Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

May 11, 2018
10:00 a.m.
Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

Notice is hereby given that the Missouri Board of Pharmacy’s Hospital Advisory Committee will be meeting at 10:00 a.m. on May 11, 2018. A tentative agenda is attached. If any member of the public wishes to attend, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Blvd., Jefferson City, Missouri at 10:00 a.m. on May 11, 2018.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy’s Hospital Advisory Committee is authorized to closed meetings, records and votes pursuant to Section 610.021(1). The Committee may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

Please see the attached tentative agenda for this meeting.
TENTATIVE ***AMENDED*** AGENDA
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

May 11, 2018
10:00 a.m.
Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

1. Board of Pharmacy Updates
2. DHSS Updates
3. Missouri Hospital Association Updates (Amended)
4. 2018 Legislative Update
5. Automated Distribution/Dispensing
6. After-Hours Dispensing (Amended)
7. Guidance for non-Class B hospital pharmacies (Amended)
   a. Non-sterile packaging for clinics
   b. USP 800
   c. Pharmacist scope of practice
8. Future Meeting Dates
9. Adjournment
AN ACT

To amend chapter 197, RSMo, by adding thereto one new section relating to multidose medications given to patients at discharge.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 197, RSMo, is amended by adding thereto one new section, to be known as section 197.180, to read as follows:

197.180. 1. Medications in multidose containers that were administered to or used for a patient during the patient's hospital stay may, if so ordered by an authorized health care provider, be sent with the patient at discharge to the patient's home or to another health care facility.

2. Multidose medications shall include, but are not limited to, inhalers, ointments, creams, medications requiring the original container for dispensing, insulin pens and vials, eye drops, ear drops, wearable or on-body medication delivery systems, and infusions that are currently connected to the patient's infusion device.

3. Multidose medications shall be labeled with the date, patient’s name, prescriber’s name, name and address of the hospital, medication name and strength, instructions for use, and other pertinent information. Labeling shall be performed by a pharmacist, prescriber, or registered nurse. Labeled instructions for use may refer to specific written instructions provided by a pharmacist, prescriber, or registered nurse at the time of discharge.

4. Controlled substances shall not be sent with the patient, except that wearable or on-body medication delivery systems of controlled substances or controlled substance infusions currently connected to the patient’s infusion device may be sent if:

   (1) The medication is necessary for administration during transport of the patient;

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in bold-face type in the above bill is proposed language.
(2) The quantity of the controlled substance sent is documented in the patient’s medical record by the person sending the medication; and

(3) The pharmacy is notified that the medication was sent with the patient.

5. Nothing in this section shall require a class B hospital pharmacy to obtain or comply with additional licensure or regulatory requirements.
AN ACT

To repeal sections 197.052, 197.305, and 536.031, RSMo, and to enact in lieu thereof three new sections relating to licensure of healthcare facilities.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 197.052, 197.305, and 536.031, RSMo, are repealed and three new sections enacted in lieu thereof, to be known as sections 197.052, 197.305, and 536.031, to read as follows:

197.052. An applicant for or holder of a hospital license may define or revise the premises of a hospital campus to include tracts of property which are adjacent but for a common street, single intersection, or highway, as such terms are defined in section 300.010, and its accompanying public right-of-way.

197.305. As used in sections 197.300 to 197.366, the following terms mean:

1. "Affected persons", the person proposing the development of a new institutional health service, the public to be served, and health care facilities within the service area in which the proposed new health care service is to be developed;

2. "Agency", the certificate of need program of the Missouri department of health and senior services;

3. "Capital expenditure", an expenditure by or on behalf of a health care facility which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance;

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in bold-face type in the above bill is proposed language.
(4) "Certificate of need", a written certificate issued by the committee setting forth the committee's affirmative finding that a proposed project sufficiently satisfies the criteria prescribed for such projects by sections 197.300 to 197.366;

(5) "Develop", to undertake those activities which on their completion will result in the offering of a new institutional health service or the incurring of a financial obligation in relation to the offering of such a service;

(6) "Expenditure minimum" shall mean:
   (a) For beds in existing or proposed health care facilities licensed pursuant to chapter 198 and long-term care beds in a hospital as described in subdivision (3) of subsection 1 of section 198.012, six hundred thousand dollars in the case of capital expenditures, or four hundred thousand dollars in the case of major medical equipment, provided, however, that prior to January 1, 2003, the expenditure minimum for beds in such a facility and long-term care beds in a hospital described in section 198.012 shall be zero, subject to the provisions of subsection 7 of section 197.318;
   (b) For beds or equipment in a long-term care hospital meeting the requirements described in 42 CFR, Section 412.23(e), the expenditure minimum shall be zero; and
   (c) For health care facilities, new institutional health services or beds not described in paragraph (a) or (b) of this subdivision one million dollars in the case of capital expenditures, excluding major medical equipment, and one million dollars in the case of medical equipment;

(7) "Health service area", a geographic region appropriate for the effective planning and development of health services, determined on the basis of factors including population and the availability of resources, consisting of a population of not less than five hundred thousand or more than three million;

(8) "Major medical equipment", medical equipment used for the provision of medical and other health services;

(9) "New institutional health service":
   (a) The development of a new health care facility costing in excess of the applicable expenditure minimum;
   (b) The acquisition, including acquisition by lease, of any health care facility, or major medical equipment costing in excess of the expenditure minimum;
   (c) Any capital expenditure by or on behalf of a health care facility in excess of the expenditure minimum;
   (d) Predevelopment activities as defined in subdivision (12) hereof costing in excess of one hundred fifty thousand dollars;
   (e) Any change in licensed bed capacity of a health care facility licensed under chapter 198 which increases the total number of beds by more than ten or more than ten percent of total
bed capacity, whichever is less, over a two-year period, provided that any such health care facility seeking a nonapplicability review for an increase in total beds or total bed capacity in an amount less than described in this paragraph shall be eligible for such review only if the facility has had no patient care class I deficiencies within the last eighteen months and has maintained at least an eighty-five percent average occupancy rate for the previous six quarters;

(f) Health services, excluding home health services, which are offered in a health care facility and which were not offered on a regular basis in such health care facility within the twelve-month period prior to the time such services would be offered;

(g) A reallocation by an existing health care facility of licensed beds among major types of service or reallocation of licensed beds from one physical facility or site to another by more than ten beds or more than ten percent of total licensed bed capacity, whichever is less, over a two-year period;

(10) "Nonsubstantive projects", projects which do not involve the addition, replacement, modernization or conversion of beds or the provision of a new health service but which include a capital expenditure which exceeds the expenditure minimum and are due to an act of God or a normal consequence of maintaining health care services, facility or equipment;

(11) "Person", any individual, trust, estate, partnership, corporation, including associations and joint stock companies, state or political subdivision or instrumentality thereof, including a municipal corporation;

(12) "Predevelopment activities", expenditures for architectural designs, plans, working drawings and specifications, and any arrangement or commitment made for financing, but excluding submission of an application for a certificate of need.

536.031. 1. There is established a publication to be known as the “Code of State Regulations”, which shall be published in a format and medium as prescribed and in writing upon request by the secretary of state as soon as practicable after ninety days following January 1, 1976, and may be republished from time to time thereafter as determined by the secretary of state.

2. The code of state regulations shall contain the full text of all rules of state agencies in force and effect upon the effective date of the first publication thereof, and effective September 1, 1990, it shall be revised no less frequently than monthly thereafter so as to include all rules of state agencies subsequently made, amended or rescinded. The code may also include citations, references, or annotations, prepared by the state agency adopting the rule or by the secretary of state, to any intraagency ruling, attorney general’s opinion, determination, decisions, order, or other action of the administrative hearing commission, or any determination, decision,
order, or other action of a court interpreting, applying, discussing, distinguishing, or otherwise affecting any rule published in the code.

3. The code of state regulations shall be published in looseleaf form in one or more volumes upon request and a format and medium as prescribed by the secretary of state with an appropriate index, and revisions in the text and index may be made by the secretary of state as necessary and provided in written format upon request.

4. An agency may incorporate by reference rules, regulations, standards, and guidelines of an agency of the United States or a nationally or state-recognized organization or association without publishing the material in full. The reference in the agency rules shall fully identify the incorporated material by publisher, address, and date in order to specify how a copy of the material may be obtained, and shall state that the referenced rule, regulation, standard, or guideline does not include any later amendments or additions, except that:

   (1) Hospital licensure regulations promulgated under this chapter and chapter 197 may incorporate by reference Medicare conditions of participation, as defined in section 197.005, and later additions or amendments to such conditions of participation; and

   (2) Hospital licensure regulations governing life safety code standards promulgated under this chapter and chapter 197 to implement section 197.065 may incorporate, by reference, later additions or amendments to such rules, regulations, standards, or guidelines as needed to consistently apply current standards of safety and practice.

5. The agency adopting a rule, regulation, standard, or guideline under this section shall maintain a copy of the referenced rule, regulation, standard, or guideline at the headquarters of the agency and shall make it available to the public for inspection and copying at no more than the actual cost of reproduction. The secretary of state may omit from the code of state regulations such material incorporated by reference in any rule the publication of which would be unduly cumbersome or expensive.

6. The courts of this state shall take judicial notice, without proof, of the contents of the code of state regulations.
AMEND House Bill No. 2183, Page 1, Section 197.052, Line 4, by inserting after all of said section and line the following:

"197.305. As used in sections 197.300 to 197.366, the following terms mean:

(1) "Affected persons", the person proposing the development of a new institutional health service, the public to be served, and health care facilities within the service area in which the proposed new health care service is to be developed;

(2) "Agency", the certificate of need program of the Missouri department of health and senior services;

(3) "Capital expenditure", an expenditure by or on behalf of a health care facility which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance;

(4) "Certificate of need", a written certificate issued by the committee setting forth the committee's affirmative finding that a proposed project sufficiently satisfies the criteria prescribed for such projects by sections 197.300 to 197.366;

(5) "Develop", to undertake those activities which on their completion will result in the offering of a new institutional health service or the incurring of a financial obligation in relation to the offering of such a service;

(6) "Expenditure minimum" shall mean:

(a) For beds in existing or proposed health care facilities licensed pursuant to chapter 198 and long-term care beds in a hospital as described in subdivision (3) of subsection 1 of section 198.012, six hundred thousand dollars in the case of capital expenditures, or four hundred thousand dollars in the case of major medical equipment, provided, however, that prior to January 1, 2003, the expenditure minimum for beds in such a facility and long-term care beds in a hospital described in section 198.012 shall be zero, subject to the provisions of subsection 7 of section 197.318;

(b) For beds or equipment in a long-term care hospital meeting the requirements described in 42 CFR, Section 412.23(e), the expenditure minimum shall be zero; and

(c) For health care facilities, new institutional health services or beds not described in paragraph (a) or (b) of this subdivision one million dollars in the case of capital expenditures, excluding major medical equipment, and one million dollars in the case of medical equipment;

(7) "Health service area", a geographic region appropriate for the effective planning and development of health services, determined on the basis of factors including population and the availability of resources, consisting of a population of not less than five hundred thousand or more than three million;

(8) "Major medical equipment", medical equipment used for the provision of medical and other health services;
(9) "New institutional health service":
   (a) The development of a new health care facility costing in excess of the applicable expenditure minimum;
   (b) The acquisition, including acquisition by lease, of any health care facility, or major medical equipment costing in excess of the expenditure minimum;
   (c) Any capital expenditure by or on behalf of a health care facility in excess of the expenditure minimum;
   (d) Predevelopment activities as defined in subdivision (12) hereof costing in excess of one hundred fifty thousand dollars;
   (e) Any change in licensed bed capacity of a health care facility licensed under chapter 198 which increases the total number of beds by more than ten or more than ten percent of total bed capacity, whichever is less, over a two-year period, provided that any such health care facility seeking a nonapplicability review for an increase in total beds or total bed capacity in an amount less than described in this paragraph shall be eligible for such review only if the facility has had no patient care class I deficiencies within the last eighteen months and has maintained at least an eighty-five percent average occupancy rate for the previous six quarters;
   (f) Health services, excluding home health services, which are offered in a health care facility and which were not offered on a regular basis in such health care facility within the twelve-month period prior to the time such services would be offered;
   (g) A reallocation by an existing health care facility of licensed beds among major types of service or reallocation of licensed beds from one physical facility or site to another by more than ten beds or more than ten percent of total licensed bed capacity, whichever is less, over a two-year period;
   (10) "Nonsubstantive projects", projects which do not involve the addition, replacement, modernization or conversion of beds or the provision of a new health service but which include a capital expenditure which exceeds the expenditure minimum and are due to an act of God or a normal consequence of maintaining health care services, facility or equipment;
   (11) "Person", any individual, trust, estate, partnership, corporation, including associations and joint stock companies, state or political subdivision or instrumentality thereof, including a municipal corporation;
   (12) "Predevelopment activities", expenditures for architectural designs, plans, working drawings and specifications, and any arrangement or commitment made for financing; but excluding submission of an application for a certificate of need."; and

Further amend said bill by amending the title, enacting clause, and intersectional references accordingly.
AN ACT

To repeal sections 195.010, 195.070, 195.080, 338.010, and 338.056, RSMo, and to enact in lieu thereof six new sections relating to pharmacy, with an emergency clause for a certain section.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 195.010, 195.070, 195.080, 338.010, and 338.056, RSMo, are repealed and six new sections enacted in lieu thereof, to be known as sections 195.010, 195.070, 195.080, 195.265, 338.010, and 338.056, to read as follows:

195.010. The following words and phrases as used in this chapter and chapter 579, unless the context otherwise requires, mean:

(1) "Acute pain", pain, whether resulting from disease, accidental or intentional trauma, or other causes, that the practitioner reasonably expects to last only a short period of time. "Acute pain" shall not include chronic pain, pain being treated as part of cancer care, hospice or other end of life care, or medication-assisted treatment for substance use disorders;

(2) "Addict", a person who habitually uses one or more controlled substances to such an extent as to create a tolerance for such drugs, and who does not have a medical need for such drugs, or who is so far addicted to the use of such drugs as to have lost the power of self-control with reference to his or her addiction;

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in bold-face type in the above bill is proposed language.
(a) A practitioner (or, in his or her presence, by his or her authorized agent); or
(b) The patient or research subject at the direction and in the presence of the practitioner;

(4) "Agent", an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. The term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman while acting in the usual and lawful course of the carrier's or warehouseman's business;

(5) "Attorney for the state", any prosecuting attorney, circuit attorney, or attorney general authorized to investigate, commence and prosecute an action under this chapter;

(6) "Controlled substance", a drug, substance, or immediate precursor in Schedules I through V listed in this chapter;

(7) "Controlled substance analogue", a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and:

(a) Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II; or

(b) With respect to a particular individual, which that individual represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II. The term does not include a controlled substance; any substance for which there is an approved new drug application; any substance for which an exemption is in effect for investigational use, for a particular person, under Section 505 of the federal Food, Drug and Cosmetic Act (21 U.S.C. Section 355) to the extent conduct with respect to the substance is pursuant to the exemption; or any substance to the extent not intended for human consumption before such an exemption takes effect with respect to the substance;

(8) "Counterfeit substance", a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance;

(9) "Deliver" or "delivery", the actual, constructive, or attempted transfer from one person to another of drug paraphernalia or of a controlled substance, or an imitation controlled substance, whether or not there is an agency relationship, and includes a sale;

(10) "Dentist", a person authorized by law to practice dentistry in this state;

(11) "Depressant or stimulant substance":

(a) A drug containing any quantity of barbituric acid or any of the salts of barbituric acid or any derivative of barbituric acid which has been designated by the United States Secretary of Health and Human Services as habit forming under 21 U.S.C. Section 352(d);

(b) A drug containing any quantity of:
   a. Amphetamine or any of its isomers;
   b. Any salt of amphetamine or any salt of an isomer of amphetamine; or
   c. Any substance the United States Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system;

(c) Lysergic acid diethylamide; or

(d) Any drug containing any quantity of a substance that the United States Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect;

[(11)] (12) "Dispense", to deliver a narcotic or controlled dangerous drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for such delivery. "Dispenser" means a practitioner who dispenses;

[(12)] (13) "Distribute", to deliver other than by administering or dispensing a controlled substance;

[(13)] (14) "Distributor", a person who distributes;

[(14)] (15) "Drug":
   a. Substances recognized as drugs in the official United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, or Official National Formulary, or any supplement to any of them;
   b. Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals;
   c. Substances, other than food, intended to affect the structure or any function of the body of humans or animals; and
   d. Substances intended for use as a component of any article specified in this subdivision. It does not include devices or their components, parts or accessories;

[(15)] (16) "Drug-dependent person", a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from the use of such substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence;
"Drug enforcement agency", the Drug Enforcement Administration in the United States Department of Justice, or its successor agency;

"Drug paraphernalia", all equipment, products, substances and materials of any kind which are used, intended for use, or designed for use, in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, storing, containing, concealing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance or an imitation controlled substance in violation of this chapter or chapter 579. It includes, but is not limited to:

(a) Kits used, intended for use, or designed for use in planting, propagating, cultivating, growing or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived;

(b) Kits used, intended for use, or designed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances or imitation controlled substances;

(c) Isomerization devices used, intended for use, or designed for use in increasing the potency of any species of plant which is a controlled substance or an imitation controlled substance;

(d) Testing equipment used, intended for use, or designed for use in identifying, or in analyzing the strength, effectiveness or purity of controlled substances or imitation controlled substances;

(e) Scales and balances used, intended for use, or designed for use in weighing or measuring controlled substances or imitation controlled substances;

(f) Dilutents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose, used, intended for use, or designed for use in cutting controlled substances or imitation controlled substances;

(g) Separation gins and sifters used, intended for use, or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana;

(h) Blenders, bowls, containers, spoons and mixing devices used, intended for use, or designed for use in compounding controlled substances or imitation controlled substances;

(i) Capsules, balloons, envelopes and other containers used, intended for use, or designed for use in packaging small quantities of controlled substances or imitation controlled substances;

(j) Containers and other objects used, intended for use, or designed for use in storing or concealing controlled substances or imitation controlled substances;

(k) Hypodermic syringes, needles and other objects used, intended for use, or designed for use in parenterally injecting controlled substances or imitation controlled substances into the human body;
(l) Objects used, intended for use, or designed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as:

a. Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;

b. Water pipes;

c. Carburetion tubes and devices;

d. Smoking and carburetion masks;

e. Roach clips meaning objects used to hold burning material, such as a marijuana cigarette, that has become too small or too short to be held in the hand;

f. Miniature cocaine spoons and cocaine vials;

g. Chamber pipes;

h. Carburetor pipes;
i. Electric pipes;
j. Air-driven pipes;
k. Chillums;
l. Bongs;
m. Ice pipes or chillers;

(m) Substances used, intended for use, or designed for use in the manufacture of a controlled substance;

In determining whether an object, product, substance or material is drug paraphernalia, a court or other authority should consider, in addition to all other logically relevant factors, the following:

a. Statements by an owner or by anyone in control of the object concerning its use;

b. Prior convictions, if any, of an owner, or of anyone in control of the object, under any state or federal law relating to any controlled substance or imitation controlled substance;

c. The proximity of the object, in time and space, to a direct violation of this chapter or chapter 579;

d. The proximity of the object to controlled substances or imitation controlled substances;

e. The existence of any residue of controlled substances or imitation controlled substances on the object;

f. Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons who he or she knows, or should reasonably know, intend to use the object to facilitate a violation of this chapter or chapter 579; the innocence of an owner, or of anyone in control of the object, as to direct violation of this chapter or chapter 579 shall not prevent a finding that the object is intended for use, or designed for use as drug paraphernalia;
g. Instructions, oral or written, provided with the object concerning its use;

h. Descriptive materials accompanying the object which explain or depict its use;

i. National or local advertising concerning its use;

j. The manner in which the object is displayed for sale;

k. Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products;

l. Direct or circumstantial evidence of the ratio of sales of the object to the total sales of the business enterprise;

m. The existence and scope of legitimate uses for the object in the community;

n. Expert testimony concerning its use;

o. The quantity, form or packaging of the product, substance or material in relation to the quantity, form or packaging associated with any legitimate use for the product, substance or material;

[18] (19) "Federal narcotic laws", the laws of the United States relating to controlled substances;

[19] (20) "Hospital", a place devoted primarily to the maintenance and operation of facilities for the diagnosis, treatment or care, for not less than twenty-four hours in any week, of three or more nonrelated individuals suffering from illness, disease, injury, deformity or other abnormal physical conditions; or a place devoted primarily to provide, for not less than twenty-four consecutive hours in any week, medical or nursing care for three or more nonrelated individuals. The term "hospital" does not include convalescent, nursing, shelter or boarding homes as defined in chapter 198;

[20] (21) "Immediate precursor", a substance which:

(a) The state department of health and senior services has found to be and by rule designates as being the principal compound commonly used or produced primarily for use in the manufacture of a controlled substance;

(b) Is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance; and

(c) The control of which is necessary to prevent, curtail or limit the manufacture of the controlled substance;

[21] (22) "Imitation controlled substance", a substance that is not a controlled substance, which by dosage unit appearance (including color, shape, size and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance. In determining whether the substance is an imitation controlled substance the court or authority concerned should consider, in addition to all other logically relevant factors, the following:
(a) Whether the substance was approved by the federal Food and Drug Administration for over-the-counter (nonprescription or nonlegend) sales and was sold in the federal Food and Drug Administration approved package, with the federal Food and Drug Administration approved labeling information;

(b) Statements made by an owner or by anyone else in control of the substance concerning the nature of the substance, or its use or effect;

(c) Whether the substance is packaged in a manner normally used for illicit controlled substances;

(d) Prior convictions, if any, of an owner, or anyone in control of the object, under state or federal law related to controlled substances or fraud;

(e) The proximity of the substances to controlled substances;

(f) Whether the consideration tendered in exchange for the noncontrolled substance substantially exceeds the reasonable value of the substance considering the actual chemical composition of the substance and, where applicable, the price at which over-the-counter substances of like chemical composition sell. An imitation controlled substance does not include a placebo or registered investigational drug either of which was manufactured, distributed, possessed or delivered in the ordinary course of professional practice or research;

(23) "Initial prescription", a prescription issued to a patient who has never previously been issued a prescription for the drug or its pharmaceutical equivalent or who was previously issued a prescription for the drug or its pharmaceutical equivalent, but the date on which the current prescription is being issued is more than five months after the date the patient last used or was administered the drug or its equivalent;

(24) "Laboratory", a laboratory approved by the department of health and senior services as proper to be entrusted with the custody of controlled substances but does not include a pharmacist who compounds controlled substances to be sold or dispensed on prescriptions;

(25) "Manufacture", the production, preparation, propagation, compounding or processing of drug paraphernalia or of a controlled substance, or an imitation controlled substance, either directly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include the preparation or compounding of a controlled substance or an imitation controlled substance or the preparation, compounding, packaging or labeling of a narcotic or dangerous drug:

(a) By a practitioner as an incident to his or her administering or dispensing of a controlled substance or an imitation controlled substance in the course of his or her professional practice, or
(b) By a practitioner or his or her authorized agent under his or her supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale;

[24] (26) "Marijuana", all parts of the plant genus Cannabis in any species or form thereof, including, but not limited to Cannabis Sativa L., Cannabis Indica, Cannabis Americana, Cannabis Ruderalis, and Cannabis Gigantea, whether growing or not, the seeds thereof, the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seed of the plant which is incapable of germination;

[25] (27) "Methamphetamine precursor drug", any drug containing ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers;

[26] (28) "Narcotic drug", any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical analysis:
(a) Opium, opiate, and any derivative, of opium or opiate, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation. The term does not include the isoquinoline alkaloids of opium;
(b) Coca leaves, but not including extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;
(c) Cocaine or any salt, isomer, or salt of isomer thereof;
(d) Ecgonine, or any derivative, salt, isomer, or salt of isomer thereof;
(e) Any compound, mixture, or preparation containing any quantity of any substance referred to in paragraphs (a) to (d) of this subdivision;

[27] (29) "Official written order", an order written on a form provided for that purpose by the United States Commissioner of Narcotics, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided, then on an official form provided for that purpose by the department of health and senior services;

[28] (30) "Opiate" or "opioid", any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. The term includes its racemic and
levorotatory forms. It does not include, unless specifically controlled under section 195.017, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts (dextromethorphan);

(29) (31) "Opium poppy", the plant of the species Papaver somniferum L., except its seeds;

(30) (32) "Over-the-counter sale", a retail sale licensed pursuant to chapter 144 of a drug other than a controlled substance;

(31) (33) "Person", an individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, joint venture, association, or any other legal or commercial entity;

(32) (34) "Pharmacist", a licensed pharmacist as defined by the laws of this state, and where the context so requires, the owner of a store or other place of business where controlled substances are compounded or dispensed by a licensed pharmacist; but nothing in this chapter shall be construed as conferring on a person who is not registered nor licensed as a pharmacist any authority, right or privilege that is not granted to him by the pharmacy laws of this state;

(33) (35) "Poppy straw", all parts, except the seeds, of the opium poppy, after mowing;

(34) (36) "Possessed" or "possessing a controlled substance", a person, with the knowledge of the presence and nature of a substance, has actual or constructive possession of the substance. A person has actual possession if he has the substance on his or her person or within easy reach and convenient control. A person who, although not in actual possession, has the power and the intention at a given time to exercise dominion or control over the substance either directly or through another person or persons is in constructive possession of it. Possession may also be sole or joint. If one person alone has possession of a substance possession is sole. If two or more persons share possession of a substance, possession is joint;

(35) (37) "Practitioner", a physician, dentist, optometrist, podiatrist, veterinarian, scientific investigator, pharmacy, hospital or other person licensed, registered or otherwise permitted by this state to distribute, dispense, conduct research with respect to or administer or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in this state, or a pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research;

(36) (38) "Production", includes the manufacture, planting, cultivation, growing, or harvesting of drug paraphernalia or of a controlled substance or an imitation controlled substance;

(37) (39) "Registry number", the number assigned to each person registered under the federal controlled substances laws;
"Sale", includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal, proprietor, agent, servant or employee;

"State" when applied to a part of the United States, includes any state, district, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States of America;

"Synthetic cannabinoid", includes unless specifically excepted or unless listed in another schedule, any natural or synthetic material, compound, mixture, or preparation that contains any quantity of a substance that is a cannabinoid receptor agonist, including but not limited to any substance listed in paragraph (ll) of subdivision (4) of subsection 2 of section 195.017 and any analogues; homologues; isomers, whether optical, positional, or geometric; esters; ethers; salts; and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, or salts is possible within the specific chemical designation, however, it shall not include any approved pharmaceutical authorized by the United States Food and Drug Administration;

"Ultimate user", a person who lawfully possesses a controlled substance or an imitation controlled substance for his or her own use or for the use of a member of his or her household or immediate family, regardless of whether they live in the same household, or for administering to an animal owned by him or by a member of his or her household. For purposes of this section, the phrase "immediate family" means a husband, wife, parent, child, sibling, stepparent, stepchild, stepbrother, stepsister, grandparent, or grandchild;

"Wholesaler", a person who supplies drug paraphernalia or controlled substances or imitation controlled substances that he himself has not produced or prepared, on official written orders, but not on prescriptions.

195.070. 1. A physician, podiatrist, dentist, a registered optometrist certified to administer pharmaceutical agents as provided in section 336.220, or an assistant physician in accordance with section 334.037 or a physician assistant in accordance with section 334.747 in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense controlled substances or he or she may cause the same to be administered or dispensed by an individual as authorized by statute.

2. An advanced practice registered nurse, as defined in section 335.016, but not a certified registered nurse anesthetist as defined in subdivision (8) of section 335.016, who holds a certificate of controlled substance prescriptive authority from the board of nursing under section 335.019 and who is delegated the authority to prescribe controlled substances under a collaborative practice arrangement under section 334.104 may prescribe any controlled substances listed in Schedules III, IV, and V of section 195.017, and may have restricted authority in Schedule II. Prescriptions for Schedule II medications prescribed by an advanced
practice registered nurse who has a certificate of controlled substance prescriptive authority are restricted to only those medications containing hydrocodone. However, no such certified advanced practice registered nurse shall prescribe controlled substance for his or her own self or family. Schedule III narcotic controlled substance and Schedule II - hydrocodone prescriptions shall be limited to a one hundred twenty-hour supply without refill.  

3. A veterinarian, in good faith and in the course of the veterinarian's professional practice only, and not for use by a human being, may prescribe, administer, and dispense controlled substances and the veterinarian may cause them to be administered by an assistant or orderly under his or her direction and supervision.

4. A practitioner shall not accept any portion of a controlled substance unused by a patient, for any reason, if such practitioner did not originally dispense the drug. However, unused controlled substances may be accepted from ultimate consumers through collection receptacles, drug disposal boxes, and other means provided through drug take back programs by a Drug Enforcement Agency-authorized collector in accordance with federal regulations, even if the authorized collector did not originally dispense the drug. This subsection shall supersede and preempt any local ordinances or regulations, including any ordinances or regulations enacted by any political subdivision of the state, regarding the disposal of unused controlled substances.

5. An individual practitioner shall not prescribe or dispense a controlled substance for such practitioner's personal use except in a medical emergency.

195.080. 1. Except as otherwise provided in this chapter and chapter 579, this chapter and chapter 579 shall not apply to the following cases: prescribing, administering, dispensing or selling at retail of liniments, ointments, and other preparations that are susceptible of external use only and that contain controlled substances in such combinations of drugs as to prevent the drugs from being readily extracted from such liniments, ointments, or preparations, except that this chapter and chapter 579 shall apply to all liniments, ointments, and other preparations that contain coca leaves in any quantity or combination.

2. Unless otherwise provided in sections 334.037, 334.104, and 334.747, a practitioner, other than a veterinarian, shall not issue an initial prescription for more than a seven-day supply of any opioid controlled substance upon the initial consultation and treatment of a patient for acute pain. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription in compliance with the general provisions of this chapter and chapter 579. Prior to issuing an initial prescription for an opioid controlled substance, a practitioner shall consult with the patient regarding the quantity of the opioid and the patient's option to fill the prescription in a lesser quantity and shall inform the patient of the risks associated with
the opioid prescribed. If, in the professional medical judgment of the practitioner, more
than a seven-day supply is required to treat the patient's acute pain, the practitioner may
issue a prescription for the quantity needed to treat the patient; provided, that the
practitioner shall document in the patient's medical record the condition triggering the
necessity for more than a seven-day supply and that a nonopioid alternative was not
appropriate to address the patient's condition. The provisions of this subsection shall not
apply to prescriptions for opioid controlled substances for a patient who is currently
undergoing treatment for cancer, is receiving hospice care from a hospice certified under
chapter 197 or palliative care, is a resident of a long-term care facility licensed under
chapter 198, or is receiving treatment for substance abuse or opioid dependence.

3. A pharmacist or pharmacy shall not be subject to disciplinary action or other
civil or criminal liability for dispensing or refusing to dispense medication pursuant to an
otherwise valid prescription that exceeds the prescribing limits established by subsection
2 of this section.

4. Unless otherwise provided in this section, the quantity of Schedule II controlled
substances prescribed or dispensed at any one time shall be limited to a thirty-day supply. The
quantity of Schedule III, IV or V controlled substances prescribed or dispensed at any one time
shall be limited to a ninety-day supply and shall be prescribed and dispensed in compliance with
the general provisions of this chapter and chapter 579. The supply limitations provided in this
subsection may be increased up to three months if the physician describes on the prescription
form or indicates via telephone, fax, or electronic communication to the pharmacy to be entered
on or attached to the prescription form the medical reason for requiring the larger supply. The
supply limitations provided in this subsection shall not apply if:

   (1) The prescription is issued by a practitioner located in another state according to and
       in compliance with the applicable laws of that state and the United States and dispensed to a
       patient located in another state; or

   (2) The prescription is dispensed directly to a member of the United States Armed Forces
       serving outside the United States.

5. The partial filling of a prescription for a Schedule II substance is permissible as
defined by regulation by the department of health and senior services.

195.265. By August 28, 2019, the department of health and senior services shall
develop an education and awareness program regarding drug disposal, including
controlled substances. The education and awareness program may include, but not be
limited to:

   (1) A web-based resource that:
(a) Describes available drug disposal options including take back, take back events, mailers, in-home disposal options that render a product safe from misuse, or any other methods that comply with state and federal laws and regulations, may reduce the availability of unused controlled substances, and may minimize the potential environmental impact of drug disposal;

(b) Provides a list of drug disposal take back sites, which may be sorted and searched by name or location;

(c) Provides a list of take back events in the state, including the date, time, and location information for each event; and

(d) Provides information for authorized collectors regarding state and federal requirements to comply with the provisions of subsection 4 of section 195.070; and

(2) Promotional activities designed to ensure consumer awareness of proper storage and disposal of prescription drugs, including controlled substances.

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons [twelve] seven years of age or [older as authorized by rule] the Centers for Disease Control and Prevention recommendations, whichever is higher, or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis, and viral influenza vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will
be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written protocol from the physician who refers the patient for medication therapy services. The written protocol and the prescription order for a medication therapeutic plan shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a physician assistant engaged in a supervision agreement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services [and administration of viral influenza vaccines]. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services [and administration of viral influenza vaccines]. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the
grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be
invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan
authority to a licensed pharmacist who submits proof of successful completion of a
board-approved course of academic clinical study beyond a bachelor of science in pharmacy,
including but not limited to clinical assessment skills, from a nationally accredited college or
university, or a certification of equivalence issued by a nationally recognized professional
organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority
may engage in the designing, initiating, implementing, and monitoring of a medication
therapeutic plan as defined by a prescription order from a physician that is specific to each
patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic
substitution of a pharmaceutical prescribed by a physician unless authorized by the written
protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary
medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or
an equivalent title means a person who has received a doctor's degree in veterinary medicine
from an accredited school of veterinary medicine or holds an Educational Commission for
Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical
Association (AVMA).

12. In addition to other requirements established by the joint promulgation of rules by
the board of pharmacy and the state board of registration for the healing arts:

   (1) A pharmacist shall administer vaccines by protocol in accordance with treatment
guidelines established by the Centers for Disease Control and Prevention (CDC);

   (2) A pharmacist who is administering a vaccine shall request a patient to remain in the
pharmacy a safe amount of time after administering the vaccine to observe any adverse reactions.
Such pharmacist shall have adopted emergency treatment protocols;

   (3) In addition to other requirements by the board, a pharmacist shall receive additional
training as required by the board and evidenced by receiving a certificate from the board upon
completion, and shall display the certification in his or her pharmacy where vaccines are
delivered.

13. A pharmacist shall inform the patient that the administration of the vaccine will
be entered into the ShowMeVax system, as administered by the department of health and
senior services. The patient shall attest to the inclusion of such information in the system
by signing a form provided by the pharmacist. If the patient indicates that he or she does
not want such information entered into the ShowMeVax system, the pharmacist shall provide a written report within fourteen days of administration of a vaccine to the patient's primary health care provider, if provided by the patient, containing:

(1) The identity of the patient;
(2) The identity of the vaccine or vaccines administered;
(3) The route of administration;
(4) The anatomic site of the administration;
(5) The dose administered; and
(6) The date of administration.

338.056. 1. Except as provided in subsection 2 of this section, the pharmacist filling prescription orders for drug products prescribed by trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form, and of the same generic drug or interchangeable biological product type, as determined by the United States Adopted Names and accepted by the Federal Food and Drug Administration. Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subsection 2 of this section. The pharmacist who selects the drug or interchangeable biological product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug or biological product as would be incurred in filling a prescription for a drug or interchangeable biological product prescribed by generic or interchangeable biologic name. The pharmacist shall not select a drug or interchangeable biological product pursuant to this section unless the product selected costs the patient less than the prescribed product.

2. A pharmacist who receives a prescription for a brand name drug or biological product may[, unless requested otherwise by the purchaser,] select a less expensive generically equivalent or interchangeable biological product [under the following circumstances:

(1) If a written prescription is involved, the prescription form used shall have two signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words “Dispense as Written”. Under the line at the left side shall be clearly printed the words “Substitution Permitted”. The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line unless requested otherwise by the patient or the prescribing practitioner who indicates that substitution is prohibited or clearly displays “brand medically necessary”, “dispense as written”, “do not substitute”, “DAW”, or words of similar import on the prescription. No prescription shall be valid without the signature of the prescriber [on one of these lines;]

(2) ].
3. If an oral prescription is involved, the practitioner or the practitioner’s agent, communicating the instructions to the pharmacist, shall instruct the pharmacist [as to whether or not] if a therapeutically equivalent generic drug or interchangeable biological product [may] shall not be substituted. The pharmacist shall note the instructions on the file copy of the prescription.

[3. All prescriptions written in the state of Missouri by practitioners authorized to write prescriptions shall be on forms which comply with subsection 2 hereof.]

4. Notwithstanding the provisions of subsection 2 of this section to the contrary, a pharmacist may fill a prescription for a brand name drug by substituting a generically equivalent drug or interchangeable biological product when substitution is allowed in accordance with the laws of the state where the prescribing practitioner is located.

5. Violations of this section are infractions.

Section B. Because immediate action is necessary to allow for the safe disposal of unused pharmaceuticals, the repeal and reenactment of section 195.070 of this act is deemed necessary for the immediate preservation of the public health, welfare, peace, and safety, and is hereby declared to be an emergency act within the meaning of the constitution, and the repeal and reenactment of section 195.070 of this act shall be in full force and effect upon its passage and approval.
20 CSR 2220-2.0XX

(This could either be done as a new rule, placed in the DD section or added to an existing rule).

(1) Definitions.

(A) “Automated Distribution Cabinet”- A computerized or electronic drug storage device or cabinet used to store prepackaged medication that electronically tracks and records medication access and drug distribution.

(B) “Electronic Verification System”- 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 placed or loaded into an automated distribution cabinet or drug storage area.

(C) “Health Care Facility”-

1. The practice location of a licensed health care practitioner authorized to prescribe or dispense/administer medication; or

2. An entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility, or a habilitation center as defined by Chapter 630, RSMo.

(D) “Secure Drug Storage Area”- A locked room or other locked area used to store medication that is only accessible to licensed health care practitioners or to designated pharmacy staff as authorized by the pharmacist-in-charge.

(F) “Supervising Pharmacy”- The Missouri licensed pharmacy operating or maintaining an automated distribution cabinet or a secure drug storage area.

(2) A Missouri licensed pharmacy may operate or maintain an automated distribution cabinet (“ADC”) or a secure drug storage area at a health care facility for the purposes of distributing medication to licensed health care practitioners for patient use or administration.

An automated distribution cabinet or secure drug storage area may only be used to distribute medication for use or administration by a licensed health care practitioner and shall not be used by, or accessible to, patients or the general public.
(A) A current written or electronic list of all locations/addresses where ADCs or secure drug storage areas are located must be maintained at the pharmacy and available on inspection or on request of the Board or the Board’s authorized designee.

(B) A drug distributor license is not required for an automated distribution cabinet or secure drug storage area used solely to distribute medication as authorized by this rule if the total amount of medication annually distributed via an ADC or from a secure drug storage area does not exceed five-percent (5%) of the pharmacy’s total gross sales. For purposes of this rule, total gross sales is calculated based on the pharmacy’s total annual prescription medication sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total annual medication purchases.

(C) Pharmacies providing prescription services for residents in long-term care facilities must comply with 20 CSR 2220-2.140, including, pharmacies operate or providing remote dispensing systems in a long-term care facility for emergency dispensing (e.g., an e-kit).

(3) Standards of Operation. The supervising pharmacy and the pharmacist-in-charge shall ensure:

(A) Medication is properly and accurately distributed;

(B) Automated distribution cabinets and secure drug storage areas are operated in compliance with this rule and all applicable state and federal laws, including, any applicable controlled substance laws.

(C) Automated distribution cabinets are maintained in good working order;

(D) Medication is properly stored and maintain within temperature and humidity requirements as provided in the FDA approved drug product labeling or the United States Pharmacopeia (USP). A temperature monitoring system or device must be used to ensure proper temperature storage.

(E) No outdated, misbranded or adulterated drugs or devices are stored in an automated distribution cabinet or secure drug storage area;

(F) Medication is labeled in accordance with section 338.059, RSMo, or alternatively labeled with the drug name, strength, expiration date, lot number and, if applicable, beyond-use date; and

(G) A pharmacist is available to answer questions in the event of an emergency.
(4) Stocking.
   (A) Automated distribution cabinets and secure drug storage areas may be stocked/re-
   stocked by a Missouri licensed pharmacist or by a registered Missouri pharmacy technician or
   intern pharmacist without a pharmacist physically present if-
   1. An electronic verification [or other mechanical] system is used to verify medication
   has been properly stocked or loaded; or
   2. The system is stocked using manufacturer unit of use packages or prepackaged
   containers that have been verified by a pharmacist to ensure the container has been properly
   packaged and labeled. The identity of the verifying pharmacist must be documented in the
   pharmacy’s records. Prepackaging must comply with 20 CSR 2220-2.130.

(5) Security. Adequate security must be maintained to deter drug theft and diversion.
   (A) ADCs and secure drug storage areas shall not be accessible to the public and must be
   securely placed or located within the designated health care facility. ADCs may not be located
   in or near exit doors.
   (B) All access to an ADC or secured drug storage area must be manually or electronically
   documented, including, the date and time the ADC/secure area was accessed, the identity of
   individuals making access and the name, strength, quantity and dosage form of medication
   placed in, distributed by or removed by each individual.
   (C) All medication distributed by an ADC must be reviewed by a pharmacist on a
   (monthly/weekly) basis to ensure proper distribution. The identity of the pharmacist, date of
   review and any medication discrepancies or errors must be documented in writing and
   maintained in the pharmacy’s records.
   (D) Medication inventory must be reconciled for each ADC or secure drug storage area
   every (2-weeks, month/six (6) months). A perpetual inventory must [also] be maintained for any
   ADC that stocks or provides controlled substances.
   (E) Any theft or diversion of or from an automated dispensing system or secure drug storage
   area must be reported to the Board in writing within fourteen (14) days in a manner designated
   by the Board. Any suspected or discovered theft or diversion from an automated dispensing
system must be promptly investigated and prompt corrective action taken to prevent future theft or losses.

(6) Policies and Procedures. The pharmacy shall establish and follow written policies and procedures to ensure the proper, safe and secure operation of an ADC or secure drug storage area. Policies and procedures must be current and accurate and, at a minimum, include policies and procedures for:

(A) Maintaining the automated dispensing system and any accompanying electronic verification system in good working order;

(B) Ensuring adequate security and accurate stocking and distribution of the system;

(C) Reporting, investigating, and addressing known or suspected errors, system malfunctions, thefts/diversion or security breaches;

(E) Tracking, documenting and investigating medication errors;

(F) Conducting routine and preventive maintenance and, if applicable, calibration;

(G) Removing expired, adulterated, misbranded, or recalled drugs;

(H) Monitoring and preventing unauthorized access to the system, including, assigning, discontinuing, restricting or changing security access as deemed necessary or appropriate; and

(I) Ensuring compliance with state and federal law, including, all applicable controlled substance laws.

(7) Records. Distribution records must be maintained for all medication stocked in, distributed by or removed from an ADC or a secure drug storage area. At a minimum, distribution records must include the date of distribution and the identity, quantity and dosage form of medication distributed or removed. Except as otherwise provided by law or other rule of the Board, all records required by this rule shall be manually or electronically maintained in the pharmacy’s records for a minimum of two (2) years and available on inspection or request of the Board.

(8) This rule is solely applicable to pharmacies operating an ADC or secure drug storage area pursuant to this rule. This rule does not apply to compounding, administering, prescribing
or dispensing of medication by a non-pharmacist healthcare practitioner as otherwise authorized by law.