Missouri Board of Pharmacy
Hospital Advisory Committee Meeting
CONFERENCE CALL

January 18, 2019
9:00 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 via conference call at 9:00 a.m. on January 18, 2019. A tentative agenda is attached. If any member of the public wishes to attend the meeting by participating in the conference call, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 9:00 a.m. on January 18, 2019 or call (573) 526-5398.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy’s Hospital Advisory Committee is authorized to close 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 AGENDA
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting
CONFERENCE CALL

January 18, 2019
9:00 a.m.
Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

1. Welcome & Introductions

2. Hospital Advisory Committee Members/Vacant Seats

3. Board Updates
   a. 2019 Legislation
   b. Chapter 338 Review
   c. Automated Distribution Rule

4. DHSS Updates

5. Missouri Hospital Association Updates
   a. Pharmacy Technician Proposed Legislation
   b. Pharmacist Scope of Practice

6. Disposal of Patient Home Medications in a Hospital
   a. Medication abandoned by the patient
   b. Patient death
   c. Prescriber requested disposal

7. Pharmacist Administration in Hospital/Acute Care Settings

8. Non-Sterile Packaging in Clinics
   a. FDA guidance on non-sterile repackaging for a health system

9. 2019 Discussion Items
   a. Non-Class B Hospital Guidance
   b. Other suggested Items

10. Future Meeting Dates/Topics

11. Adjournment
AN ACT

To repeal section 191.875, RSMo, and to enact in lieu thereof one new section relating to the health care cost reduction and transparency act.

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

Section A. Section 191.875, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 191.875, to read as follows:

191.875. 1. This section shall be known as the "Health Care Cost Reduction and Transparency Act".

2. As used in this section, the following terms shall mean:

(1) "Ambulatory surgical center", as such term is defined under section 197.200;

(2) "Estimate of cost", an estimate based on the information entered and assumptions about typical utilization and costs for health care services. Such estimates of cost shall encompass only those services within the direct control of the health care provider and shall include the amount that will be charged to a patient for the health services if all charges are paid in full without a public or private third party paying for any portion of the charges;

(3) "Health care provider", any ambulatory surgical center, assistant physician, chiropractor, clinical psychologist, dentist, hospital, imaging center, long-term care facility, nurse anesthetist, optometrist, pharmacist, physical therapist, physician, physician assistant, podiatrist, registered nurse, or other licensed health care facility or professional providing health care services in this state. "Health care provider" shall also include any provider located in a Kansas border county, as defined under section 135.1670, who participates in the MO HealthNet program;

(4) "Hospital", as such term is defined under section 197.020;

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.
(5) "Imaging center", any facility at which diagnostic imaging services are provided including, but not limited to, magnetic resonance imaging;

(6) "Medical treatment plan", a patient-specific plan of medical treatment for a particular illness, injury, or condition determined by such patient’s health care provider, which includes the applicable current procedural terminology code or codes;

(7) "Public or private third party", a state government, the federal government, employer, health carrier as such term is defined under section 376.1350, third-party administrator, or managed care organization.

3. Beginning January 1, 2020, a health care provider shall provide public access to a price list of the services and products the provider offers at each of the provider’s business locations; each service and product listed shall include an industry standard name and code, layperson description, and the amount that will be charged to a patient for the health services if all charges are paid in full without a public or private third party paying for any portion of the charges.

4. Beginning July 1, [2017] 2019, upon written request by a patient or potential patient[, which shall include a medical treatment plan from the patient’s health care provider,] for an estimate of cost of the amount that will be charged to a patient for the health services if all charges are paid in full without a public or private third party paying for any portion of the charges of a particular health care service or procedure, imaging procedure, or surgery procedure, a health care provider shall provide, in writing, the estimate of cost to the patient electronically, by mail, or in person within three business days after receiving the [written] request. [Providing a patient a specific link to such estimates of cost and making such estimates of cost publicly available or posting such estimates of cost on a website of the health care provider shall constitute compliance with the provisions of this subsection.

4. Health care providers shall include with any estimate of cost the following: “Your estimated cost is based on the information entered and assumptions about typical utilization and costs. The actual amount billed to you may be different from the estimate of costs provided to you. Many factors affect the actual bill you will receive, and this estimate of costs does not account for all of them. Additionally, the estimate of costs is not a guarantee of insurance coverage. You will be billed at the health care provider’s charge for any service provided to you that is not a covered benefit under your plan. Please check with your insurance company to receive an estimate of the amount you will owe under your plan or if you need help understanding your benefits for the service chosen.”] Upon request by an insured to his or her insurance company for an estimate of cost of the amount that will be charged to the insured for the health services and products of a particular health care service or procedure, imaging procedure, or surgery procedure, the insurance company shall provide,
in writing, the estimate of cost to the patient electronically, by mail, or in person within three business days after receiving the request.

5. Beginning July 1, 2017, hospitals shall make available to the public the amount that would be charged without discounts for each of the one hundred most prevalent diagnosis-related groups as defined by the Medicare program, Title XVIII of the Social Security Act. The diagnosis-related groups shall be described in layperson's language suitable for use by reasonably informed patients. Disclosure of data under this subsection shall constitute compliance with subsection [3] 4 of this section regarding any diagnosis-related group for which disclosure is required under this subsection.

6. It shall be a condition of participation in the MO HealthNet program for a health care provider located in a Kansas border county, as defined under section 135.1670, to comply with the provisions of this section.

7. No health care provider shall be required to report the information required by this section if the reporting of such information reasonably could lead to the identification of the person or persons receiving health care services or procedures in violation of the federal Health Insurance Portability and Accountability Act of 1996 or other federal law. This section shall not apply to emergency departments, which shall comply with requirements of the Emergency Medical Treatment and [Active] Labor Act, 42 U.S.C. Section 1395dd.
AN ACT

To repeal sections 195.060, 196.100, 221.111, 338.015, 338.055, and 338.056, RSMo, and to enact in lieu thereof seven new sections relating to electronic prescriptions, with a penalty provision.

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

Section A. Sections 195.060, 196.100, 221.111, 338.015, 338.055, and 338.056, RSMo, are repealed and seven new sections enacted in lieu thereof, to be known as sections 195.060, 195.550, 196.100, 221.111, 338.015, 338.055, and 338.056 to read as follows:

195.060. 1. Except as provided in subsection 4 of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute, provided that the controlled substances listed in Schedule V may be sold without prescription in accordance with regulations of the department of health and senior services. All written prescriptions shall be signed by the person prescribing the same, except for electronic prescriptions. All prescriptions shall be dated on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is prescribed, and the full name, address, and the registry number under the federal controlled substances laws of the person prescribing, if he or she is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of the animal for which the drug is prescribed. The person filling the prescription shall either write the date of filling and his or her own signature on the prescription or retain the date of filling and the identity of the dispenser as electronic prescription information. The prescription or electronic prescription information shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of two years, so as to be readily accessible for inspection by any public

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.
officer or employee engaged in the enforcement of this law. No prescription for a drug in
Schedule I or II shall be filled more than six months after the date prescribed; no prescription for
a drug in Schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall
be filled or refilled more than six months after the date of the original prescription or be refilled
more than five times unless renewed by the practitioner.

2. A pharmacist, in good faith, may sell and dispense controlled substances to any person
upon a prescription of a practitioner located in another state, provided that the:

(1) Prescription was issued according to and in compliance with the applicable laws of
that state and the United States; and

(2) Quantity limitations in subsection 4 of section 195.080 apply to prescriptions
dispensed to patients located in this state.

3. The legal owner of any stock of controlled substances in a pharmacy, upon
discontinuance of dealing in such drugs, may sell the stock to a manufacturer, wholesaler, or
pharmacist, but only on an official written order.

4. A pharmacist, in good faith, may sell and dispense any Schedule II drug or drugs to
any person in emergency situations as defined by rule of the department of health and senior
services upon an oral prescription by an authorized practitioner.

5. Except where a bona fide physician-patient-pharmacist relationship exists,
prescriptions for narcotics or hallucinogenic drugs shall not be delivered to or for an ultimate
user or agent by mail or other common carrier.

195.550. 1. Notwithstanding any other provision of this section or any other law
to the contrary, beginning August 28, 2020, no person shall issue any prescription in this
state unless the prescription is made by electronic prescription from the person issuing the
prescription to a pharmacy, except for prescriptions:

(1) Issued by veterinarians;

(2) Issued in circumstances where electronic prescribing is not available due to
temporary technological or electrical failure;

(3) Issued by a practitioner to be dispensed by a pharmacy located outside the state;

(4) Issued when the prescriber and dispenser are the same entity;

(5) Issued that include elements that are not supported by the most recently
implemented version of the National Council for Prescription Drug Programs
Prescriber/Pharmacist Interface SCRIPT Standard;

(6) Issued by a practitioner for a drug that the federal Food and Drug
Administration requires the prescription to contain certain elements that are not able to
be accomplished with electronic processing;
(7) Issued by a practitioner allowing for the dispensing of a nonpatient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a nonpatient specific prescription;

(8) Issued by a practitioner prescribing a drug under a research protocol;

(9) Issued by practitioners who have received a waiver or a renewal thereof for a specified period determined by the commissioner, not to exceed one year, from the requirement to use electronic prescribing, pursuant to a process established in regulation by the department of health and senior services, due to economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

(10) Issued by a practitioner under circumstances where, notwithstanding the practitioner's present ability to make an electronic prescription as required by this subsection, such practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition.

2. A pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription properly falls under one of the exceptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from otherwise valid written, oral, or fax prescriptions that are consistent with current laws and regulations.

3. An individual who violates this section commits a civil violation for which a fine of two hundred and fifty dollars per violation, not to exceed five thousand dollars per calendar year, may be assessed. The department of health and senior services is responsible for the enforcement of this section.

196.100. 1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

2. A drug dispensed on an electronic prescription or a written prescription signed by a licensed physician, dentist, or veterinarian, except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to a diagnosis by mail, shall be exempt from the requirements of this section if such physician, dentist, or veterinarian is licensed by law to administer such drug, and such drug bears a label containing the name and place of business of
the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian.

3. The department is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of sections 196.010 to 196.120, drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of said sections upon removal from such processing, labeling, or repacking establishment.

221.111. 1. A person commits the offense of possession of unlawful items in a prison or jail if such person knowingly delivers, attempts to deliver, possesses, deposits, or conceals in or about the premises of any correctional center as the term "correctional center" is defined under section 217.010, or any city, county, or private jail:

(1) Any controlled substance as that term is defined by law, except upon the written or electronic prescription of a licensed physician, dentist, or veterinarian;

(2) Any other alkaloid of any kind or any intoxicating liquor as the term intoxicating liquor is defined in section 311.020;

(3) Any article or item of personal property which a prisoner is prohibited by law, by rule made pursuant to section 221.060, or by regulation of the department of corrections from receiving or possessing, except as herein provided;

(4) Any gun, knife, weapon, or other article or item of personal property that may be used in such manner as to endanger the safety or security of the institution or as to endanger the life or limb of any prisoner or employee thereof.

2. The violation of subdivision (1) of subsection 1 of this section shall be a class D felony; the violation of subdivision (2) of this section shall be a class E felony; the violation of subdivision (3) of this section shall be a class A misdemeanor; and the violation of subdivision (4) of this section shall be a class B felony.

3. The chief operating officer of a county or city jail or other correctional facility or the administrator of a private jail may deny visitation privileges to or refer to the county prosecuting attorney for prosecution any person who knowingly delivers, attempts to deliver, possesses, deposits, or conceals in or about the premises of such jail or facility any personal item which is prohibited by rule or regulation of such jail or facility. Such rules or regulations, including a list of personal items allowed in the jail or facility, shall be prominently posted for viewing both inside and outside such jail or facility in an area accessible to any visitor, and shall be made available to any person requesting such rule or regulation. Violation of this subsection shall be an infraction if not covered by other statutes.
4. Any person who has been found guilty of a violation of subdivision (2) of subsection 1 of this section involving any alkaloid shall be entitled to expungement of the record of the violation. The procedure to expunge the record shall be pursuant to section 610.123. The record of any person shall not be expunged if such person has been found guilty of knowingly delivering, attempting to deliver, possessing, depositing, or concealing any alkaloid of any controlled substance in or about the premises of any correctional center, or city or county jail, or private prison or jail.

338.015. 1. The provisions of sections 338.010 to 338.015 shall not be construed to inhibit the patient's freedom of choice to obtain prescription services from any licensed pharmacist. However, nothing in sections 338.010 to 338.315 abrogates the patient's ability to waive freedom of choice under any contract with regard to payment or coverage of prescription expense.

2. All pharmacists may provide pharmaceutical consultation and advice to persons concerning the safe and therapeutic use of their prescription drugs.

3. All patients shall have the right to receive a written prescription from their prescriber to take to the facility of their choice or to have an electronic prescription transmitted to the facility of their choice.

338.055. 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

(1) Use of any controlled substance, as defined in chapter 195, or alcoholic beverage to an extent that such use impairs a person's ability to perform the work of any profession licensed or regulated by this chapter;

(2) The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud,
dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;

(3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;

(4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

(7) Impersonation of any person holding a certificate of registration or authority, permit or license or allowing any person to use his or her certificate of registration or authority, permit, license, or diploma from any school;

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

(9) A person is finally adjudged incapacitated by a court of competent jurisdiction;

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

(11) Issuance of a certificate of registration or authority, permit or license based upon a material mistake of fact;

(12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

(13) Violation of any professional trust or confidence;

(14) Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

(16) The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written, electronic, or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided,
however, that nothing contained herein shall prohibit a pharmacist from substituting or changing
the brand of any drug as provided under section 338.056, and any such substituting or changing
of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional
or dishonorable conduct unless a violation of section 338.056 occurs;

(17) Personal use or consumption of any controlled substance unless it is prescribed,
dispensed, or administered by a health care provider who is authorized by law to do so.

3. After the filing of such complaint, the proceedings shall be conducted in accordance
with the provisions of chapter 621. Upon a finding by the administrative hearing commission
that the grounds, provided in subsection 2 of this section, for disciplinary action are met, the
board may, singly or in combination, censure or place the person named in the complaint on
probation on such terms and conditions as the board deems appropriate for a period not to exceed
five years, or may suspend, for a period not to exceed three years, or revoke the license,
certificate, or permit. The board may impose additional discipline on a licensee, registrant, or
permittee found to have violated any disciplinary terms previously imposed under this section
by agreement. The additional discipline may include, singly or in combination, censure, placing
the licensee, registrant, or permittee named in the complaint on additional probation on
such terms and conditions as the board deems appropriate, which additional probation shall not
exceed five years, or suspension for a period not to exceed three years, or revocation of the
license, certificate, or permit.

4. If the board concludes that a licensee or registrant has committed an act or is engaging
in a course of conduct which would be grounds for disciplinary action which constitutes a clear
and present danger to the public health and safety, the board may file a complaint before the
administrative hearing commission requesting an expedited hearing and specifying the activities
which give rise to the danger and the nature of the proposed restriction or suspension of the
licensee's or registrant's license. Within fifteen days after service of the complaint on the
licensee or registrant, the administrative hearing commission shall conduct a preliminary hearing
to determine whether the alleged activities of the licensee or registrant appear to constitute a
clear and present danger to the public health and safety which justify that the licensee's or
registrant's license or registration be immediately restricted or suspended. The burden of proving
that the actions of a licensee or registrant constitute a clear and present danger to the public
health and safety shall be upon the state board of pharmacy. The administrative hearing
commission shall issue its decision immediately after the hearing and shall either grant to the
board the authority to suspend or restrict the license or dismiss the action.

5. If the administrative hearing commission grants temporary authority to the board to
restrict or suspend the licensee's or registrant's license, such temporary authority of the board
shall become final authority if there is no request by the licensee or registrant for a full hearing
within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the licensee or registrant named in the complaint, set a date to hold a full hearing under the provisions of chapter 621 regarding the activities alleged in the initial complaint filed by the board.

6. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 4 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.

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 select a less expensive generically equivalent or interchangeable biological product unless:
   (1) The patient requests a brand name drug or biological product; or
   (2) The prescribing practitioner indicates that substitution is prohibited or displays "brand medically necessary", "dispense as written", "do not substitute", "DAW", or words of similar import on the prescription.

3. No prescription shall be valid without the signature of the prescriber, except an electronic prescription.

4. 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 a therapeutically equivalent generic drug or interchangeable biological product may be substituted. The pharmacist shall note the instructions on the file copy of the prescription.

5. 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.

6. Violations of this section are infractions.
FIRST REGULAR SESSION

SENNATE BILL NO. 127

100TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATERT.

Pre-filed December 1, 2018, and ordered printed.

ADRIANE D. CROUSE, Secretary.

03778.011

AN ACT

To amend chapter 192, RSMo, by adding thereto one new section relating to a prescription drug importation study.

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

Section A. Chapter 192, RSMo, is amended by adding thereto one new section, to be known as section 192.340, to read as follows:

192.340. The department of health and senior services shall conduct a study regarding the processes by which the state may import certain prescription drugs from other countries for eventual consumption by Missouri consumers. The department shall:

1. Determine how the state may become certified by the U.S. Secretary of Health and Human Services to operate a prescription drug importation program;
2. Determine how to ensure that only drugs meeting U.S. Food and Drug Administration safety, effectiveness, and other standards are imported by the state;
3. Identify prescription drugs with the highest potential for consumer savings through importation;
4. Estimate potential consumer savings attributable to importation;
5. Determine with whom the state could contract to distribute imported drugs;
6. Determine how to limit the distribution of imported drugs to only Missouri consumers who would benefit most from the associated savings;
7. Consult with the Missouri state board of registration for the healing arts, representatives of the pharmaceutical industry, patient
advocates, and others representing persons who could be affected by importation; and

(8) Propose changes, if necessary, to state statutes and regulations to facilitate importation by the state.

The department shall report the study's findings and recommendations to the general assembly by December 31, 2020.
AN ACT

To amend chapter 195, RSMo, by adding thereto six new sections relating to the monitoring of certain prescribed controlled substances, with penalty provisions.

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

Section A. Chapter 195, RSMo, is amended by adding thereto six new sections, to be known as sections 195.450, 195.453, 195.456, 195.459, 195.462, and 195.465, to read as follows:

195.450. 1. Sections 195.450 to 195.465 shall be known and may be cited as the "Narcotics Control Act".

2. As used in sections 195.450 to 195.465, the following terms shall mean:

(1) "Controlled substance", the same meaning as given such term in section 195.010;

(2) "Department", the department of health and senior services;

(3) "Dispenser", a person who delivers a Schedule II, III, or IV controlled substance to a patient, but does not include:

(a) A hospital, as defined in section 197.020, that distributes such substances for the purpose of inpatient care or dispenses prescriptions for controlled substance at the time of discharge from such facility;

(b) A practitioner or other authorized person who administers such a substance; or

(c) A wholesale distributor of a controlled substance;

(4) "Patient", a person who is an ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed, not including a hospice patient enrolled in a Medicare-certified hospice program who has controlled substances dispensed to him or her by such hospice program;
(5) "Schedule II, III, or IV controlled substance", a controlled substance that is listed in Schedule II, III, or IV of the schedules provided under this chapter or the Controlled Substances Act, 21 U.S.C. Section 812.

3. The provisions of sections 195.450 to 195.465 shall not apply to persons licensed under chapter 340.

195.453. 1. The department shall establish and maintain a narcotics control program for the monitoring of prescribing and dispensing all Schedule II, III, and IV controlled substances by professionals licensed to prescribe or dispense such substances in this state. The funding of the narcotics control program shall be subject to appropriations. In addition to appropriations from the general assembly, the department may apply for available grants and shall be able to accept other gifts, grants, and donations to develop and maintain the program.

2. Each dispenser shall submit to the department by electronic means information regarding each dispensation of a drug included in subsection 1 of this section. The information submitted for each dispensation shall include:

(1) The pharmacy's Drug Enforcement Agency (DEA) number;
(2) The date of the prescription;
(3) The following, if there is a prescription:
   (a) The prescription number or other unique identifier;
   (b) Whether the prescription is new or a refill; and
   (c) The prescriber's DEA or National Provider Identification (NPI) number;
(4) The National Drug Code (NDC) for the drug dispensed;
(5) The quantity and dosage of the drug dispensed;
(6) The patient's identification number including, but not limited to, any one of the following:
   (a) The patient's drivers license number;
   (b) The patient's government-issued identification number; or
   (c) The patient's insurance cardholder identification number;
and
(7) The patient's name, address, and date of birth.

The addition of any further information to the list of data required to be submitted in this subsection shall be the sole purview of the general
assembly.

3. Each dispenser shall submit the information in accordance with transmission standards established by the American Society for Automation in Pharmacy or any successor organization and shall report data within twenty-four hours of dispensation. Beginning January 1, 2021, the department shall begin phasing in a requirement that dispensers report data in real time with all report data to be submitted in real time by January 1, 2022.

4. (1) The department may issue a waiver to a dispenser who is unable to submit the dispensation information by electronic means. Such waiver may permit the dispenser to submit dispensation information by paper form or other means, provided all information required in subsection 2 of this section is submitted in such alternative format.

(2) The department may grant an extension to dispensers who are temporarily unable to electronically submit the dispensation information required in subsection 2 of this section in accordance with the time frame established in subsection 3 of this section due to unforeseen circumstances. In cases in which an extension is granted, dispensers shall be responsible for reporting the required data in a subsequent transmission.

195.456. 1. Dispensation information submitted to the department shall be confidential and not subject to public disclosure under chapter 610 except as provided in subsections 3 to 5 of this section.

2. The department shall maintain procedures to ensure that the privacy and confidentiality of patients and personal information collected, recorded, transmitted, and maintained are not disclosed to persons except as provided in subsections 3 to 5 of this section.

3. The department shall review the dispensation information and, if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the department shall notify the appropriate law enforcement or professional licensing board, and provide any dispensation information required for an investigation.

4. The department may provide data in the narcotics control program to the following persons:
(1) Persons both in-state and out-of-state authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients;

(2) An individual who requests his or her own dispensation information in accordance with state law;

(3) Any state board charged with regulating a professional who has the authority to prescribe or dispense controlled substances that requests data related to a specific professional under the authority of such board if such board has a current and open investigation into such professional and the data is limited to such professional;

(4) Local, state, and federal law enforcement or prosecutorial officials, both in-state and out-of-state, engaged in the investigation or enforcement of the laws governing prescription drugs only when based on a specific case and under a subpoena or court order issued by a court of competent jurisdiction; and

(5) The MO HealthNet division within the department of social services regarding MO HealthNet program recipients.

5. The department may provide data to public or private entities for statistical, research, or educational purposes only after removing information that could be used to identify individual patients, prescribers, dispensers, or persons who received dispensations from dispensers.

6. Nothing in sections 195.450 to 195.465 shall be construed to require a pharmacist or prescriber to obtain information about a patient from the database.

7. No dispensation information submitted to the department shall be used by any local, state, or federal authority to prevent an individual from owning or obtaining a firearm.

8. No dispensation information submitted to the department shall be the sole basis for probable cause to obtain an arrest or search warrant as part of a criminal investigation.

9. Beginning August 28, 2021, the department shall maintain an individual's prescription and dispensation information obtained under sections 195.450 to 195.465 for a maximum of three years from the date of dispensation, after which such information shall be deleted from the program.

195.459. 1. The department is authorized to contract with any
other agency of this state, a political subdivision of this state, any other
state with a private vendor, or any state government that currently
operates a narcotics control program. Any contractor shall comply
with the provisions regarding confidentiality or prescription
information in section 195.456.

2. If a political subdivision of this state is operating a narcotics
control program, the political subdivision’s program shall be permitted
to continue operating until such time as the department's program is
available for utilization by prescribers and dispensers throughout the
state.

195.462. The department shall promulgate rules setting forth the
procedures and methods of implementing sections 195.450 to
195.465. 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 powers vested in
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, 2019, shall be invalid and void.

195.465. 1. A dispenser who knowingly fails to submit
dispensation information to the department as required in sections
195.450 to 195.465 or knowingly submits the incorrect dispensation
information shall be subject to an administrative penalty in the amount
of one thousand dollars for each violation. The penalty shall be
assessed through an order issued by the director of the
department. Any person subject to an administrative penalty may
appeal to the administrative hearing commission under the provisions
of chapter 621.

2. Any person who unlawfully or knowingly accesses or discloses,
or any person authorized to have prescription or dispensation
information under sections 195.450 to 195.465 who knowingly discloses
such information in violation of sections 195.450 to 195.465 or
knowingly uses such information in a manner and for a purpose in
violation of sections 195.450 to 195.465 is guilty of a class E felony.
From: Grinston, Kimberly
To: Grinston, Kimberly
Subject: FW: FDA and hospital repackaging
Date: Thursday, January 17, 2019 8:25:42 AM

From: Loebach, Paul M [mailto:Paul.Loebach@fda.hhs.gov]
Sent: Monday, December 04, 2017 9:46 AM
To: Glenski, Tom
Cc: Vosilus, Julie N
Subject: RE: Missouri Board of Pharmacy Inquiry

Mr. Glenski,

That is correct. As long as the repackaged products stay within the hospital network for dispensing and are not sold to any other entity, then they are not considered in commercial distribution and are exempt from registration and listing requirements.

Paul M. Loebach
Director, Drug Registration and Listing Staff
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Silver Spring, MD 20993
301-796-2173
paul.loebach@fda.hhs.gov
eDRLS HelpDesk: edrls@fda.hhs.gov

From: Glenski, Tom [mailto:tom.glenski@pr.mo.gov]
Sent: Friday, December 01, 2017 4:33 PM
To: Loebach, Paul M <Paul.Loebach@fda.hhs.gov>
Cc: Vosilus, Julie N <Julie.Vosilus@fda.hhs.gov>
Subject: Missouri Board of Pharmacy Inquiry

Mr. Loebach,

We received information from one of our drug distributors that a hospital-owned repackaging facility is no longer required to register with the FDA and list its products as long as the products are distributed within the same hospital network.

Would you please confirm this interpretation is correct for us?

Has the FDA issued any guidance on this?

Thank you for your assistance.
Thank you for bearing with me while I check with several of our hospitals. The regulatory guidance hospitals primarily follow are the Conditions of Participation (Appendix A for hospitals; Appendix W for CAH); state hospital licensing regulations, state laws concerning controlled substances and DEA rules concerning controlled substances. The Conditions of Participation primarily address patients bringing their medications from home whether they will use them while in the hospital or not. Unless there are special circumstances, patients/families/guardians, etc. are encouraged to take all medications home with them at time of admission. If they cannot or will not, the hospital should have policies and procedures in place for logging the medications, consent for hospital to lock and keep safe, etc. returning the medications to the patient upon discharge. If the patient will be taking a home medication while in the hospital, there is guidance for appropriate inspection, labeling and storage of the medication. Each hospital should have a policy and procedure in place.

If the patient/family/guardian refuses to take medications home upon discharge or they forget them, the hospitals have policies for notification of the patient/family/guardian about the need to come pick up the medication. Typically, hospitals have policies for logging and keeping a medication for 30 days and then using a “reverse distributor” to pick up and destroy the medication. Some companies have started to refuse to take controlled substances. Hospitals are now preparing to be drug take-back sites and will have to register with the DEA and follow their rules (developing policies and procedures) for the collection and destruction of controlled substances. Even so, the patient or family needs to place the controlled substance in receptacle. If the hospital does not have a reverse distributor, they have a policy of two pharmacists disposal according to DEA guidelines for destruction of medication and logging the disposal.

Physician disposal against the will of the patient/family/guardian is a complex situation. This could constitute a patient rights issue and isn’t likely a fight worth the bad publicity. Hopefully, by understanding the physicians concerns and the concerns of the patient/family, we could come to a compromise and make a decision where everyone is validated. This is a situation I would need to run up the pole at CMS. Patients who come to the hospital in possession of illegal drugs are also difficult cases. Some hospitals have a policy to notify law enforcement. Some law enforcement agencies do not want to be notified if the person has a small amount of marijuana or other drug on them. Additionally, hospitals cannot do anything which would dissuade a person from seeking emergency medical care. This could be a federal EMTALA violation. This is very serious and results in huge regulatory and financial burden for the hospital. The hospital should have a policy, collaborate with local law enforcement and ensure they are acting in accordance with their policy.

All pharmacists licensed in the state are subject to the pharmacists practice requirements, scope of practice, licensure rules, etc. found in 20 CSR 2220-2.095. The hospital inpatient pharmacies, unlike retail pharmacies, are not under the Board of Pharmacy.
A pharmacists should make sure they are within their scope of practice, that the policies of the hospital support an appropriate scope of practice and if they have concerns, they should meet with hospital administrators to work towards a resolution. Does this help?

Warm Regards,

Sarah Willson, BSN, MBA, FACHE
Vice President Clinical and Regulatory Affairs
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“"You make a living by what you get. You make a life by what you give."—Winston Churchill

Hello,

I am asking about medications that a patient brings from home to the hospital with them regardless of whether the home medication will be used during the hospital stay, like a prescription bottle of medications the patient takes at home or used to take at home and the patient doesn’t want to take the medication back home for some reason after the hospital stay. Maybe the mediation was discontinued at discharge, the patient just doesn’t take that medication anymore, the patient passes away or leaves the medication at the hospital, or the physician doesn’t think it’s safe to send the medication back home with the patient so the patient or the physician asks the inpatient hospital pharmacy to destroy it.

In reference to the above:

1) Is it possible for an inpatient hospital pharmacy to destroy patients’ own medications under any circumstances?
2) If so, are inpatient hospital pharmacies subject to 20 CSR 2220-2.095?
3) Are there any other sections of Missouri pharmacy law or Missouri Hospital Association regulations, etc. governing this practice for inpatient hospital destruction of patients’ own non-controlled OR controlled substances?

More specifically, are there any special requirements (policies, documentation, record keeping, consent forms) for the different circumstances under which a request for patient medication destruction is made? For example:
1) If the patient or patient’s power of attorney requests old home medications to be destroyed?
2) If the family of a deceased patient requests old home medications to be destroyed?
3) If the patient abandons medications at the hospital and cannot be contacted or refuses to pick up medications?
4) If the physician (who did NOT originally prescribe the medications) requests the medications be destroyed against the patient’s will?
5) If the medications are controlled substances, and are there differences between destroying schedule 2 controlled substances vs. other controlled substances (C-III through C-V)?
6) If the pharmacy has knowledge that the medications were obtained illegally, whether controlled or non-controlled substances?
7) If the patient presents to the hospital with illegal medications in their possession and the physician does not wish to contact law enforcement so the patient is not punished for seeking medical help?