FIRST REGULAR SESSION

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 609

103RD GENERAL ASSEMBLY

1674H.02C JOSEPH ENGLER, Chief Clerk

AN ACT

To repeal sections 195.010, 195.030, and 338.165, RSMo, and to enact in lieu thereof three new sections relating to health care providers.

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

Section A. Sections 195.010, 195.030, and 338.165, RSMo, are repealed and three new sections enacted in lieu thereof, to be known as sections 195.010, 195.030, and 338.165, to read as follows: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;

(3) "Administer", to apply a controlled substance, whether by injection, inhalation, ingestion, or any other means, directly to the body of a patient or research subject by:

(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;

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) "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;

(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;

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

(14) "Distributor", a person who distributes;

(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;

(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;

(17) "Drug enforcement agency", the Drug Enforcement Administration in the United States Department of Justice, or its successor agency;

(18) "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;

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

(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**, but shall include outpatient facilities owned and operated by a hospital**;

(21) "Illegal industrial hemp":

(a) All nonseed parts and varieties of the *Cannabis sativa L.* plant, growing or not, that contain an average delta-9 tetrahydrocannabinol (THC) concentration exceeding three-tenths of one percent on a dry weight basis;

(b) Illegal industrial hemp shall be destroyed in the most effective manner possible, and such destruction shall be verified by the Missouri state highway patrol;

(22) "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;

(23) "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;

(24) "Industrial hemp":

(a) All nonseed parts and varieties of the *Cannabis sativa L.* plant, growing or not, that contain an average delta-9 tetrahydrocannabinol (THC) concentration that does not exceed three-tenths of one percent on a dry weight basis or the maximum concentration allowed under federal law, whichever is greater;

(b) Any *Cannabis sativa L.* seed that is part of a growing crop, retained by a grower for future planting, or used for processing into or use as agricultural hemp seed;

(c) Industrial hemp includes industrial hemp commodities and products and topical or ingestible animal and consumer products derived from industrial hemp with a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent on a dry weight basis;

(25) "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;

(26) "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;

(27) "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;

(28) "Marijuana", all parts of the plant genus *Cannabis* in any species or form thereof, including, but not limited to *Cannabis Sativa L.*, except industrial hemp, *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;

(29) "Methamphetamine precursor drug", any drug containing ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers;

(30) "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;

(31) "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;

(32) "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);

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

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

(35) "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;

(36) "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;

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

(38) "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;

(39) "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;

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

(41) "Registry number", the number assigned to each person registered under the federal controlled substances laws;

(42) "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;

(43) "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;

(44) "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;

(45) "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;

(46) "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.

195.030. 1. The department of health and senior services upon public notice and hearing pursuant to this section and chapter 536 may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this state. No rule or portion of a rule promulgated pursuant to the authority of this chapter shall become effective unless it has been promulgated pursuant to the provisions of section 536.024.

2. No person shall manufacture, compound, mix, cultivate, grow, or by any other process produce or prepare, distribute, dispense or prescribe any controlled substance and no person as a wholesaler shall supply the same, without having first obtained a registration issued by the department of health and senior services in accordance with rules and regulations promulgated by it. No registration shall be granted for a term exceeding three years.

3. Persons registered by the department of health and senior services pursuant to this chapter to manufacture, distribute, or dispense or conduct research with controlled substances are authorized to possess, manufacture, distribute or dispense such substances, including any such activity in the conduct of research, to the extent authorized by their registration and in conformity with other provisions of this chapter and chapter 579.

4. The following persons shall not be required to register and may lawfully possess controlled substances pursuant to this chapter and chapter 579:

(1) An agent or employee, excluding physicians, dentists, optometrists, podiatrists or veterinarians, of any registered manufacturer, distributor, or dispenser of any controlled substance if such agent is acting in the usual course of his or her business or employment;

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance.

5. The department of health and senior services may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.

6. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances. **A hospital may obtain a separate registration for each outpatient facility owned or operated by the hospital in which behavioral health or substance abuse services are delivered. Such outpatient facility may distribute or dispense drugs to the extent allowed under a hospital registration.**

7. The department of health and senior services is authorized to inspect the establishment of a registrant or applicant in accordance with the provisions of this chapter.

338.165. 1. As used in this section, the following terms mean:

(1) "Board", the Missouri board of pharmacy;

(2) "Hospital", a hospital as defined in section 197.020;

(3) "Hospital clinic or facility", a clinic or facility under the common control, management, or ownership of the same hospital or hospital system;

(4) "Medical staff committee", the committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management;

(5) "Medication order", an order for a legend drug or device that is:

(a) Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee; and

(b) To be distributed or administered to the patient by a health care practitioner or lawfully authorized designee at a hospital or a hospital clinic or facility;

(6) "Patient", an individual receiving medical diagnosis, treatment or care at a hospital or a hospital clinic or facility.

2. The department of health and senior services shall have sole authority and responsibility for the inspection and licensure of hospitals as provided by chapter 197 including, but not limited to all parts, services, functions, support functions and activities which contribute directly or indirectly to patient care of any kind whatsoever. However, the board may inspect a class B pharmacy or any portion thereof that is not under the inspection authority vested in the department of health and senior services by chapter 197 to determine compliance with this chapter or the rules of the board. This section shall not be construed to bar the board from conducting an investigation pursuant to a public or governmental complaint to determine compliance by an individual licensee or registrant of the board with any applicable provisions of this chapter or the rules of the board.

3. The department of health and senior services shall have **the sole** authority to promulgate rules **governing pharmacy services in hospitals, but may promulgate rules** in conjunction with the board governing medication distribution and the provision of medication therapy services**, as described in section 338.010,** by a pharmacist at or within a hospital. **[**~~Rules may include, but are not limited to, medication management, preparation, compounding, administration, storage, distribution, packaging and labeling. Until such rules are jointly promulgated, hospitals shall comply with all applicable state law and department of health and senior services rules governing pharmacy services and medication management in hospitals.~~**] The board shall have the sole authority to promulgate rules governing inspection and licensure of class B pharmacies.** The rulemaking authority

granted herein to the department of health and senior services shall not include the dispensing of medication by prescription.

4. All pharmacists providing medication therapy services shall obtain a certificate of medication therapeutic plan authority as provided by rule of the board. Medication therapy services may be provided by a pharmacist for patients of a hospital pursuant to a protocol with a physician as required by section 338.010 or pursuant to a protocol approved by the medical staff committee. However, the medical staff protocol shall include a process whereby an exemption to the protocol for a patient may be granted for clinical efficacy should the patient's physician make such request. The medical staff protocol shall also include an appeals process to request a change in a specific protocol based on medical evidence presented by a physician on staff.

5. Medication may be dispensed by a class B hospital pharmacy pursuant to a prescription or a medication order.

6. A drug distributor license shall not be required to transfer medication from a class B hospital pharmacy to a hospital clinic or facility for patient care or treatment.

7. Medication dispensed by a class A pharmacy located in a hospital to a hospital patient for use or administration outside of the hospital under a medical staff-approved protocol for medication therapy shall be dispensed only by a prescription order for medication therapy from an individual physician for a specific patient.

8. Medication dispensed by a hospital to a hospital patient for use or administration outside of the hospital shall be labeled as provided by rules jointly promulgated by the department of health and senior services and the board including medication distributed for administration by or under the supervision of a health care practitioner at a hospital clinic or facility.

9. This section shall not be construed to preempt any law or rule governing controlled substances.

10. Any rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall only become effective 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 under 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, 2014, shall be invalid and void.

11. The board shall appoint an advisory committee to review and make recommendations to the board on the merit of all rules and regulations to be jointly promulgated by the board and the department of health and senior services pursuant to the joint rulemaking authority granted by this section. The advisory committee shall consist of:

(1) Two representatives designated by the Missouri Hospital Association, one of whom shall be a pharmacist;

(2) One pharmacist designated by the Missouri Society of Health System Pharmacists;

(3) One pharmacist designated by the Missouri Pharmacy Association;

(4) One pharmacist designated by the department of health and senior services from a hospital with a licensed bed count that does not exceed fifty beds or from a critical access hospital as defined by the department of social services for purposes of MO HealthNet reimbursement;

(5) One pharmacist designated by the department of health and senior services from a hospital with a licensed bed count that exceeds two hundred beds; and

(6) One pharmacist designated by the board with experience in the provision of hospital pharmacy services.

12. Nothing in this section shall be construed to limit the authority of a licensed health care provider to prescribe, administer, or dispense medications and treatments within the scope of their professional practice.

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