be considered closed whenever the establishment is open and a pharmacist is not present and on duty. A sign with bold letters not less than two (2) inches in width and height, shall be displayed in a prominent place in the prescription department so that it may easily be read by patrons of that establishment. The sign shall contain the following language: "Prescription Department Closed."

(2) The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purpose of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, taking a meal break pursuant to Rule 64B16-27.1001, F.A.C., or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(3) At all times when the prescription department is closed, either because of the absence of a pharmacist or for any other reason, it shall be separated from the remainder of the establishment by partition or other means of enclosure, thereby preventing access to the prescription department by persons not licensed in Florida to practice the profession of pharmacy.

(4) The partition or other means of enclosure shall be securely locked or padlocked and only a pharmacist shall have the means to gain access to the prescription department.

(5) Whenever the prescription department of any community pharmacy establishment is closed, no person other than a pharmacist shall enter, be permitted to enter or remain in the prescription department.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 8-20-63, 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, Formerly 21S-1.14, 21S-1.014, Amended 7-31-91, Formerly 21S-28.109, 61F10-28.109, 59X-28.109, Amended 6-15-98, 4-10-05.

64B16-28.110 Outdated Pharmaceuticals.

Persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.17, 21S-1.017, 21S-28.110, 61F10-28.110, 59X-28.110.

64B16-28.111 Storage of Equipment.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Promulgated 12-18-74, Formerly 21S-1.19, 21S-1.019, 21S-28.111, 61F10-28.111, 59X-28.111, Repealed 4-10-05.

64B16-28.112 Violations.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-63, Amended 5-19-72, Promulgated 12-18-74, Formerly 21S-1.23, 21S-1.023, Amended 7-31-91, Formerly 21S-28.112, 61F10-28.112, 59X-28.112, Repealed 4-10-05.

64B16-28.113 Permits; Single Entity; Single Location.

A Board of Pharmacy permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:

(1) A contiguous area under the control of the permit holder. For purposes of this section, a public thoroughfare will be considered to have not broken the area of contiguity; and,

(2) An area not more than one-half mile from the central location of the permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196 FS. History–New 1-30-96, Formerly 59X-28.113.

64B16-28.1135 Change of Ownership.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022(7) FS. History–New 4-19-00, Amended 1-2-02, Transferred to 64B16-28.2021.

64B16-28.114 Prescription Refills.

Rulemaking Authority 465.005, 465.016(1), 465.022, 465.022(1)(a), 893.04 FS. Law Implemented 465.022 FS. History–New 12-18-74, Formerly 21S-1.28, 21S-1.028, Amended 7-31-91, Formerly 21S-28.114, 61F10-28.114, 59X-28.114, Amended 2-4-02, 7-1-02, Repealed 10-5-09.

64B16-28.118 Unit Dose and Customized Patient Medication Package Returns.

(1) Definitions. As used herein:

(a) A "unit dose system" means a system wherein all individually sealed unit doses are physically connected as a unit. For purpose of this rule, a product in an unopened, sealed, manufacture's container is deemed to be a unit dose package.

(b) A "customized patient medication package" means a system wherein all USP approved multi-dose units are physically connected (also referred to as a "container"). The use of customized patient medication packages must comply with the provisions of subsection 64B16-28.108(5), F.A.C.

(c) A "closed drug delivery system" is a system in which the actual control of the unit dose or customized patient medication package is maintained by the facility rather than by the individual patient.

(d) For purposes of this rule, "facility" shall mean any health care institution operating with a Class I, Class II, Modified Class II, or Special ALF permit.

(2) No pharmacist shall place into the stock of any pharmacy permittee any part of any prescription, compounded or dispensed, which is returned by a patient except under the following conditions:

(a) In a closed drug delivery system in which unit dose or customized patient medication packages are dispensed to in-patients, the unused medication may be returned to the pharmacy for redispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system, or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any.

(b) In the case of controlled substances, as it is allowed by Federal Law.

(3) All pharmacies utilizing unit dose or customized patient medication packages shall address specific policies and procedures regarding their preparation and use in the pharmacy's Policy and Procedures Manual.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.016(1)(l), 465.019 FS. History–New 11-10-80, Formerly 21S-1.36, 21S-1.036, Amended 7-31-91, Formerly 21S-28.118, 61F10-28.118, 59X-28.118, Amended 9-23-99, 7-1-02, 9-18-17.

64B16-28.119 Data Processing Systems in Pharmacy.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 9-21-83, Formerly 21S-1.38,

21S-1.038, Amended 7-31-91, Formerly 21S-28.119, Amended 3-16-94, Formerly 61F10-28.119, 59X-28.119, Repealed 7-15-99.

64B16-28.1191 Unclaimed Prescriptions.

Prescriptions that are unclaimed may be retained by a pharmacy and reused for a period up to one year from the date of filling; however, any product reaching the product's expiration date prior to one year or any product subject to a recall shall not be reused.

Rulemaking Authority 465.0255 FS. Law Implemented 465.0255 FS. History–New 4-10-05.

64B16-28.120 All Permits – Storage of Legend Drugs; Prepackaging.

(1) All medicinal drugs or drug preparations as defined by Section 465.003(8), F.S., shall be stored:

(a) Within the confines of the prescription department of a community pharmacy permittee as defined in Section 465.018, F.S.

(b) In a Class II Institutional pharmacy as defined by Section 465.019(2)(b), F.S., within the confines of the pharmacy provided, however, that those medicinal drugs established by the consultant pharmacist as supportive to treatment procedures such as medical drugs, surgical, obstetrical, diagnostic, etc., may be permitted to be stored in those areas where such treatment is conducted consistent with proper control procedures as provided by the policy and procedure manual of the pharmacy.

(2) All medicinal drugs or drug preparations as defined in Section 465.003(8), F.S., within Class I Institutional permittees as defined in Section 465.019(2)(a), F.S., and Special ALF Permit 64B16-28.870, F.A.C., shall:

(a) Be administered from individual prescription containers to the individual patient; and,

(b) Be prohibited within the confines of Class I Institutional pharmacies unless obtained upon a proper prescription and properly labeled in accordance with Chapter 499, F.S., and the rules and regulations contained in Chapter 59A-4, F.A.C., incorporated by reference and effective August 1, 2006, pertaining to the licensure of nursing homes and related facilities.

(3) Prepackaging of medication, whether a part of a unit dose system or a part of a multiple dose drug distribution system in an extended care facility or hospital holding a valid Class II Institutional pharmacy permit, must be done in accordance with procedures set up by the consultant pharmacist of record in the policy and procedure manual; and in the case of a pharmacy holding a valid community pharmacy permit must be done in accordance with procedures set up by the prescription department manager.

(4) Medicinal drugs and proprietary preparations as identified above that are stored in treatment areas must be accessible only to licensed staff (pharmacists, nurses, physicians, advanced registered nurse practitioners, physician assistants, respiratory and physical therapist, radiology technicians and registered pharmacy technicians, etc.) in accordance with their license, practice act, or to other personnel specifically authorized by the institution.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 435.019(2), 465.003(7), 465.022 FS. History–New 9-18-84, Formerly 21S-1.44, 21S-1.044, Amended 7-31-91, Formerly 21S-28.120, 61F10-28.120, 59X-28.120, Amended 2-8-07, 8-16-10.

64B16-28.121 Permit Fees.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 7-31-91, Formerly 21S-28.121, 61F10-28.121, 59X-28.121, Amended 10-30-00, Repealed 4-10-05.

64B16-28.130 Transmission of Prescription Orders.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 3-16-94, Formerly 61F10-28.130, 59X-28.130, Repealed 4-10-05.

64B16-28.140 Record Maintenance Systems for All Pharmacy Permits.

(1) Requirements for records maintained in a data processing system.

(a) The pharmacy must comply with the provisions of 21 C.F.R. Section 1304.04 (a regulation of the Federal Drug Enforcement Administration), which is hereby incorporated by reference as of March 1, 1998, when such is applicable to operate such a data processing system if any controlled substances (as that term is used in Chapter 893, F.S.) are dispensed from the pharmacy.

(b) Any pharmacy using a data processing system must meet the requirements of 21 C.F.R. Section 1306.22, which is hereby incorporated by reference as of March 1, 1998.

(c) If a pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual recordkeeping system as specified in Rule 64B16-27.800, F.A.C., and Section 893.07, F.S.

(d) Original prescriptions, including prescriptions received as provided for in Rule 64B16-28.1003, F.A.C., Transmission of Prescription Orders, shall be reduced to a hard copy if not received in written form. All original prescriptions shall be retained for a period of not less than four (4) years from date of last filling. To the extent authorized by 21 C.F.R. §1304.04, a pharmacy may, in lieu of retaining the actual original prescriptions, use an electronic imaging recordkeeping system, provided such system is capable of capturing, storing, and reproducing the exact image of the prescription, including the reverse side of the prescription if necessary, and that such image be retained for a period of no less than four (4) years from the date of last filling.

(e) Original prescriptions shall be maintained in a two or three file system as specified in 21 C.F.R. §1304.04(h).

(f) Requirements for back-up systems.

1. The pharmacy shall maintain a back-up copy of information stored in the data processing system using disk, tape or other electronic back-up system and update this back-up copy on a regular basis, at least weekly, to assure that data is not lost due to system failure.

2. Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding four (4) years as specified in Rule 64B16-27.800, F.A.C.

(g) Change or discontinuance of a data processing system.

1. Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records of dispensing to the new data processing system, or

b. Purge the records of dispensing to a printout which contains the same information required on the daily printout as specified in paragraph (3)(b), of this section. The information on this hard-copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.

2. Other records. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system, or

b. Purge the records to a printout which contains all of the information required on the original document.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for four (4) years from the date of initial entry into the data processing system.

(h) Loss of Data. The prescription department manager shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) All transfers of prescriptions must be strictly in accordance with the provisions of Section 465.026, F.S., and Rule 64B16-27.105, F.A.C.

(3) Records of dispensing.

(a) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(b) The data processing system shall have the capacity to produce a daily hard-copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

1. Unique identification number of the prescription,

2. Date of dispensing,

3. Patient name,

4. Prescribing practitioner’s name,

5. Name and strength of the drug product actually dispensed, if generic name, the brand name or manufacturer of drug dispensed,

6. Quantity dispensed,

7. Initials or an identification code of the dispensing pharmacist; and,

8. If not immediately retrievable via CRT display, the following shall also be included on the hard-copy printout:

a. Patient’s address,

b. Prescribing practitioner’s address,

c. Practitioner’s DEA registration number, if the prescription drug order is for a controlled substance,

d. Quantity prescribed, if different from the quantity dispensed,

e. Date of issuance of the prescription drug order, if different from the date of dispensing; and,

f. Total number of refills dispensed to date for that prescription drug order.

(c) The daily hard-copy printout shall be produced within 72 hours of the date on which the prescription drug orders were

dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(d) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(e) In lieu of producing the printout described in paragraphs (b) and (c), of this section, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of four (4) years after the date of dispensing provided, however, that the data processing system can produce the hard-copy printout on demand by an authorized agent of the Department of Health. If no printer is available on site, the hard-copy printout shall be available within 48 hours with a certification by the individual providing the printout, which states that the printout is true and correct as of the date of entry and such information has not been altered, amended or modified.

(f) The prescription department manager and the permit holder are responsible for the proper maintenance of such records and responsible that such data processing system can produce the records outlined in this section and that such system is in compliance with this subsection.

(g) Failure to provide the records set out in this section, either on site or within 48 hours for whatever reason, constitutes failure to keep and maintain records.

(h) In the event that a pharmacy which uses a data processing system experiences system downtime, the following is applicable;

1. An auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded or that authorization from the prescribing practitioner has been obtained prior to dispensing a refill; and,

2. All of the appropriate data shall be retained for online data entry as soon as the system is available for use again.

(4) Compounding records. A written record shall be maintained for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C. This record shall include:

(a) Date of compounding.

(b) Control number for each batch/sub-batch of a compounded product. This may be the manufacture’s lot number or new numbers assigned by the pharmacist. If the number is assigned by the pharmacist, the pharmacist shall also record the original manufacture’s lot number and expiration dates. If the original numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the component.

(c) A complete formula for the compounded product maintained in a readily retrievable form including methodology and necessary equipment.

(d) A signature or initials of the pharmacist or pharmacy technician performing the compounding.

(e) A signature or initials of the pharmacist responsible for supervising pharmacy technicians involved in the compounding process.

(f) The name(s) of the manufacturer(s) of the raw materials used.

(g) The quantity in units of finished products or grams of raw materials.

(h) The package size and number of units prepared.

(i) The name of the patient who received the particular compounded product.

(5) Authorization of additional refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(a) On the daily hard-copy printout, or

(b) Via the CRT display.

(6) Any other records, policy and procedure manuals, or reference materials which are not specifically required by statute or rule to be kept in a hard copy may be kept in a readily retrievable data processing system which complies with the provisions of subparagraph (1)(f)1.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(14), 465.022, 465.026, 465.035, 893.07 FS. History–New 3-16-94, Formerly 61F10-28.140, Amended 3-12-97, 6-4-97, Formerly 59X-28.140, Amended 10-29-97, 6-15-98, 11-11-98, 10-15-01, 3-24-14.

64B16-28.141 Requirements for an Automated Pharmacy System in a Community Pharmacy.

(1) Definitions. “Automated pharmacy system” means a mechanical system, located within or adjacent to the prescription department, that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(2) General Requirements. A pharmacy may use an automated pharmacy system provided that:

(a) The pharmacy develops and maintains a policy and procedure manual that includes:

1. The type or name of the system including a serial number or other identifying nomenclature.

2. A method to ensure security of the system to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.

3. A process of filling and stocking the system with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.

4. A method of identifying all the registered pharmacy interns or registered pharmacy technicians involved in the dispensing process.

5. Compliance with a Continuous Quality Improvement Program.

6. A method to ensure that patient confidentiality is maintained.

7. A process to enable the prescription department manager or designee to revoke, add, or change access at any time.

(b) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.

(c) The system shall maintain a readily retrievable electronic record to identify all pharmacists, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.

(d) The system shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(3) Additional Requirements for Patient Accessed Automated Pharmacy Systems. A pharmacy may use a patient accessed automated pharmacy system, provided that:

(a) Meets the requirements in subsection (2), above.

(b) The stocking or restocking of a medicinal drug shall only be completed by a Florida pharmacist, except as provided in paragraph (c), below.

(c) If the automated pharmacy system uses removable cartridges or container to store the drug, the stocking or restocking of the cartridges or containers may occur at a licensed repackaging facility and be sent to the provider pharmacy to be loaded by personnel designated by the pharmacist if:

1. A Florida pharmacist verifies the cartridge or container has been properly filled and labeled.

2. The individual cartridge or container is transported to the provider pharmacy in a secure, tamper-evident container.

3. The automated pharmacy system uses a bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the cartridge or container is accurately loaded into the automated pharmacy system.

4. The Florida pharmacist verifying the filling and labeling is responsible if the cartridge or container is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(d) The automated pharmacy system must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from the automated system.

(e) The medication shall bear a patient specific label that complies with Rule 64B16-28.108, F.A.C.

(f) The record of transactions with the patient accessed automated pharmacy system shall be available to authorized agents of the Department of Health. The record of transactions shall include:

1. Name of the patient.

2. Name, strength, and dosage form of the drug product dispensed.

3. Quantity of drug dispensed.

4. Date and time of dispensing.

5. Name of provider pharmacy.

6. Prescription number.

7. Name of prescribing practitioner.

8. Identity of the pharmacist who approved the prescription or order.

9. Identity of the person to whom the drug was released.

(4) The Florida pharmacist responsible for filling, verifying, or loading the automated pharmacy system shall be responsible for her or his individual action.

(5) A prescription dispensed pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.022 FS. History–New 11-29-04, Amended 12-30-07, 1-1-10.

64B16-28.150 Record Maintenance Systems for Institutional and Animal Shelter Permits.

Rulemaking Authority 465.005, 465.0155, 465.022, 828.055 FS. Law Implemented 465.022, 465.019, 465.026, 893.07, 828.055 FS. History–New 4-12-95, Formerly 59X-28.150, Repealed 5-3-05.

64B16-28.201 Definitions.

Rulemaking Authority 465.005, 465.022, 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History–New 12-26-79, Amended 4-28-83, 4-30-85, Formerly 21S-16.01, 21S-16.001, Amended 7-31-91, Formerly 21S-28.201, 61F10-28.201, 59X-28.201, Repealed 4-5-05.

64B16-28.202 Closing of a Pharmacy; Transfer of Prescription Files.

(1) The term "prescription files" as used herein shall mean the drug dispensing records of a pharmacy which shall include all orders for drugs or medicinal supplies as defined by Section 465.003(7), F.S., inclusive of dispensing records for medicinal drugs listed within the provisions of Section 893.03, F.S., issued by a duly licensed practitioner, which serve to transfer possession of medicinal drugs from the pharmacy to the ultimate consumer.

(2) The term "closing of a pharmacy" as used herein shall mean the cessation or termination of professional and business activities within a pharmacy for which a permit has been issued under Chapter 465, F.S.

(3) Prior to closure of a pharmacy the permittee shall notify the Board of Pharmacy in writing as to the effective date of closure, and shall:

(a) Return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy;

(b) Advise the Board of Pharmacy which permittee is to receive the prescription files.

(4) On the date of closure of a pharmacy the former permittee shall:

(a) Physically deliver the prescription files to a pharmacy operating within reasonable proximity of the pharmacy being closed and within the same locality. This delivery of prescription files may occur prior to the return of the pharmacy permit to the Board of Pharmacy office; and,

(b) Affix a prominent sign to the front entrance of the pharmacy advising the public of the new location of the former permittee's prescription files or otherwise provide a means by which to advise the public of the new location of their prescription files.

(5) After the closing of a pharmacy as defined herein, the custody of the prescription files of the pharmacy shall be transferred to the new permittee, unless the former permittee and the new permittee inform the Board in writing that custody of the prescription files have been or are to be transferred to a pharmacy other than the new permittee.

(6) A pharmacy receiving custody of prescription files from another pharmacy shall maintain the delivered prescriptions in separate files so as to prevent intermingling with the transferee pharmacy's prescription files.

Rulemaking Authority 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History–New 12-26-79, Formerly 21S-16.02, 21S-16.002, Amended 7-31-91, Formerly 21S-28.202, 61F10-28.202, 59X-28.202, Amended 4-5-05.

64B16-28.2021 Change of Ownership.

(1) A pharmacy permit is not transferable. If upon the sale of an existing pharmacy, there is any change in the identity of the natural person, partnership, or business entity which holds the permit, a new application must be filed and a new permit obtained. For purposes of this rule, the test for determining change of identity shall be whether the person or entity's Federal Employer Identification Number (FEIN) remains the same following the sale.

(2) Permits held by business entities with no change in identity. In those cases where the permit is held by a business entity (e.g. a corporation, limited liability company, limited partnership, etc.) which entity continues to hold the permit without change in identity, the transfer of the ownership interests of said business entity to another person or business entity does not constitute a change of ownership (requiring application for and issuance of a new pharmacy permit). Upon transfer of the ownership interests in the business entity, the following steps shall be taken:

(a) Within fifteen (15) days of closing the transfer, the permittee shall notify the Board office of the transfer of ownership interests; and,

(b) As specified in Section 465.022(3), F.S., all persons, members, partners, officers, directors, and agents having an ownership or other financial interest of greater than five percent (5%), and all persons who directly or indirectly manage, oversee, or control the operation of the business entity, must file with the board a set of fingerprints as specified in paragraph 64B16-28.100(1)(c), F.A.C.

(3) If a criminal history check identifies any person listed in paragraph (2)(b), above, as meeting any of the provisions of Section 465.022(5) or (6), F.S., the Board staff shall refer the matter to the Department for investigation and possible prosecution as provided in Section 465.023, F.S.

(4) A change in ownership (and issuance of a new permit number) requires that new records be started and old records closed. The process for closing a pharmacy, including the transfer of prescription files and medicinal drugs, as outlined in Rules 64B16-28.202 and 64B16-28.203, F.A.C., must be followed for the old permit. If the old permit has controlled substances, the new permit must record an "opening inventory" for DEA purposes. Both the new permit and the old permit must keep appropriate records for four (4) years for the transfer of legend drugs and controlled substances.

(5) A change in the company or person who leases the building where the permit is housed or a change in the management company which contracts with the owner of the permit for the operation of the permit does not constitute a change in ownership.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022, 465.023 FS. History–New 4-19-00, Amended 1-2-02, Formerly 64B16-28.1135, Amended 4-5-05, 7-14-14, 7-14-16.

64B16-28.203 Transfer of Medicinal Drugs; Change of Ownership; Closing of a Pharmacy.

Ownership of medicinal drugs, including those medicinal drugs within the provisions of Section 893.03, F.S., may be transferred to a new owner upon the change of ownership of a pharmacy, as defined in Rule 64B16-28.202, F.A.C., or upon the closing of a pharmacy, as defined in Rule 64B16-28.202, F.A.C. The transferee entity acquiring ownership shall be authorized to prescribe, dispense or distribute such drugs. The transferor pharmacy shall provide the Florida Board of Pharmacy with the following information:

(1) The name, address, pharmacy permit number and D.E.A. registration number of the transferor pharmacy.

(2) The name, address, permit number, D.E.A. registration number (if available), and authorized business activity of the transferee entity.

(3) The date on which the transfer will occur.

(4) A complete inventory of all medicinal drugs within the provisions of Section 893.03, F.S., as of the date of transfer. If the medicinal drug is listed in Schedule II, the transferor shall make an exact count or measure of the contents. If the medicinal drugs are listed in Schedule III, IV, or V, the transferor shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents shall be made. This inventory shall serve as the final inventory of the permittee transferor and the transfer inventory of the transferee entity. The transferor and transferee shall each retain a copy of the inventory in their records and shall provide the Board of Pharmacy with a copy of such inventory. Transfer of any controlled substance in Schedule II shall require the use of order form, D.E.A. form number 222.

(5) Unless the permittee-transferor is informed by the Board of Pharmacy or the regional D.E.A. Administrator prior to the date on which the transfer was stated to occur, that the transfer may not occur, the permittee-transferor may proceed with the transfer.

(6) On the date of transfer of the medicinal drugs, all records required to be kept by the permittee-transferor of the transferred drugs which are listed in Section 893.03, F.S., shall be transferred to the permittee-transferor. Responsibility for the accuracy of records prior to the date of transfer remains with the permittee-transferor, but responsibility for custody and maintenance shall be upon the permittee-transferee. It is the responsibility of the permittee-transferor to return all unused Schedule II order forms (D.E.A. form no. 222) to the regional D.E.A. office.

Rulemaking Authority 465.005, 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History–New 12-26-79, Formerly 21S-16.03, 21S-16.003, 21S-28.203, 61F10-28.203, 59X-28.203, Amended 4-5-05.

64B16-28.301 Destruction of Controlled Substances – Institutional Class I Pharmacies (Nursing Homes).

(1) Controlled substances that have been dispensed and not used by the patient shall not be returned to the pharmacy and shall be securely stored by the nursing home until destroyed.

(2) For each controlled substance destroyed, documentation must be completed showing the name and quantity of the drug, strength and dosage form, patient's name, prescription number and name of the institution. Destruction of the controlled substance shall be witnessed by at least two (2) of the following individuals:

(a) Consultant pharmacist;

(b) Director of nursing

(c) Facility administrator;

(d) A licensed physician, mid-level practitioner, nurse, or another pharmacist employed by or under contract or written agreement with the facility, or

(e) A sworn law enforcement officer.

Those individuals witnessing the destruction of the controlled substance shall sign the completed documentation.

(3) The consultant pharmacist shall be responsible for the creation and implementation of policies and procedures to ensure that controlled substances are disposed of in accordance with applicable state and federal laws and rules. Furthermore, the consultant pharmacist shall review all controlled substance destruction documentation monthly to ensure compliance with this rule and federal and state law.

(4) The consultant pharmacist shall ensure that non-controlled substances are returned to the provider pharmacy in compliance with Rule 64B16-28.118, F.A.C.

Rulemaking Authority 465.005, 465.022(12) FS. Law Implemented 465.022(12), 465.019, 893.07(1), (3), (5) FS. History–New 4-21-87, Formerly 21S-19.001, Amended 7-31-91, Formerly 21S-28.301, 61F10-28.301, Amended 1-30-96, Formerly 59X-28.301, Amended 7-21-09, 2-10-14, 11-5-17.

64B16-28.303 Destruction of Controlled Substances All Permittees (Excluding Institutional Class I Nursing Homes).

(1) Controlled substances that cannot be retained as usable shall be securely stored in the pharmacy/prescription department of the permittee pharmacy until destroyed.

(2) Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form DEA-41 "Registrants Inventory of Drugs Surrendered" (effective 8/31/2014), herein incorporated by reference, available at http://www.flrules.org/Gateway/reference.asp?No=Ref-03998 or http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/. This form, at the time of destruction, shall be witnessed and signed by the prescription department manager or the consultant pharmacist of record and D.E.A. agent, or a Department inspector. This method of destruction requires that a copy of the completed and witnessed Form DEA 41 be mailed to the D.E.A. office in his/her area within one (1) business day after the destruction.

(3) Another method of destruction shall be conducted by at least two persons: One will be the prescription department manager or the consultant pharmacist of record. The other will be one of the following: medical director or his/her physician designee, director of nursing or his/her licensed nurse designee, or a sworn law enforcement officer. These persons shall serve as the witnesses for the Form DEA-41 and the destruction. This method of destruction requires that a copy of the completed and witnessed Form DEA-41 be mailed to the D.E.A. office in the permittee's area within one (1) business day after destruction.

(4) In lieu of destruction on the premises as outlined in subsections (2) and (3), above, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.

(5) For patient specific controlled substance prescriptions in a Modified Institutional Class II B pharmacy, the destruction method in subsection 64B16-28.301(2), F.A.C., must be followed.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.018 FS. History–New 4-21-87, Formerly 21S-19.003, Amended 7-31-91, Formerly 21S-28.303, 61F10-28.303, Amended 1-30-96, Formerly 59X-28.303, Amended 2-5-07, 10-27-09, 2-1-12, 4-20-14.

64B16-28.402 Labels and Labeling of Medicinal Drugs – Community Pharmacy Permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1), 465.0255 FS. History–New 7-3-91, Formerly 21S-28.402, Amended 12-27-93, Formerly 61F10-28.402, 59X-28.402, Amended 9-17-97, Repealed 5-11-05.

64B16-28.404 Regulation of Daily Operating Hours.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-65, Amended 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, 3-31-81, Formerly 21S-1.24, Amended 7-14-88, Formerly 21S-1.024, Amended 7-31-91, 3-15-92, Formerly 21S-28.404, 61F10-28.404, Amended 9-21-94, Formerly 59X-28.404, 59X-28.404, Repealed 2-28-07.

64B16-28.404 Regulation of Daily Operating Hours (Repealed).

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-65, Amended 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, 3-31-81, Formerly 21S-1.24, Amended 7-14-88, Formerly 21S-1.024, Amended 7-31-91, 3-15-92, Formerly 21S-28.404, 61F10-28.404, Amended 9-21-94, Formerly 59X-28.404, 59X-28.404, Repealed 2-28-07.

64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

(1) As used herein:

(a) The term "originating pharmacy" means a pharmacy wherein the prescription which will be filled by the central fill pharmacy is initially presented; and,

(b) The term "central fill pharmacy" means a pharmacy which performs centralized prescription filling, delivering, and returning for one or more originating pharmacies.

(2) Pharmacies acting as the central fill pharmacy must:

(a) Be authorized to dispense medications under the provisions of Chapter 465, F.S., and the rules promulgated thereto; and,

(b) Have the same owner as the originating pharmacy or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.

(3) All central fill and originating pharmacies engaged in centralized prescription filling shall create and keep current a Policy and Procedure Manual which shall:

(a) Be maintained at the locations of the central fill and originating pharmacies;

(b) Include the information required by Sections 465.0265(2)(a)-(f), F.S.;

(c) Designate the types of medications that may and may not be filled by the central fill pharmacy;

(d) Set forth procedures for communicating orders from the originating pharmacy to the central fill pharmacy;

(e) Set forth procedures for securely transporting the filled prescriptions from the central fill pharmacy to the originating pharmacy; and,

(f) Designate the specific services provided and the duties and responsibilities of the central fill and originating pharmacies.

(4) The central fill and originating pharmacy shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:

(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:

1. Electronically record in the pharmacy record keeping system or document on the face of the original prescription that the prescription has been filled at a central fill pharmacy. If a controlled substance, write the word "central fill" on the face of the original prescription and record the name, address, and DEA registration number of the originating pharmacy to which the prescription has been transmitted and the name of the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal,

2. Ensure all the information required to be on a prescription pursuant to Sections 456.0392 and 893.04, F.S., is transmitted to the central fill pharmacy either on the face of the prescription or in the electronic transmission of information,

3. Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining,

4. Maintain the original prescription for a period of four (4) years from the date the prescription was last filled,

5. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the originating pharmacy's employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

1. Keep a copy of the prescription if sent via facsimile, or an electronic record of all the information transmitted by the

originating pharmacy, including the name, address, and DEA registration number, if a controlled substance, of the originating pharmacy transmitting the prescription,

2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription,

3. Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (private, common or contract carrier),

4. A central fill pharmacy's pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of filling, the originating pharmacy's name and address, a unique identifier (e.g., the central fill pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

(5) Delivery of medications. All deliveries of medications from the central fill pharmacy to the originating pharmacy or to the ultimate consumer must be made in a timely manner.

(a) A community central fill pharmacy may deliver medications for an originating pharmacy to the ultimate consumer or the consumer's agent under the following additional conditions:

1. The pharmacies are under the same ownership or have a written contract specifying the services to be provided by each pharmacy, including delivery services to the ultimate consumer or the consumer's agent.

2. The pharmacies shall have a pharmacist available 40 hours a week, either in person or via two-way communication technology, such as a telephone, to provide patient counseling.

3. The pharmacies shall include a toll-free number that allows the patient to reach a pharmacist for the purposes of patient counseling.

4. The central fill pharmacy shall only deliver via carrier to the ultimate consumer or the consumer's agent those medications which could have been delivered via carrier by the originating pharmacy.

5. The central fill pharmacy shall not deliver to the ultimate consumer or consumer's agent substances listed as controlled substances under Chapter 893, F.S.

(b) The delivery of a filled prescription by a community central fill pharmacy to the ultimate consumer or the consumer's agent pursuant to a contract with an originating pharmacy shall not be considered dispensing within the definition set forth in Section 465.003(6), F.S.

(c) A Class II institutional central fill pharmacy may only deliver medications to the originating pharmacy.

(6) Each pharmacist that performs a specific function within the processing of a central fill prescription shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(7) A community pharmacy which acts as the central fill pharmacy and which notifies the Board that its pharmacy practice is limited only to such practice shall be exempt from the following rules:

(a) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;

(b) The signage requirement of subsection 64B16-28.109(1), F.A.C.; and,

(c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours.

Rulemaking Authority 465.005, 465.0155, 465.0265 FS. Law Implemented 465.003(16), 465.019, 465.022, 465.0265 FS. History–New 9-23-03, Amended 7-27-04, 4-28-08, 2-5-14, 8-27-15, 3-15-16.

64B16-28.451 Pharmacy Common Database; Exceptions for Prescription Drug Processing Only Pharmacies.

(1) A pharmacy licensed under this chapter may perform prescription drug processing for other pharmacies, provided that all pharmacies are under common ownership, utilize a common database, and are properly licensed, permitted or registered in this state or another state. Nothing in this subsection shall prohibit a pharmacist employee of said pharmacies who is licensed in Florida or in another state from remotely accessing the pharmacy's electronic database from outside the pharmacy in order to process prescriptions, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(2) Prescription drug processing shall include the following:

(a) Receiving, interpreting, or clarifying a prescription;

(b) Entering prescription data into the pharmacy's record;

(c) Verifying or validating a prescription;

(d) Performing prospective drug review as defined by the Board;

(e) Obtaining refill and substitution authorizations;

(f) Interpreting or acting on clinical data;

(g) Performing therapeutic interventions;

(h) Providing drug information concerning a patient's prescription; and,

(i) Providing patient counseling.

(3) Each pharmacist that performs a specific function within the prescription drug processing process via use of a common database shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(4) Each pharmacy performing prescription drug processing pursuant to this section must maintain a policy and procedure manual, which shall be made available to the Board or its agent upon request. The policy and procedures manual shall include the following information:

(a) A description for how each pharmacy will comply with federal and state laws, rules and regulations;

(b) The procedure for maintaining appropriate records to identify the pharmacies and pharmacists responsible for the prescription drug processing and dispensing of the prescription;

(c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and,

(d) The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.

(5) The prescription drug processing of a prescription by one pharmacy for another pursuant to this section shall not be construed as the transferring of a prescription as set forth in Section 465.026, F.S.

(6) In addition to all record requirements of Rule 64B16-28.140, F.A.C., all pharmacies participating in prescription drug processing, shall maintain appropriate records which identify, by prescription, the name(s), initials, or identification code(s) of each pharmacist or registered pharmacy technician who performs a processing function for a prescription. Such records shall be maintained:

(a) Separately by each pharmacy and pharmacist, or

(b) In a common electronic file, as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy, pharmacist, registered pharmacy intern and registered pharmacy technician.

(7) Prescription drug processing only pharmacies. A pharmacy permittee which solely performs prescription drug processing for other pharmacies pursuant to this rule, and at which medicinal drugs are not compounded, dispensed, stored or sold, nor are prescriptions filled or dispensed, and which notifies the Board that its pharmacy practice is limited solely to prescription drug processing shall be exempt from the following rules:

(a) Rule 64B16-28.102, F.A.C., Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment;

(b) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;

(c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours; and,

(d) Rule 64B16-28.109(1), F.A.C., relating to signage.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0266 FS. History–New 3-24-08, Amended 1-1-10, 7-14-16.

64B16-28.501 Institutional Permit – Consultant Pharmacist of Record.

(1) Each facility holding a Class I, a Class II, or a Modified Class II Institutional permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within ten (10) days of any change in the consultant pharmacist of record.

(2) The consultant pharmacist of record for a Class I, Class II, or Modified Class II permit shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and in the monthly facility inspection.

(3) A consultant pharmacist licensed in Florida may remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct any services additional or supplemental to regular drug regimen reviews, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations.

Rulemaking Authority 465.005, 465.0125, 465.022 FS. Law Implemented 465.0125, 465.019, 465.022, 465.0266 FS. History–New 7-18-94, Formerly 61F10-28.501, 59X-28.501, Amended 1-2-02, 12-30-07, 11-5-17.

64B16-28.502 Class I Institutional Permit and Class II Institutional Permit – Labels and Labeling of Medicinal Drugs for Inpatients of a Nursing Home.

(1) The label affixed to a container used in conventional dispensing to a Class I Institutional permit or a Class II Institutional permit which, within the scope of its practice, services only the inpatients of a nursing home as defined by Section 400.021(5), F.S., shall contain at least the following information:

(a) The name of and address of the pharmacy;

(b) The name of the prescriber;

(c) The name of the patient;

(d) The date of the original filling or the refill date;

(e) The prescription number or other prescription identification adequate to readily identify the prescription;

(f) The directions for use;

(g) The name of the medicinal drug dispensed (except where the health care practitioner prescribing the drug specifically denotes that the name is to be withheld);

(h) The quantity of the drug in the container.

(2) The label affixed to a container used in dispensing substances listed in any of the schedules appearing in Chapter 893, F.S., in regard to conventional dispensing shall contain at least the following information:

(a) All of the information required by subsection (1), of this rule;

(b) The number of the prescription as recorded in the prescription files of the pharmacy in which it is filled; and,

(c) A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.502, 61F10-28.502, 59X-28.502, Amended 8-16-10.

64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I or Modified II B Institutional Facilities.

(1) Definitions.

(a) "Vendor pharmacy" means a community pharmacy or special closed system pharmacy which has a contract to dispense a medicinal drug to a patient in a facility holding a Class I Institutional Permit or Modified II B Permit.

(b) "Starter dose pharmacy" means a pharmacy that dispenses a medicinal drug pursuant to a starter dose prescription for a patient in a facility served by the vendor pharmacy.

(c) "Starter dose prescription" means a prescription transmitted by a vendor pharmacy to a starter dose pharmacy for the purpose of initiating drug therapy for a patient in a facility served by the vendor pharmacy. The term "starter dose prescription" does not include prescriptions for controlled substances.

(2) A vendor pharmacy may transmit a starter dose prescription, excluding a prescription for a controlled substance, to a starter dose pharmacy if the vendor pharmacy:

(a) Has written authorization from the facility to utilize a starter dose pharmacy.

(b) Has written authorization from a prescribing practitioner, directly or via facility agreement, to act as the practitioner's agent for the purpose of transmitting a starter dose prescription.

(c) Possess a valid prescription from the prescribing practitioner prior to transmitting the starter dose prescription.

(d) Maintains a record of each starter dose prescription.

(e) Maintains a policy and procedure manual that references starter dose prescriptions.

(3) A starter dose pharmacy may dispense a medicinal drug, excluding a controlled substance, pursuant to a starter dose prescription for a patient in a facility that holds a Class I Institutional Permit or Modified II B Permit if the starter dose pharmacy

maintains a record of each starter dose prescription and maintains a policy and procedure manual that references starter dose prescriptions.

(4) A record of each starter dose prescription shall be readily retrievable and maintained for four (4) years.

Rulemaking Authority 465.005, 465.019(4), 465.022 FS. Law Implemented 465.019, 465.022(12) FS. History–New 11-29-04, Amended 7-14-14, 7-19-17.

64B16-28.602 Institutional Class II Dispensing.

(1) Pharmaceutical preparations which are administered to patients of a hospital by the personnel of such institution shall only be taken from the original container, or from a container which has been prepared by a Florida licensed pharmacist. Only single doses of such preparations shall be removed from the container, and then only after the preparation has been prescribed for a specific patient, and the order has been duly recorded upon the records of the institution. This requirement shall not apply to nor be construed as preventing the administration of treatment in bona fide emergency cases, or further as prohibiting any person who is a duly licensed physician from dispensing medicinal drugs as defined in Chapter 465, F.S. A single dose of medicinal drugs based upon a valid physician's drug order may also be obtained and administered under the supervision of the nurse in charge consistent with good institutional practice procedures as established by the consultant pharmacist of record and written in the policy and procedure manual which shall be available within the pharmacy.

(2) A Class II institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity, including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

3. A pharmacist for the institutional pharmacy shall provide drug utilization review and shall review each prescription order prior to transmission to the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(b), 465.0196, 465.022(1) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, Formerly 21S-1.11, 21S-1.011, Amended 7-31-91, Formerly 21S-28.602, 61F10-28.602, Amended 9-4-96, Formerly 59X-28.602, Amended 8-16-10.

64B16-28.6021 Institutional Class II Pharmacy – Emergency Department Dispensing.

(1) Individuals licensed to prescribe medicinal drugs in this state may dispense from the emergency department of a hospital holding a class II institutional pharmacy permit. Such dispensing must meet the requirements provided in Section 465.019(4), F.S., and this section.

(2) The following records of prescribing and dispensing must be created by the prescriber/dispenser and maintained by the consultant pharmacist of record within the facility:

(a) Patient name and address.

(b) Drug and strength prescribed/dispensed.

(c) Quantity prescribed/dispensed.

(d) Directions for use.

(e) Prescriber/dispenser.

(f) Prescriber DEA registration, if applicable.

(g) Reason community pharmacy services were not readily accessible.

(3) Labeling of the prescription container must meet the requirements of Section 465.0276, F.S.

(4) Quantity dispensed must not exceed a 24-hour supply or the minimal dispensable quantity, whichever is greater.

Rulemaking Authority 465.005, 465.019(4), 465.022 FS. Law Implemented 465.019(2)(b), (4), 465.0196, 465.022(1) FS. History–New 9-20-99,

Amended 8-16-10.

64B16-28.603 Class II Institutional Pharmacy Operating Hours.

Any person who receives a Class II Institutional permit pursuant to Section 465.019, F.S., and commences to operate such a pharmacy shall, for the benefit of the institutions' patients' health and welfare, keep the pharmacy of the establishment open for a sufficient number of daily operating hours required to provide adequate and quality pharmaceutical services to the patients of said institution.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 7-31-91, Formerly 21S-28.603, 61F10-28.603, 59X-28.603.

64B16-28.604 Class II Institutional Pharmacy Department Security.

The pharmacy department shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. At all times when the pharmacy department is closed, either because of the absence of a Florida licensed pharmacist or for any other reason, it shall be secured to prevent access. When the pharmacy department is closed, no person other than a Florida licensed pharmacist shall enter, except as authorized by Section 465.019(2)(b), F.S., and Rule 64B16-28.602, F.A.C.

Rulemaking Authority 465.005, 465.022(1), 465.019 FS. Law Implemented 465.019, 465.022(1) FS. History–New 9-21-94, Formerly 59X-28.604.

64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.

(1) Definitions.

(a) "Automated medication system" means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:

1. Distribute medications in a licensed health care facility, or

2. Package medications for final distribution by a pharmacist.

(b) "Centralized automated medication system" means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.

(c) "Decentralized automated medication system" means an automated medication system that is located outside of a pharmacy department but within the same institution.

(d) "Distribute" or "Distribution" means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of Florida pursuant to an order issued by an authorized prescriber.

(e) "Medication" means a medicinal drug or proprietary preparation.

(f) "Override medication" means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., determined that the clinical status of the patient would be significantly compromised by delay.

(g) "Low risk override medication" is a medication determined by a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.

(h) "Physician controlled medication" is medication distributed in an environment where a practitioner controls the order, preparation and administration of the medication.

(2) General Requirements for the Use of Automated Medication Systems.

(a) The consultant pharmacist of record shall be responsible for:

1. Maintaining a record of each transaction or operation.

2. Controlling access to the system.

3. Maintaining policies and procedures for:

a. Operation of the automated medication system.

b. Training personnel who use the automated medication system.

c. Maintaining patient services whenever the automated medication system is not operating; and,

d. Defining a procedure for a pharmacist to grant or deny access to the medication in the system.

4. Security of the system.

5. Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner.

6. Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality.

7. Establishing a comprehensive Quality Assurance program.

8. Establishing a procedure for stocking or restocking the automated medication system; and,

9. Ensuring compliance with all requirements for packaging and labeling.

(b) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except an override medication, a low risk override medication or a physician controlled medication.

(c) A pharmacist shall perform retrospective drug use review for an override medication.

(3) Multidisciplinary Committee for Decentralized Automated Medication Systems.

(a) The consultant pharmacist of record shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.

(b) The Multidisciplinary Committee shall:

1. Include at least one pharmacist,

2. Establish the criteria and process for determining which medication qualifies as an override medication or a low risk override medication in a decentralized automated medication system,

3. Develop policies and procedures regarding the decentralized automated medication system; and,

4. Have its decisions reviewed and approved by the consultant pharmacist of record.

(4) Stocking or Restocking of a Decentralized Automated Medication System.

(a) Medications in a decentralized Automated Medication System shall be stocked or restocked by a pharmacist, registered pharmacy intern, or by a registered pharmacy technician supervised by a pharmacist.

(b) The stocking or restocking of a decentralized automated medication system shall follow one of the following procedures to assure correct medication selection:

1. A pharmacist shall conduct a daily audit of medications placed or to be placed into an automated medication system that includes random sampling.

2. A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation followed by a monthly quality assurance review by a pharmacist.

(5) Centralized Automated Medication Systems. A pharmacist utilizing a centralized medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if:

(a) The initial medication order has been reviewed and approved by a pharmacist; and,

(b) The medication is distributed for subsequent administration by a health care professional permitted by Florida law to administer medication; and,

(c) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic verification, or similar verification technology shall require an initial quality assurance validation, followed by monthly quality assurance review by a pharmacist.

(6) Quality Assurance Program. The consultant pharmacist of record shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

(a) Review of override and low risk override medication utilization;

(b) Investigation of a medication error related to the automated medication system;

(c) Review of a discrepancy or transaction reports and identify patterns of inappropriate use or access;

(d) Review of the operation of the system;

(e) Integration of the automated medication system quality assurance program with the overall continuous quality improvement of the pharmacy as defined in Rule 64B16-27.300, F.A.C.; and,

(f) Assurance that individuals working with the automated medication system receive appropriate training on the operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(7) Record Keeping.

(a) The consultant pharmacist of record shall maintain records related to the automated medication system in a readily retrievable manner.

(b) The following records shall be maintained for at least 60 days:

1. Daily audits of stocking or restocking, if applicable,

2. Daily audits for the output of centralized automated medication system, if applicable; and,

3. Transaction records for all non-controlled medications or devices distributed by the automated medication system.

(c) The following records shall be maintained for at least four (4) years:

1. Any report or analysis generated as part of the quality assurance program,

2. A report or database related to access to the system or any change in the access to the system or to medication in the system; and,

3. Transaction records from the automated medication system for all controlled substances dispensed or distributed.

(8) Compliance. The consultant pharmacist of record shall assure compliance with all requirements of Chapter 465, F.S., and the rules of Chapter 64B16, F.A.C.

(9) Security. A decentralized automated medication system that contains controlled substances shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances, unless otherwise contained in labeled patient-specific form.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235, 465.026 FS. History–New 4-22-07, Amended 1-1-10, 7-14-14.

64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies or Special Pharmacy Permits Servicing Class I, Class II, Modified Class II, and Special ALF Permitted Facilities.

(1) Definitions.

(a) "Remote Medication Order Processing" includes any of the following activities performed for a Class II Institutional Pharmacy or for Special Pharmacy Permits servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities from a remote location:

1. Receiving, interpreting, or clarifying medication orders,

2. Entering or transferring medication order data,

3. Performing prospective drug use review,

4. Obtaining substitution authorizations,

5. Interpreting and acting on clinical data,

6. Performing therapeutic interventions,

7. Providing drug information,

8. Authorizing the release of a medication for administration.

(b) "Medication" means a medicinal drug or proprietary preparation.

(c) "Prospective drug use review" means an evaluation of medication orders and patient medication records for:

1. Over-utilization or under-utilization of medication,

2. Therapeutic duplication of medication,

3. Drug-disease contraindications,

4. Drug interactions,

5. Incorrect drug dosage or duration of drug treatment,

6. Clinical abuse or misuse of medication.

(2) General requirements.

(a) All pharmacists participating in remote medication order processing shall be Florida licensed pharmacists.

(b) A Class II Institutional pharmacy or Special Pharmacy servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities may utilize remote medication order processing if the pharmacist performing the remote medication order processing has access to sufficient patient information necessary for prospective drug use review and approval of medication orders.

(c) A pharmacist shall perform the final check of a medication order.

(d) If the pharmacist performing remote medication order processing is not an employee of the pharmacy, the Class II Institutional pharmacy or Special Pharmacy servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities must

have a written agreement or contract with the pharmacist or entity employing the pharmacist. The written agreement or contract shall:

1. Outline the services to be provided,

2. Delineate the responsibilities of each party including compliance with federal and state laws and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements including compliance with applicable Federal HIPAA regulations,

3. Require that the parties adopt a policies and procedures manual,

4. Provide that the parties have access to or share a common electronic file such that the pharmacist performing remote medication order processing has sufficient patient information necessary for prospective drug use review and approval of medication orders.

(3) Policy and Procedures. A policy and procedures manual shall:

(a) Be accessible to each party involved in remote medication order processing;

(b) Be available for inspection by the Board or an authorized agent of the Department;

(c) Outline the responsibilities of each party involved in remote medication order processing;

(d) Include a current list of the name, address, telephone number, and license number of each pharmacist involved in remote medication order processing;

(e) Include policies and procedures for:

1. Ensuring the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations,

2. Ensuring that a pharmacist performing prospective drug use review has access to appropriate drug information resources,

3. Ensuring that medical and nursing staff understand how to contact a pharmacist,

4. Maintaining records to identify the name, initials, or identification code of each person who performs a processing function for a medication order,

5. Complying with federal and state laws and regulations,

6. Operating or participating in 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,

7. Reviewing the written policies and procedures and documenting the review every year.

(4) Records.

(a) A Class II Institutional Pharmacy or Special Pharmacy Permits servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities involved in remote medication order processing shall maintain a record that identifies the name, initials, or identification code of each person who performed a processing function for every medication order. The record shall be available by medication order or by patient name.

(b) The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a processing function for a medication order.

(c) The record shall be readily retrievable for at least the past four (4) years.

(d) The record shall be available for inspection by the Board or an authorized agent of the Department.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019, 465.022, 465.026, 465.0266 FS. History–New 11-29-04, Amended 7-14-14, 7-19-17.

64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.

(1) Definitions.

(a) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and delivery of a medicinal drug, and which collects, controls, and maintains a record of each transaction.

(b) "Provider pharmacy" means a pharmacy that provides pharmacy services by using an automated pharmacy system at a remote site.

(c) "Remote site" means a long term care facility or hospice licensed under Chapter 400, F.S., or a state correctional institution operated under Chapter 944, F.S., that is not located at the same location as the provider pharmacy, at which pharmacy services are

provided using an automated pharmacy system.

(d) “Controlled substance” means a substance listed in Chapter 893, F.S., or 21 C.F.R. Part 1308.

(2) Provider Pharmacy Requirements.

(a) A provider pharmacy may provide pharmacy services to a long term care facility or hospice licensed under Chapter 400, F.S., or a state correctional institution operated under Chapter 944, F.S., through the use of an automated pharmacy system.

(b) An automated pharmacy system shall only be used to provide pharmacy services to an inpatient or a resident of the remote site.

(c) Supervision of the automated pharmacy system shall be the responsibility of a Florida pharmacist employed by the provider pharmacy.

(d) Every medicinal drug stored in the automated pharmacy system shall be owned by the provider pharmacy.

(e) An automated pharmacy system shall be under the supervision of a pharmacist employed by the provider pharmacy. The pharmacist need not be physically present at the remote site if the system is supervised electronically.

(f) A provider pharmacy shall have policies and procedures to ensure adequate security.

(3) Prescription Department Manager Requirements.

(a) The prescription department manager shall ensure that the automated pharmacy system complies with Chapter 893, F.S., and 21 C.F.R., relating to the regulation of controlled substances, for each automated pharmacy system that contains a controlled substance.

(b) The prescription department manager shall ensure that the use of an automated pharmacy system does not compromise patient confidentiality.

(c) The prescription department manager or a designee shall:

1. Authorize or deny access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.

2. Document the training of each person who has access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.

(4) Automated Pharmacy System Requirements.

(a) A medicinal drug stored in bulk or unit-of-use in an automated pharmacy system is part of the inventory of the provider pharmacy and is not part of the inventory of any other pharmacy permit for the facility.

(b) A medicinal drug may be removed from an automated pharmacy system for administration to a patient only after a prescription or order has been received and approved by a pharmacist at the provider pharmacy. This provision does not apply to a medication designated as an emergency medication if the automated pharmacy system is also used as an emergency medication kit in compliance with Section 400.142, F.S., and Rule 59A-4.112, F.A.C.

(c) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve release of the initial dose of a prescription or order. A subsequent dose from an approved prescription or order may be released without additional approval of a pharmacist. However, any change made in a prescription or order shall require a new approval by a pharmacist to release the drug.

(d) A pharmacist at the provider pharmacy shall comply with the patient record requirements in Rule 64B16-27.800, F.A.C., and prospective drug use review requirements in Rule 64B16-27.810, F.A.C., for every medicinal drug delivered through an automated pharmacy system.

(e) If the facility where pharmacy services are being provided maintains a medication administration record that includes directions for use of the medication, a unit dose medication may be utilized if the provider pharmacy or the automated pharmacy system identifies and records the dispensing pharmacy, the prescription or order number, the name of the patient, and the name of the prescribing practitioner for each medicinal drug delivered.

(f) Stocking or Restocking of an Automated Pharmacy System.

1. The stocking or restocking of a medicinal drug in an automated pharmacy system at the remote site shall be completed by a pharmacist or other licensed personnel, except as provided in subparagraph 2., below, of this subsection.

2. If the automated pharmacy system uses removable cartridges or containers to store the drug, the stocking or restocking of the cartridges or containers may occur at the provider pharmacy and be sent to the remote site to be loaded by personnel designated by the pharmacist if:

a. A pharmacist verifies the cartridge or container has been properly filled and labeled.

b. The individual cartridge or container is transported to the remote site in a secure, tamper-evident container.

c. The automated pharmacy system uses bar code verification, electronic verification, or similar process to assure that the cartridge or container is accurately loaded into the automated pharmacy system.

(g) A medicinal drug that has been removed from the automated pharmacy system shall not be replaced into the system unless a pharmacist has examined the medication, the packaging, and the labeling and determined that reuse of the medication is appropriate.

(h) Medication to be returned to the provider pharmacy's stock shall meet the requirements of Rule 64B16-28.118, F.A.C.

(5) Security Requirements.

(a) If a provider pharmacy intends to store a controlled substance in an automated pharmacy system:

1. It shall maintain a separate DEA registration for each remote site at which a controlled substance is stored.

2. It may utilize one DEA registration to include multiple automated pharmacy systems located at a single address.

(b) A provider pharmacy shall only store a medicinal drug at a remote site within an automated pharmacy system which is locked by a mechanism that prevents access to a drug or to data by unauthorized personnel.

(c) Access to the drugs shall be limited to a pharmacist or a registered pharmacy technician employed by the provider pharmacy or licensed personnel in the facility or institution who are authorized to administer medication.

(d) An automated pharmacy system that contains a controlled substance shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances.

(6) Emergency medication. If an automated pharmacy system is utilized for both a medication ordered for a specific patient and an emergency medication for which the review of a pharmacist is not required:

(a) The emergency medication shall be stored separately from other patient medications.

(b) The record shall identify the storage location from which the medication was released.

(c) The record shall include the name of the medication, the patient, the prescriber, the person who accessed the automated pharmacy system, and the date and time of the release.

(7) Record Keeping Requirements.

(a) The record of transactions with the automated pharmacy system shall be maintained in a readily retrievable manner.

(b) The record shall be available to an authorized agent of the Department of Health or the Board of Pharmacy.

(c) The record shall include:

1. Name or identification of the patient or resident.

2. Name, strength and dosage form of the drug product released.

3. Quantity of drug released.

4. Date and time of each release of a drug.

5. Name of provider pharmacy.

6. Prescription number or order number.

7. Name of prescribing practitioner.

8. Identity of the pharmacist who approved the prescription or order.

9. Identity of the person to whom the drug was released.

(d) A record of every transaction with the automated pharmacy system shall be maintained for four (4) years.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235 FS. History–New 4-22-07, Amended 1-1-10, 7-14-14.

64B16-28.608 Automated Filling Systems within a Pharmacy.

(1) Definitions. The following definitions shall be applicable for purposes of this rule:

(a) "Automated filling system" means an automated system used within a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated filling system" shall not include automated devices used solely to count medication, vacuum tube drug delivery systems, or systems governed by Rule 64B16-28.606 or 64B16-28.607, F.A.C.

(b) "Electronic verification process" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly prepared for dispensing by an automated filling system.

(c) "Manufacturer Unit of Use Package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager.

(d) “Repackager” means a repackager registered with the United States Food and Drug Administration (FDA), as defined by Section 499.003(50), F.S.

(e) “Prepacked” means any drug that has been removed from the original packaging of the manufacturer or an FDA Repackager and is placed in a container for use in an automated filling system, as referenced by Section 499.003(42), F.S.

(f) “System drug identifier database” means the database or other system which positively identifies the drug to be dispensed by the automated filling system.

(2) The system drug identifier database shall be maintained by a pharmacist and shall not be delegated.

(3) Medication Stocking. Automated filling systems (hereinafter “system”) may be stocked or restocked by a pharmacist, pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist, as each are defined by subsection 64B16-27.1001(7), F.A.C.

(4) Verification. Except as provided herein, a licensed pharmacist must verify the accuracy of the final contents of any medication filled or packaged by a system, and any label affixed thereto, prior to dispensing, as defined by subsection 64B16-27.1001(3), F.A.C.

(5) The pharmacist verification requirements of subsection (4), shall be deemed satisfied if:

(a) The pharmacy establishes and follows a policy and procedure manual that complies with subsection (6), of this rule;

(b) The system is fully automated from the time the medication is stocked into the machine until a completed, labeled and sealed prescription is produced by the system that is ready for dispensing to the patient. No manual intervention with the medication may occur after the medication is stocked into the system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(c) A pharmacist must perform a prospective drug review and verify the accuracy of the prescription information used by or entered into the system for a specific patient prior to initiation of the automatic fill process. The name, initials or identification codes(s) of the verifying pharmacist shall be recorded in the pharmacy’s records and maintained for four (4) years after dispensing, or longer if required by applicable law;

(d) All medication Prepacked by the pharmacy must be verified by a pharmacist pursuant to subsection 64B16-27.1001(3), F.A.C.

(e) A pharmacist verifies the correct medication, either the Manufacturer Unit of Use Package, Repacked, or Prepacked container, was properly filled and stocked in the system. Alternatively, an electronic verification process may be used to verify a Manufacturer Unit of Use Package, repackaged, or prepacked containers;

(f) The medication to be dispensed is selected, filled, labeled, or sealed in the prescription container by the system or dispensed by the system in a Manufacturer’s Unit of Use Package, repacked, or prepacked container;

(g) An electronic verification process is used to verify the proper prescription label has been affixed to the correct medication, prepackaged medication or Manufacturer Unit of Use Package for the correct patient; and,

(h) An audit trail is maintained for the prescription from the beginning of the system to the dispensing from the system, and maintain for four (4) years.

(6) The pharmacist verification requirements of subsection (4), shall be deemed satisfied for a system that is not fully automated when all or part of the system is used for Manufacturer Unit of Use Packages if:

(a) The system utilizes an Electronic Verification Process to verify that the correct drug matches the correct prescription label;

(b) The Electronic Verification Process activities are undertaken by a pharmacist, pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist, as each are defined by subsection 64B16-27.1001(7), F.A.C., and consistent with Section 64B16-27.4001, F.A.C.; and,

(c) An audit trail is maintained for the prescription from the beginning of the system to the dispensing from the system, and maintained for four (4) years.

(7) Policies and Procedures. Pharmacies verifying prescriptions pursuant to subsection (5) or (6), of this rule, shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the prescription department manager or consultant pharmacist of record and shall be maintained in the pharmacy’s records for a minimum of four (4) years. The required annual review shall be documented in the pharmacy’s records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for:

(a) Maintaining the system and any accompanying electronic verification process in good working order;

(b) Ensuring the integrity of the system drug identifier database and identification of persons responsible for database entries;

(c) Ensuring accurate filling, stocking, and verification of the system, as applicable;

(d) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(e) Testing the accuracy of the system and any accompanying electronic verification process. At a minimum, the system and electronic verification process shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification process that changes or alters the filling or electronic verification process;

(f) Training persons authorized to access, stock, restock, or utilize the system in equipment use and operations, as applicable;

(g) Conducting routine and preventive maintenance and, if applicable, calibration;

(h) Removing expired, adulterated, misbranded or recalled drugs;

(i) Preventing unauthorized access to the system, including assigning, discontinuing or changing security access;

(j) Identifying and recording persons responsible for stocking, and filling the system;

(k) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;

(l) Maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification process to ensure proper and accurate functioning, including tracking and documenting of automated filling system errors that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for four (4) years and produced to the Board upon request.

(8) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy's records electronically or in writing for a minimum of four (4) years, or longer if required under applicable law. If the verification requirements of paragraph (5)(d), of this rule, are completed by a pharmacist, the name, initials or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for four (4) years after dispensing. Records shall be made available for inspection and produced to the Board or the Board's authorized designee upon request.

Rulemaking Authority 465.005, 465.0155, 465.022(1) FS. Law Implemented 465.003(17), 465.0155, 465.022(1) FS. History–New 3-24-14, Amended 11-5-17.

64B16-28.702 Modified Class II Institutional Pharmacies.

(1) Modified Class II Institutional Pharmacies are those Institutional Pharmacies which provide specialized pharmacy services restricted in scope of practice and designed to provide certain health care pharmacy services that are not generally obtainable from other pharmacy permittees. These specialized institutional pharmacy practices are generally identifiable with short-term or primary care treatment modalities in entities such as primary alcoholism treatment centers, free-standing emergency rooms, rapid in/out surgical centers, certain county health programs, and correctional institutions. Medicinal drugs may not be administered, except to patients of the institution for use on the premises of the institution, in any facility which has been issued a Modified Class II Institutional Pharmacy Permit. All medicinal drugs as defined by Section 465.003(7), F.S., which are stocked in these pharmacies are only to be administered on premises as defined by Section 465.003(1), F.S., to inpatients on an inpatient or in-program basis. In-program patients are defined as those patients who have met program admission criteria required by the institution.

(2) Modified Class II Institutional Pharmacies are categorized according to the type of specialized pharmaceutical delivery system utilized and the following criteria (Categories are designated as Type "A," Type "B," and Type "C"):

(a) The type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and, the quantity of the medicinal drug formulary at the facility.

(b) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist shall provide on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual.

(c) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(d) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide onsite consultations not less than once per month, unless otherwise directed by the Board after review of the policy and

procedure manual.

(3) All Modified Class II Institutional Pharmacies shall be under the control and supervision of a certified consultant pharmacist.

(4) The consultant pharmacist of record for the Modified Class II Institutional Pharmacy shall be responsible for establishing a written protocol and a policy and procedure manual for the implementation of a drug delivery system to be utilized and the requirements of this rule.

(5) A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Modified Class II Institutional Pharmacy and shall be available for inspection by the Department of Health.

(6) Drugs as defined in Section 465.003(7), F.S., stocked in Modified Class II Institutional Pharmacies, Type "A," and Type "B," as provided herein, shall be those drugs generally utilized in the treatment modalities encompassed within the health care scope of the particular institutional care entity. The protocol and the policy and procedure manual for Type "A," and Type "B," Modified Class II Institutional Pharmacies shall contain definitive information as to drugs and strengths thereof to be stocked.

(a) The policy and procedure manual of facilities which are issued Type A Modified Class II Institutional Permits shall provide the following:

1. Definitive information as to drugs and strengths to be stored.

2. The establishment of a Pharmacy Services Committee which shall meet at least annually.

3. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.

4. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

5. Provisions for the utilization of proof-of-use forms for all medicinal drugs within the facility.

6. A diagram of the facility and the security and storage of the medicinal drugs.

7. Provisions for maintaining the records of consultations for not less than four (4) years at the facility which shall be stored onsite and available for inspection by the Department of Health.

(b) The policy and procedure manual of facilities which are issued Type B Modified Class II Institutional Permits shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.

2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.

3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

4. Provisions for the utilization of a perpetual inventory system for all controlled substances.

5. Provisions for the utilization of an inventory system for injectables and other medicinal drugs as required by the Pharmacy Services Committee.

6. A diagram of the facility and the security and storage of the medicinal drugs.

7. Provisions for maintaining the records of consultations for not less than four (4) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(c) The policy and procedure manual of facilities which are issued Type C Modified Class II Institutional Permit shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.

2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.

3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

4. Provisions for the utilization of a Medication Administration Record (MAR) for all medicinal drugs administered to patients of the facility.

5. A diagram of the facility and the security and storage of the medicinal drugs.

6. Provisions for maintaining the records of consultations for not less than four (4) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(7) Controlled drugs as defined in Chapter 893, F.S., stocked as provided herein within a Type "A" Modified Class II Institutional Pharmacy shall be stocked in unit size not to exceed 100 dosage units unless an exception thereto is granted by the Board of Pharmacy. Proof of use record sheets showing patient's name, date of administration, initials of person administering drug, and other pertinent control requirements are required for both controlled and noncontrolled substance medicinal drugs in Type "A" Modified Class II Institutional Pharmacies.

(8) A Modified Class II institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(c), 465.022 FS. History–New 4-22-82, Amended 11-5-85, Formerly 21S-1.37, Amended 4-16-86, Formerly 21S-1.037, Amended 7-31-91, Formerly 21S-28.702, 61F10-28.702, Amended 9-4-96, Formerly 59X-28.702, Amended 10-15-01, 7-14-14, 3-15-16.

64B16-28.800 Special Pharmacies.

(1) Special pharmacies are pharmacies providing miscellaneous specialized pharmacy service functions. The Board of Pharmacy, by this rule, provides for the establishment of the following special pharmacy permits:

(a) Special-Limited Community.

(b) Special-Parenteral and Enteral.

(c) Special-Closed System Pharmacy.

(d) Special-End Stage Renal Disease.

(e) Special-Parenteral/Enteral Extended Scope.

(f) Special-ALF.

(g) Special Sterile Compounding.

(2) An applicant for any special pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual which sets for a detailed description of the type of pharmacy services to be provided within the special pharmacy practice. The Policy and Procedures Manual shall contain detailed provisions for compliance with the provision of Section 465.0196, F.S., and other applicable requirements contained in the chapter.

(3) The Policy and Procedure Manual shall be prepared, maintained, and will be reviewed and is subject to approval by the Board of Pharmacy or its designee prior to the issuance of the permit and the initiation of the operation of the permittee. The policy and procedure manual is reviewed to determine if the operation of the facility will be in compliance with Chapters 465 and 893, F.S., and Chapter 64B16, F.A.C. The Policy and Procedure Manual shall be made available upon request of the Board or its agents. The applicant who requests a special permit shall be subject to inspection prior to the issuance of the permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196, 456.022 FS. History–New 2-21-84, Formerly 21S-1.39, 21S-1.039, Amended 7-31-91, 10-14-91, Formerly 21S-28.800, 61F10-28.800, Amended 3-10-96, 6-4-97, Formerly 59X-28.800, Amended 11-11-98, 10-15-01, 7-2-13, 4-26-17.

64B16-28.802 Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities.

(1) A Special Sterile Compounding Permit (SSCP) is required before any pharmacy may engage in the preparation of compounded sterile products. For purposes of this rule, an outsourcing facility shall be deemed a pharmacy.

(2) An SSCP shall be issued by the department as an additional permit with a separate permit number that differs from the permit number of the pharmacy obtaining the SSCP.

(3) All sterile compounding shall be done in strict compliance with the standards set forth in Rules 64B16-27.700 and 64B16-27.797, F.A.C.

(4) An outsourcing facility shall comply with current good manufacturing practices as adopted and incorporated in Rule 64B16-27.797, F.A.C.

(a) If a pharmacy is not registered as an outsourcing facility at the time the pharmacy applies for an SSCP, the applicant shall amend the application within 7 business days if the pharmacy becomes a registered outsourcing facility before the SSCP is issued.

(b) If a pharmacy is issued an SSCP and later becomes registered as an outsourcing facility, the pharmacy will not be required to obtain a new or additional SSCP. However, the pharmacy shall comply with current good manufacturing practices to be eligible to retain the issued SSCP and the pharmacy shall notify the department in writing within 7 business days of becoming a registered outsourcing facility.

(c) An outsourcing facility that does not engage in patient specific sterile compounding and dispensing pursuant to such prescription shall only be required to obtain the SSCP. However, if the outsourcing facility engages in patient-specific sterile compounding, in addition to the SSCP, the outsourcing facility shall be required to obtain a pharmacy permit specific to the type of patient dispensing that the pharmacy will be engaged in (i.e., community pharmacy permit or institutional pharmacy permit).

(5) The SSCP is not required for a Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope pharmacy if that pharmacy holds no other pharmacy permit and is not registered as an outsourcing facility.

(6) The SSCP is not required for a Type B Modified Class II Institutional Pharmacy under the following conditions:

(a) The pharmacy only compounds low-risk level compounded sterile preparations; and

(b) The pharmacy only compounds those low-risk level compounded sterile preparations for immediate use pursuant to the provisions the United States Pharmacopeia adopted and incorporated in rule 64B16-27.797, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History–New 6-18-13, Amended 10-20-13, 5-8-16, 12-18-16, 11-5-17.

64B16-28.810 Special Pharmacy – Limited Community Permit.

A Special-Limited Community Permit shall be obtained by a Class II Institutional Pharmacy that dispenses medicinal drugs, including controlled substances to:

(1) Employees, medical staff and their dependents for their personal use;

(2) Patients of the hospital who are under a continuation of a course of therapy not to exceed a three (3) day supply;

(3) Patients obtaining medical services in the facility's emergency room and, whenever it is otherwise appropriate, as indicated in the applicant's policy and procedure manual; and,

(4) Discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs if the following requirements are met:

(a) The label affixed to a container used in dispensing multi-dose medicinal drugs contains at least the following information:

1. The name of and contact information of the pharmacy.
2. The name of the prescriber.
3. The name of the patient.
4. The date of the original filling and any applicable expiration date.
5. The prescription number or other prescription identification adequate to readily identify the prescription.
6. The directions for use.
7. The name, strength, and size of the medicinal drug dispensed; and,
8. The quantity of the drug in the container.

(b) The patient is deemed competent to handle and administer the multi-dose medicinal drug.

(c) A specific order is written by the patient's physician to authorize that the multi-dose medicinal drug is appropriate to dispense upon discharge.

(d) Before the hospital dispenses a multi-dose medicinal drug as specified in paragraph (4), of this subsection, the hospital shall establish protocols to ensure the following:

1. Infection control during transport and handling of multi-dose medicinal drug containers that have been in contact with a patient.

2. Patient or caregiver education on administration of the multi-dose medicinal drug if necessary on an individual basis.

(e) A "multi-dose medicinal drug" as used in this rule means, but is not limited to, commercially available multi-dose packages such as inhalers, ocular products, insulin vials or pens, otic products, bulk antibiotic suspensions, topical agents, and methylprednisolone dose packets dispensed to inpatients, provided in containers that may exceed a three (3) day supply, and are intended to be continued by the patient on an outpatient basis but not to be re-filled by the hospital. Controlled substances are not considered multi-dose medicinal drugs as defined in this rule.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History–New 7-31-91, Formerly 21S-28.810, 61F10-28.810, 59X-28.810, Amended 7-17-05, 2-10-14.

64B16-28.820 Sterile Products and Special Parenteral/Enteral Compounding.

(1) Sterile Products and Parenteral/Enteral Compounding.

(a) A sterile products and parenteral/enteral compounding pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to render sterile products and parenteral/enteral compounding functions. This pharmacy practice facilitates the utilization of certain institutional therapeutic measures by patients in the home environment or by patients in an institutional environment where such pharmacy service is unavailable. Pharmacy services, sterile products and parenteral/enteral products provided by a special sterile products and parenteral/enteral compounding pharmacy pursuant to prescription as defined by Section 465.003(13), F.S., shall be limited to the compounding and/or dispensing of:

1. Sterile preparations for parenteral therapy, parenteral nutrition; and/or
2. Sterile preparations for jejunostomy feeding and sterile irrigation solutions; and/or
3. Sterile preparations of cytotoxic or antineo-plastic agents; and/or
4. Sterile products (i.e., injectables, eye drops, etc.).

(b) Prior to engaging in a sterile products and parenteral/enteral compounding pharmacy practice an entity shall obtain a special sterile products and parenteral/enteral compounding pharmacy permit as provided herein.

(2) Pharmacy Environment. The compounding and dispensing of sterile products and parenteral/enteral prescription preparations within a special sterile products and parenteral/enteral compounding pharmacy shall be accomplished in a pharmacy environment subject to the pharmacy permit laws of this state and in accordance with those requirements for the safe handling of drugs. The environment for this practice shall be set apart, and designed, and equipped to facilitate controlled aseptic conditions. Aseptic techniques shall prevail in this practice to minimize the possibility of microbial contamination.

(3) General Requirements.

(a) A special sterile products and parenteral/enteral compounding pharmacy shall be under the control and supervision of a licensed pharmacist, who shall be designated prescription department manager on the application for a special sterile products and parenteral/enteral compounding pharmacy. The prescription department manager or other licensed qualified pharmacist as provided herein shall be present on duty during all hours of operation of said pharmacy. Changes in prescription department manager shall be reported to the Board of Pharmacy office within 10 days by the permit holder and prescription department manager of record. A prescription department manager of a special sterile products and parenteral/enteral compounding pharmacy shall not be designated prescription department manager of record of more than one special sterile products and parenteral/enteral compounding pharmacy, unless otherwise approved by the Board. The Board will consider the proximity of the facility as well as the administrative workload created by the two permits, in determining whether or not it will approve the designation of someone as a prescription department manager of more than one special sterile products and parenteral/enteral compounding pharmacy.

(b) A special sterile products and parenteral/enteral compounding pharmacy shall provide special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. All such preparations shall include the time and/or date of expiration on the label. Delivery from the pharmacy to the patient shall be made within a reasonable time. A special sterile products and parenteral/enteral compounding pharmacy shall provide telephone accessibility to its pharmacist(s) for its patients at all hours.

(c) A patient profile shall be maintained for each patient. The profile must contain available medical information consistent with prevailing pharmacy standards which shall be confidential.

(d) A Policy and Procedure Manual shall be prepared and maintained at each special sterile products and parenteral/enteral compounding pharmacy, and be available for inspection by authorized agents of the Board of Pharmacy and the Department. The Policy and Procedure Manual shall set forth in detail the objectives and operational guidelines of the permittee. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance, equipment facilities, and random production sampling consistent with recommended standards for compounding and dispensing intravenous admixtures as set forth by the Joint Commission on Accreditation of Health Organizations, the National Coordinating Committee and Large Volume Parenteral, and as provided by the Florida Board of Pharmacy.

(e) Compounding shall be conducted within an annually certified laminar air flow (LAF) hood, except in the existence of a Class 100 certified compounding environment, or certified mobile isolation chamber, in which case compounding may be conducted without the use of a certified laminar air flow hood. All cytotoxins must be compounded in a certified vertical laminar air flow hood or certified mobile isolation chamber. The use of a Type A or Type B LAF hood used shall be dependent upon the volume of work anticipated. All certifications shall be performed following manufacturer specification.

(f) Protective garb: gloves, face and eye, and gowns should be provided and used.

(g) Proper aseptic procedures must be used at all times to prevent bacterial contamination of the product as well as chemical contamination of the operator.

(h) All unused cytotoxic agents and material must be disposed of properly in accordance with accepted professional standards and applicable law.

(4) An applicant for a special sterile products and parenteral/enteral compounding pharmacy permit shall provide the Board of Pharmacy with the following:

(a) Completed Board of Pharmacy permit application form (Form DPR/PH/107/9-88).

(b) Copy of Policy and Procedure Manual.

(c) Permit fee as provided in Rule 64B16-28.121, F.A.C.

(5) Minimum Requirements for Space, Equipment, Supplies and Publications.

(a) To ensure compliance with the general requirements as set forth, the following minimum requirements for space, equipment, supplies and publications shall be met by a pharmacy which operates under the special permit of a sterile products and parenteral/enteral compounding pharmacy. These requirements are in addition to the minimum requirements for space and equipment required of other types of pharmacies when applicable. The minimum permit requirements are set forth as follows:

(b) Space:

1. The area for preparing sterile prescriptions as provided for by this rule referred to as the sterile admixture room shall be set apart from general work and storage areas. The room shall be adequately air conditioned or shall be under positive pressure.

2. The sterile admixture room shall provide space for a minimum of one laminar flow hood. Additionally, the space shall be of adequate size to accommodate other equipment as provided herein and sufficient space to allow pharmacists and other employees working therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(c) Equipment:

1. Laminar Air Flow Hood(s):

a. Horizontal; and/or

b. Vertical.

2. Refrigerator/freezer convenient to the clean room.

3. Sink and wash area convenient to the clean room.

4. Appropriate waste containers for:

a. Used needles and syringes.

b. All cytotoxic waste including apparel.

(d) Supplies:

1. Gloves, masks and gowns.

2. Needles and syringes of various standard sizes.

3. Disinfectant cleaning agents.

4. Clean towels.

5. Handwashing materials with bactericidal properties.

6. Vacuum containers and various transfer sets.

7. “Spill kits” for cytotoxic agent spills.

(e) Current References:

1. Chapter 465, F.S.

2. Chapter 499, F.S.

3. Chapter 893, F.S.

4. Title 64B16, F.A.C., Rules of the Florida Board of Pharmacy.

5. United States Pharmacopeia and National Formulary, or Remington Pharmaceutical Sciences, or the United States Dispensatory (along with the latest supplements), or an equivalent thereof sufficient in scope to meet the professional practice needs of the pharmacy, and a current authoritative therapeutic reference.

6. Handbook of Injectable Drugs by American Society of Hospital Pharmacists.

7. “Practice Guidelines For Personnel Dealing With Cytotoxic Drugs.”

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 456.0196 FS. History–New 4-26-84, Formerly 21S-1.40, Amended 7-27-

86, Formerly 21S-1.040, Amended 7-31-91, 10-14-91, Formerly 21S-28.820, 61F10-28.820, Amended 3-11-96, 6-4-97, Formerly 59X-28.820, Amended 7-1-02, 1-29-03, 6-4-14.

64B16-28.830 Special – Closed System Pharmacy.

(1) A Special – Closed System Pharmacy permit is a type of special pharmacy as provided for by Section 465.0196, F.S., which dispenses medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, ALF's (Adult Congregate Living Facilities), ICF-MR's (Intermediate Care Facility/Mentally Retarded) or other custodial care facilities when defined by AHCA rules which the Board may approve.

(2) A special – closed system pharmacy permittee shall maintain a policy and procedure manual including drug procurement, storage, handling, compounding, dispensing, record keeping and disposition.

(3) A special – closed system pharmacy permittee shall provide twenty-four hour emergency and on-call service.

(4) A special – closed system pharmacy permittee may dispense parenteral and enteral medications as provided by rule.

(5) A special – closed system pharmacy permittee shall be under the supervision of a prescription department manager who is responsible for maintaining all drug records, providing security of the prescription department and following other rules as relate to the practice of pharmacy. The prescription department manager of a closed system pharmacy shall not be the prescription department manager of any other pharmacy permit except when the permit is within the premises of a community pharmacy permit.

(6) The utilization of registered pharmacy interns and registered pharmacy technicians is subject to the rules as provided by Rule 64B16-26.400, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196, 465.022 FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.830, 61F10-28.830, 59X-28.830, Amended 1-1-10.

64B16-28.840 Special – Non Resident (Mail Service).

Rulemaking Authority 465.005, 465.022, 465.0156 FS. Law Implemented 465.0156 FS. History–New 10-14-91, Formerly 21S-28.840, 61F10-28.840, 59X-28.840, Amended 10-27-09, Repealed 4-26-17.

64B16-28.850 Special Pharmacy – ESRD.

(1) An ESRD Pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Pharmacy services and dialysis supplies and products provided by an ESRD pharmacy shall be limited to the distribution and delivery of legend drugs included in schedule subsection (3), below; or legend devices included in schedule subsection (4), below; which are ordered by a physician for administration or delivery to a person with chronic kidney failure for self-administration at the person's home or specified address. All dialysis supplies and products provided by an ESRD pharmacy shall be prepackaged and shall be covered by an approved NDA or 510 (k) application issued by the Federal Food and Drug Administration.

(2) Prior to engaging in an ESRD pharmacy practice an entity shall obtain a special ESRD pharmacy permit as provided herein.

(3) Schedule of legend drugs:

(a) Saline Solutions.

(b) Porcine Heparin.

(c) Beef Heparin.

(d) Dextrose Solutions.

(e) Doxercalciferol.

(f) Epoetin Alfa.

(g) NACL INJ 50 MEQ/20 ML.

(h) Levocarnitine.

(i) Lidocaine.

(j) Vitamin Preparations (dialysate use only).

(k) Paricalcitrol.

(l) Peritoneal Dialysate Solutions.

(m) Protamine Sulfate.

(n) Potassium 20 MEQ/10ML (dialysate use only).

(o) Sodium Ferric Gluconate Complex or equivalent.

(p) Sterile Water for Irrigation.

(4) The schedule of legend devices includes:

(a) Hemodialyzers.

(b) Hemodialysis solutions.

(c) Bloodlines and Associated Connectology.

(d) Peritoneal Dialysis Tubing and Connectology.

(5) The provision of legend drugs and devices included in the schedule necessary to perform dialysis to a person with chronic kidney failure for self-administration at the person's home or specified address shall be under the professional supervision of an appropriate practitioner licensed under Florida law. The consultant pharmacist shall assure that the following occurs:

(a) The ESRD pharmacy receives a prescription from the prescribing practitioner directing the pharmacist to dispense and deliver to a person with chronic kidney failure (or such person's designee) any legend drugs and/or devices included in the formulary necessary for the self-administration of dialysis at such person's home or specified address.

(b) That no dispensing shall occur unless the person with chronic kidney failure has been trained in the proper use and administration of such products. Further, the consulting pharmacist shall ensure that the ESRD pharmacy has received records confirming the completion of such training.

(c) After the delivery of such products by the ESRD pharmacy, the ESRD pharmacy shall upon request therefor, make available to the prescribing practitioner documentation describing, in sufficient detail, the types and quantities of products dispensed and delivered by the ESRD pharmacy. The ESRD pharmacy shall also, upon request, make available to the prescribing practitioner documentation confirming shipment of such products and receipt thereof by the person with chronic kidney failure.

(6) The licensed ESRD pharmacy shall comply with all applicable state and federal regulatory requirements and shall maintain in effect all applicable permits and licenses required to dispense and deliver legend drugs and/or devices included in the formulary described in this Section.

(7) The ESRD pharmacy shall deliver products to a person with chronic kidney failure only upon receipt of a valid prescription from a prescribing practitioner specifying or including:

(a) Documentation that the intended recipient of the products has been trained in home dialysis therapy and will require such products;

(b) The duration of prescribing practitioner's order; and,

(c) The name and product code of each product prescribed and the quantity prescribed.

(d) The prescription may indicate the person with chronic kidney failure shall have the right to request refills of legend drugs, devices or both, included in the schedule and described in the order for a period of one year.

(8) The ESRD pharmacy shall assemble the products to be delivered pursuant to the prescribing practitioner's prescription. In assembling such products for delivery, the ESRD pharmacy shall take steps necessary to assure the following:

(a) The code numbers and quantities of the products assembled match the code numbers identified in the prescribing practitioner's prescription;

(b) With respect to any dated products, a minimum of three (3) full months of shelf-life remain; and,

(c) All cartons and other packaging are properly labeled as noted below:

1. "Use as Directed" statement,

2. The name and address of the person to whom the products will be delivered,

3. The name of the prescribing practitioner,

4. The name and address of the ESRD pharmacy location from which the products were shipped,

5. The prescription number identifying the shipment to the order created by the prescribing practitioner; and,

6. Any special instructions regarding delivery dates or locations.

7. The date after which the drug(s) and/or device(s) must be discarded. Notwithstanding any other rule, the ESRD pharmacy may use, in lieu of a discard after date, the manufactures expiration date when such is displayed in an unopened sealed package.

(d) All cartons and related packaging shall be visually inspected to confirm compliance with the specifications in paragraph (8)(c). Compliance with the requirements set forth in paragraph (8)(c), shall be conducted by the consulting pharmacist or independently by not less than two employees of the ESRD pharmacy trained in the performance of the foregoing activities, each of

whom shall acknowledge in writing their completion of such activities with respect to each group of products assembled for delivery.

(9) The ESRD pharmacy permit holder shall assure through visual inspection and comparison of records that products assembled for delivery to persons with chronic kidney failure are consistent with the prescribing practitioner's order therefor.

(10) The products ordered by the prescribing practitioner under this Rule shall be delivered by either the ESRD pharmacy or a carrier authorized by the ESRD pharmacy.

(11) Upon delivery of the products by the ESRD pharmacy or its carrier to the person identified on the prescribing practitioner's order, the ESRD pharmacy or its carrier shall confirm receipt by the patient or the patient's designee that the number of units delivered equals the number of units identified on the appropriate documentation. Compliance with the foregoing requirements set forth above shall be conducted by an employee or agent of the ESRD pharmacy trained in the performance of such activities, who shall acknowledge in writing the delivery of the products and the completion of such activities with respect to each delivery.

(12) In addition to the foregoing operation requirements, an ESRD pharmacy shall comply with the following:

(a) The ESRD pharmacy license shall be displayed at each ESRD pharmacy location.

(b) The Board of Pharmacy shall be notified in writing of the Consulting Pharmacist responsible, at the time of application for the permit, for supervising the ESRD pharmacy operations and within 10 days, if the Consultant Pharmacist of record changes.

(c) The ESRD pharmacy's hours of business shall be posted. The ESRD pharmacy shall be open such hours as are necessary to safely and effectively dispense and deliver supplies to those persons designated by the applicable prescribing practitioner. An ESRD pharmacy shall provide twenty-four hour emergency and on-call service.

(d) The ESRD pharmacy shall have sufficient space and storage capabilities as are necessary to carry out its operation.

(e) All legend drugs and/or legend devices included in the formulary subject to this rule shall be properly identified.

(f) The ESRD pharmacy shall maintain a current copy of the Florida pharmacy laws and rules.

(g) The ESRD pharmacy shall comply with patient counseling requirements of Rules 64B16-27.800-.810 and 64B16-27.820, F.A.C.

(13) ESRD Pharmacy Application Requirements. An applicant for an ESRD pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual setting forth in detail the operational guidelines of the applicant. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance.

(14) An ESRD pharmacy shall be under the control and supervision of licensed Consultant Pharmacist licensed under Section 465.0125, F.S. The Consulting Pharmacist shall be responsible for the drug/device delivery system.

(15) The Consultant Pharmacist of record for the ESRD Pharmacy shall be responsible for establishing a written protocol and Policy and Procedure Manual for the implementation of a delivery system to be utilized in compliance with the requirements of this rule.

(16) The Consultant Pharmacist shall inspect the permitted ESRD pharmacy on a monthly basis.

(17) A copy of the ESRD pharmacy's Policy and Procedure Manual as provided above shall accompany the permit application, shall be kept within the ESRD Pharmacy, and shall be available for inspection by the Department of Health. Changes in the Policy and Procedure Manual shall be approved by the Consulting Pharmacist.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0196, 465.022 FS. History–New 10-2-94, Formerly 59X-28.850, Amended 9-20-99, 7-17-05, 6-24-08.

64B16-28.860 Special Pharmacy – Parenteral/Enteral Extended Scope Permit.

(1)(a) A Special Parenteral/Enteral Extended Scope permit, as authorized by Section 465.0196, F.S., is required for pharmacies to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied. Prior to engaging in a parenteral/enteral compounding pharmacy practice as described in this section, an entity shall obtain a Special Parenteral/Enteral Extended Scope pharmacy permit.

(b) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity, including the following provisions:

1. When dispensing patient specific prescriptions provided by an institutional pharmacy permit, the Special Parenteral/Enteral Extended Scope pharmacy shall confirm accuracy of the prescription and dosage.

2. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

3. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special

Parenteral/Enteral Extended Scope pharmacy.

4. A pharmacist for the Class II institutional pharmacy shall provide drug utilization review and shall review each prescription order prior to transmission to the Special Parenteral/Enteral Extended Scope pharmacy.

5. The Policy and Procedure Manual for a Special Parenteral/Enteral Extended Scope pharmacy shall also meet the policy and procedure manual requirements of paragraph 64B16-28.820(3)(d), F.A.C.

(c) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(2) Facilities obtaining this permit may also provide services described in paragraph 64B16-28.820(1)(a), F.A.C., without obtaining an additional permit. Pharmacy services and parenteral/enteral products provided by a Special Parenteral/Enteral Extended Scope pharmacy shall be limited to the compounding and/or dispensing of sterile:

(a) Preparations for parental therapy, parenteral nutrition; and/or

(b) Preparations for enteral feeding and sterile irrigation solutions; and/or

(c) Preparations of cytotoxic or antineoplastic agents.

(3) Facilities operating under this permit may provide all necessary supplies and delivery systems so that the medicinal drugs listed herein may be properly administered.

(4) Pharmacy Environment. The compounding and dispensing of sterile parenteral/enteral prescription preparations within a Special Parenteral/Enteral Extended Scope pharmacy shall be accomplished in a pharmacy environment subject to the pharmacy permit laws contained in Chapter 465, F.S., and in accordance with those requirements for the safe handling of drugs. Special Parenteral/Enteral Extended Scope permittees shall comply with the requirements contained in subsections 64B16-28.820(3) through (4), F.A.C., and the following:

(a) Shall include an active and ongoing end product testing program to ensure stability, sterility, and quantitative integrity of finished prescriptions.

(b) Shall insure each compounding process undergoes an initial and thereafter annual sterility validation utilizing media fill to ensure the integrity and validity of the compounding process.

(5) Records.

(a) Special Parenteral/Enteral Extended Scope pharmacies shall comply with the record maintenance requirements as contained in Rule 64B16-28.140, F.A.C.

(b) Special Parenteral/Enteral Extended Scope pharmacies dispensing medicinal products to patients under the provisions of paragraph 64B16-28.820(1)(a), F.A.C., or to patients of Modified Class II institutional pharmacies under the provisions of Rule 64B16-28.860, F.A.C., shall comply with the records, utilization review, and patient counseling requirements of Rules 64B16-27.800, 64B16-27.810 and 64B16-27.820, F.A.C.

(c) Special Parenteral/Enteral Extended Scope pharmacies dispensing medicinal products to patients of Class II institutional pharmacies under the provisions of Rule 64B16-28.860, F.A.C., shall be exempt from the records, utilization review, and patient counseling requirements of Rules 64B16-27.800, 64B16-27.810 and 64B16-27.820, F.A.C.

(d) Compounding records shall be organized in such a manner as to include: lot number traceability of components used during compounding, documentation of any equipment used during compounding, documentation of staff performing compounding, and records recording ultimate dispensing of the compounded product.

Rulemaking Authority 465.005 FS. Law Implemented 465.0196, 465.022 FS. History–New 9-4-96, Formerly 59X-28.860, Amended 7-17-05.

64B16-28.870 Special-ALF.

(1) The Special-ALF permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

(2) Medicinal Drugs.

(a) Medicinal drugs may not be dispensed on the premises.

(b) All medicinal drugs must be maintained in individual prescription containers for the individual patient.

(c) Medicinal drugs dispensed to the residents of a Special-ALF permit shall meet the labeling requirements of Rules 64B16-28.502 and 64B16-28.108, F.A.C.

(d) Medicinal drugs may not be dispensed on the premises. Medicinal drugs dispensed to patients of Special-ALF permits may be returned to the dispensing pharmacy's stock under the provisions of Rule 64B16-28.118, F.A.C. Dispensed controlled substances that have been discontinued shall be disposed of under the provisions of Rule 64B16-28.301, F.A.C.

(3) Consultant Pharmacist of Record.

(a) Each facility holding a Special-ALF permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within ten (10) days of any change in the consultant pharmacist of record.

(b) The consultant pharmacist of record shall be responsible for the preparation of the Policy and Procedure Manual required by subsection 64B16-28.800(2), F.A.C. Policy and Procedure Manuals must provide for the appropriate storage conditions and security of the medicinal drugs stored at the facility.

(c) The consultant pharmacist of record shall inspect the facility and prepare a written report to be filed at the permitted facility at least monthly.

(d) The consultant pharmacist of record shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility, and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor the facility's system for maintaining medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and ~~or~~ in the monthly facility inspection.

(e) A consultant pharmacist licensed in Florida may remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct supplemental drug regimen review services, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.016(1)(l), 465.0196 FS. History–New 2-23-98, Amended 7-19-17.

64B16-28.900 Definitions – Nuclear Pharmacy.

(1) A "nuclear pharmacy" is a pharmacy which provides radiopharmaceutical services.

(2) A "nuclear pharmacist" is a pharmacist who has met the training qualifications as described in Rule 64B16-28.903, F.A.C., and has been licensed by the Board of Pharmacy.

(3) A "radiopharmaceutical service" shall include, but shall not be limited to, the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping and disposal of radiopharmaceuticals.

(4) A "radiopharmaceutical" is any substance defined as a drug by Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) "Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals, and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

(6) "Authentication of product history" includes, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical or other drug.

Rulemaking Authority 465.005 FS. Law Implemented 465.003(14), 465.022(1)(e) FS. History–New 1-7-76, Formerly 21S-3.01, Amended 4-4-88, Formerly 21S-3.001, Amended 7-31-91, 4-15-92, 10-1-92, Formerly 21S-28.900, 61F10-28.900, 59X-28.900, Amended 4-5-05.

64B16-28.901 Nuclear Pharmacy – General Requirements.

The process employed by any permit holder in this state concerning the handling of radioactive materials must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials. In order to insure the public health and safety in this respect, a nuclear pharmacy in this state shall meet the following general requirements:

(1) Each nuclear pharmacy shall designate a nuclear pharmacist as the prescription department manager who shall be responsible for compliance with all laws and regulations, both state and federal pertaining to radiopharmaceuticals and radiopharmaceutical services. A nuclear pharmacist must personally supervise the operation of only one nuclear pharmacy during all times when radiopharmaceutical services are being performed.

(2) The nuclear pharmacy area shall be secured from access by unauthorized personnel.

(3) Each nuclear pharmacy shall maintain accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals.

(4) All nuclear pharmacies shall provide a secured radioactive storage and decay area.

(5) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies for the procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals and other drugs.

(6) Radiopharmaceuticals are to be distributed only upon a prescription order from an authorized licensed medical practitioner or through the practitioner's agent.

(7) A nuclear pharmacist may transfer radioactive materials in accordance with all applicable laws and regulations.

(8) A nuclear pharmacist upon receiving an oral prescription order for a radiopharmaceutical shall immediately have the prescription order reduced to writing. The pharmacist may delegate this duty to a registered pharmacy technician only as authorized by Rule 64B16-27.410, F.A.C. The prescription order shall contain at least the following:

(a) The name of the user or his agent;

(b) The date of distribution and the time of calibration of the radiopharmaceutical;

(c) The name of the procedure;

(d) The name of the radiopharmaceutical;

(e) The dose or quantity of the radiopharmaceutical;

(f) Any specific instructions; and,

(g) The initials of the person who received the prescription order.

(h) The patient's name must be obtained and recorded prior to dispensing, if the prescription order is for a therapeutic or blood product radiopharmaceutical.

(9) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(a) The name of and address of the pharmacy;

(b) The name of the prescriber;

(c) The date of the original filling;

(d) The standard radiation symbol;

(e) The words "Caution Radioactive Material";

(f) The name of the procedure;

(g) The prescription order number of the radiopharmaceutical;

(h) The radionuclide and chemical form;

(i) The amount of radioactivity and the calibration date and time;

(j) The expiration date and time;

(k) The volume if a liquid;

(l) The number of items or weight, if a solid;

(m) The number of ampules or vials, if a gas;

(n) Molybdenum 99 content to USP limits, applies only to Tc 99m products; and,

(o) The name of the patient for therapeutic or blood-product radiopharmaceuticals or the words "Physician's Use Only" for diagnostic radiopharmaceuticals. If the prescription order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

(p) The initials of the pharmacist who dispensed the medication.

(10) The immediate inner container label of a radiopharmaceutical to be distributed shall be labeled with:

(a) The standard radiation symbol;

(b) The words "Caution Radioactive Material";

(c) The radionuclide;

(d) The chemical form;

(e) The prescription order number of the radiopharmaceutical.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a)3., 465.003(14), (15), 465.0126, 465.014 FS. History–New 1-7-76, Formerly 21S-3.03, Amended 12-11-86, 4-4-88, Formerly 21S-3.003, 21S-28.901, 61F10-28.901, Amended 2-26-95, Formerly 59X-28.901, Amended 4-5-05, 1-1-10, 12-31-13.

64B16-28.902 Nuclear Pharmacy – Minimum Requirements.

In order to insure compliance with the general safety requirements as previously set forth above, the following minimum requirements shall be met by a nuclear pharmacy. These requirements are in addition to the general requirements for space and equipment for other types of pharmacies, the requirements of the Department of Health for the control of radiation hazards, and the applicable requirements of the Federal Food and Drug Administration. Such minimum permit requirements are set forth as follows:

(1) Space:

(a) The area for the storage, compounding, distribution and disposal of radiopharmaceuticals shall be adequate to completely separate such radioactive pharmaceuticals from pharmacy areas which contain non-radioactive medicinal drugs;

(b) The Hot lab, storage area, and compounding and dispensing area shall be a minimum of 150 square feet.

(2) Equipment:

(a) Fume hood with appropriate air sampling equipment;

(b) Shielded radiation containment drawing station;

(c) Dose calibrator;

(d) Well scintillation counters;

(e) Area rate meters;

(f) Geiger-Mueller (GM) Survey meters;

(g) Refrigerator;

(h) Microscope;

(i) Syringe shields; and,

(j) Personnel radiation detection devices.

(3) Supplies:

(a) Syringes and vials required to perform practice;

(b) Disposable gloves and protective lab coats;

(c) Appropriate supplies to ensure sterile practices for I.V. solutions;

(d) Appropriate supplies to perform thin layer chromotography;

(e) Lead transport shields for syringes and vials. No person shall utilize reusable unit dose transport containers for radioactive doses without either an effective process to decontaminate the transport container of blood and other biohazardous substances or an effective mechanism to avoid contamination of the transport container. No person shall re-use a unit dose transport container that remains contaminated with blood or other biohazardous subtances. Any unit dose transport container that is returned with the tamper-evident seal broken and the unit dose syringe included shall be considered to be contaminated.

(f) D.O.T. Type 7A approved transport containers and other labels and supplies for shipping radioactive materials.

(4) Current references:

(a) Chapter 465, F.S.;

(b) Chapter 404, F.S.;

(c) Chapter 893, F.S.;

(d) Chapters 64B16-26 and 64B16-28, F.A.C., Rules of the Florida Board of Pharmacy;

(e) Chapter 64E-5, F.A.C., Rules of the Department of Health;

(f) Title 10 C.F.R., Code of Federal Regulations, FDA Regulations;

(g) Title 49 C.F.R., Code of Federal Regulations, Department of Transportation Regulations;

(h) United States Pharmacopeia/National Formulary;

(i) USP-DI.

It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0193, 465.022(1) FS. History–New 1-7-76, Formerly 21S-3.04, Amended 12-11-86, 4-4-88, Formerly 21S-3.004, Amended 7-31-91, Formerly 21S-28.902, 61F10-28.902, Amended 2-26-95, Formerly 59X-28.902, Amended 4-26-01, 4-5-05.

64B16-28.903 Training Qualifications.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(14), 465.0126 FS. History–New 4-17-76, Amended 4-8-80, 6-23-83, Formerly 21S-3.05, Amended 8-11-86, 4-4-88, Formerly 21S-3.005, Amended 7-31-91, Formerly 21S-28.903, 61F10-28.903, Amended 6-12-96,

Formerly 59X-28.903, Repealed 1-18-05.

64B16-28.904 Nuclear Pharmacist – Continuing Education.

Rulemaking Authority 465.0126, 465.022 FS. Law Implemented 465.009(5), 465.0126 FS. History–New 10-28-91, Formerly 21S-28.904, 61F10-28.904, 59X-28.904, Amended 1-12-03, 10-19-03, Repealed 1-18-05.

64B16-28.905 Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities.

Rulemaking Authority 465.0158 FS. Law Implemented 465.0158 FS. History–New 12-24-15, Transferred to 64B16-32.015.