Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

March 9, 2017
10:00 a.m.
Department of Health
Truman Conference Room; 3418 Knipp Dr.
Jefferson City, MO 65109

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 pursuant to § 610.021.(1) for purposes of legal advice. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

If any member of the public wishes to attend, s/he should be present at the Department of Health, Truman Conference Room, 3418 Knipp Drive, Jefferson City, Missouri at 10:00 a.m. on March 9, 2017.

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 attached tentative agenda for this meeting.
REVISED TENTATIVE AGENDA
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

March 9, 2017
10:00 a.m.
Department of Health
Truman Conference Room; 3418 Knipp Dr.
Jefferson City, MO 65109

1. Welcome & Introductions
2. Board Updates
3. Department of Health Updates
4. Approval of Minutes (January 13, 2017)
5. Class-B Rule Concept Draft
6. Review of Missouri Medication Therapy Services Requirements, including, § 338.010, RSMo, § 338.165, RSMo & 20 CSR 2220-6.080
7. Review of Automated Distribution Cabinet Concept Draft
9. Remote Supervision of Pharmacy Technicians/Tele-Pharmacy in Class-B Settings
10. Future Agenda Topics
14. Public Questions/Comments
15. Adjournment
The Missouri Hospital Advisory Committee met in open session via conference call during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed.

**Committee Members Present**
Bert McClary, R.Ph., Chairman  
Daniel Good, R.Ph., Member  
James Gray, R.Ph., Member  
Colby Grove, R.Ph., Member  
Kevin Kinkade, R.Ph., Member  
Neil Schmidt, R.Ph., Member  
Greg Teale, R.Ph., Member

**Staff Present**
Christian Tadrus, Board Vice-President  
Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector

**Others Present**
Sarah Willson, Missouri Hospital Association  
David Wolfrath, MSHP

Chairman McClary opened the meeting at 10:02 a.m. and roll-call was taken.

**Agenda Item # 2 (Board Updates):** Kimberly Grinston reported several items of interest to the Committee will be on the Board’s January agenda, including, the Class-B guidance document and a Class-N Automated Dispensing (Health Care Facilities) concept rule draft. Chairman McClary encouraged interested parties to attend.

**Agenda Item # 4 (DHSS Updates):** Ms. Grinston reported Julie Creach would not be in attendance. Ms. Grinston noted the new Governor’s office has returned all unapproved rules to the applicable state agency for reconsideration. Ms. Grinston is unaware if this affected DHSS and the hospital pharmacy rules.
Agenda Item # 5 (Review of Class-B Guidance Document): The following discussion was held:

1. Chairman McClary asked if the proposed language would allow a pharmacist to initiate medication therapy services (MTS) based on a protocol approved by the clinical care committee without an individual prescription order. Committee discussion held. Tom Glenski indicated the Board has informally suggested a separate prescription may not be required. Kimberly Grinston noted this is an open legal question that would need to be officially addressed by the Board.

2. Neil Schmidt suggested the language should clearly indicate the guidance is only applicable to pharmacy/medication therapy services under the Board’s jurisdiction. James Gray agreed, however, Mr. McClary noted there is still an open legal question as to when the Board’s MTS requirements apply. Ms. Grinston reported she has talked with the Board’s general counsel who agreed it may be inappropriate for him to advise the Committee because of a possible conflict of interest. Ms. Grinston indicated she will talk with the Division’s legal counsel for further legal guidance. Committee consensus to seek legal clarification and clarify the guidance document as appropriate.

3. Chairman McClary asked for legal clarification on whether a MTS protocol can be initiated by a nurse. Mr. McClary also asked for legal guidance on whether the Board’s MTS rules would apply if a pharmacist operating under DHSS’ jurisdiction modifies medication that will be eventually dispensed as a prescription. Ms. Grinston advised she has discussed this with legal counsel and questioned if DHSS would be the appropriate entity to answer the questions raised. Mr. Teale indicated clarification is important for hospitals like his that are primarily operating under DHSS’ jurisdiction but also providing pharmacy services under the Board’s jurisdiction (e.g., infusion centers).

4. Mr. Teale suggested the guidance document emphasize that a Class-B pharmacy permit is required if technicians will be used to assist in non-dispensing functions. Mr. Teale further asked if the distribution chart would be included in the final document; Kimberly Grinston indicated the chart became too difficult to follow after the additions added at the last Committee meeting and would be removed.

5. Kimberly Grinston noted Board member Barbara Bilek suggested alternative language for addressing medication that will be initially administered onsite but continued offsite via a pump or other implantable device. Greg Teale commented that not all administration devices are “locked”. Neil Schmidt asked how the language would apply to an insulin pump. Committee discussion held; Consensus to revise the proposed language to provide: “The Board will not consider medication to have been given to the patient for offsite use/administration if medication administration is initiated onsite but continued offsite via a programmed external or implanted medical delivery device.” Bert McClary advised this language should be consistent throughout the guidance document.
**Agenda Item # 6 (Class-B Rule):** Kimberly Grinston reported the office will begin working on a potential Class-B rule and asked for additional guidance on the questions noted in the agenda. The following discussion was held:

- Chairman McClary asked if a previous rule draft was available; Kimberly Grinston stated preliminary language was circulated several years ago and suggested the Committee consider a new draft.

- Chairman McClary suggested: (1) Class-B pharmacies should be allowed to dispense from any location included under the Class-B permit, (2) the rule should specifically address emergency department dispensing under the Board’s jurisdiction, (3) reference materials should only be required in the primary dispensing area and not in every area identified on the permit, (4) the rule should allow commingling of medication inventory used for dispensing under the Board’s jurisdiction and dispensing under DHSS’ jurisdiction and (5) patient instructions should not be required on the label if the medication will be used/administered onsite.

- Kevin Kinkade stated there may be instances where licensed healthcare professionals would need to access a Class-B pharmacy to remove medication when the pharmacy is closed or when a pharmacist is not on duty. Mr. Kinkade suggested this may be particularly important for smaller hospitals that may not be able to afford full-time pharmacist staff. Committee consensus that the Rule should allowed licensed healthcare professionals to access non-controlled medication after hours.

**BOARD VICE-PRESIDENT CHRISTIAN TADRUS JOINED THE CALL AT 11:34 A.M.**

Further Committee discussion held; Greg Teale commented pharmacies would need to ensure controlled substance stock is available outside of the pharmacy if after-hours access is limited to non-controlleds. Mr. Kinkade noted storing controlleds outside of the pharmacy may increase diversion. Committee consensus to review Class-N language that would allow the pharmacy to maintain stock outside of the pharmacy in an automated dispensing cabinet or system.

- If after-hours access is allowed by licensed healthcare professionals, the Committee recommended against requiring pharmacist approval for the first dose and suggested a pharmacist review after-hours transactions on the next day the pharmacy is in operation. Committee consensus to not require medication reconciliation.

- Chairman McClary asked if the DHSS exemption for long-term care and hospice facilities operating their own automated dispensing systems should be addressed in the Class-B rule. Mr. Glenski suggested Mr. McClary’s issue would apply to all licensed pharmacies and advised against including the requested language just in the Class-B rule.
THE CONFERENCE CALL WAS DISCONNECTED AT 11:50 A.M. DUE TO A MALFUNCTION WITH THE STATE PROVIDED CONFERENCE LINE. THE CONFERENCE CALL WAS TERMINATED PRIOR TO COMPLETING THE AGENDA.

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KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
This draft has not been approved by the Board and is not being proposed or suggested by Board staff. The included language is intended solely for discussion purposes and to assist the Board in developing a future Class-N rule.

20 CSR 2220-2.550  Class-B Hospital Pharmacy

Purpose: This rule establishes requires for Class-B Hospital pharmacies providing pharmacy services under the jurisdiction of the Board of Pharmacy.

(1) Definitions.

(A) Class-B Hospital Pharmacy- A pharmacy owned, managed, or operated by a hospital as defined by section 197.020 or a clinic or facility under common control, management or ownership of the same hospital or hospital system. A Class-B Hospital Pharmacy does not include hospitals solely providing pharmacy services under the jurisdiction of, and the licensure granted by, the department of health and senior services (DHSS) under and pursuant to chapter 197, RSMo.

(B) Electronic Medical Record (EMR)- An electronic patient medical record (EMR) that is required to be maintained by a hospital or a hospital clinic or facility pursuant to state or federal law.

(C) Hospital- A hospital as defined in section 197.020, RSMo.

(D) Hospital Clinic or Facility- A clinic or facility under common control, management or ownership of the same hospital or hospital system.

(E) Licensed Health Care Practitioner- A Missouri licensed dentist, licensed practical nurse, optometrist, pharmacist, physician, physician assistant, podiatrist, registered nurse, surgeon or veterinarian or other Missouri licensed healthcare practitioner authorized to prescribe medication.

(F) Pharmacy Permit Area: Any area designated by the pharmacy that will be used to store, compound or dispense medication or to provide pharmacy services.

(2) Pharmacy Permit Areas. Applicants for a Class-B Hospital pharmacy permit shall identify all pharmacy permit areas that will be included under the Class-B permit. All permit areas must be located at the same physical address. A separate Class-B permit is required for facilities/areas located at different addresses.

(A) Pharmacy permit areas must be inspected and approved by the Board and must be operated in compliance with applicable law. A Pharmacy Remodeling Application must be filed with the Board to add or remove facilities/areas from a Class-B permit. Newly added pharmacy permit areas must be inspected and approved by the Board prior to use for Class-B pharmacy services.

(B) Unless otherwise provided by law or DHSS, a Class-B pharmacy may be operated in the same location as, or share space with, a hospital pharmacy providing
pharmacy services under DHSS’ jurisdiction. If medication inventory is commingled or
shared, the pharmacy must maintain written dispensing and/or distribution records of all
medication transactions.

(3) Standards of Operation. Except as otherwise provided in this rule, Class-B
pharmacies shall comply with all applicable provisions of state and federal law governing
Missouri pharmacies, including, all state and federal controlled substance laws. Adequate
security must be maintained over medication inventory and Class-B pharmacy permit areas
at all times.

(A) Appropriate sewage disposal and a hot and cold water supply must be readily
accessible to the pharmacy. If compounding is performed, the hot and cold water supply
must be located within the pharmacy permit area.

(B) Class-B pharmacies that are open to the public must post Board licenses, permits
and registrations and a sign notifying the public when no pharmacist is on duty as required
by 20 CSR 2220-2.020.

(4) Medication Dispensing. Unless otherwise authorized by law, Class-B pharmacies
may only dispense medication pursuant to a medication order as defined by § 338.165,
RSMo, or pursuant to a patient-specific prescription that complies with Missouri law.

(A) Except as otherwise provided by section (4)(B), all prescriptions/medication
orders given to the patient or dispensed for offsite use/administration must be labeled in
compliance with § 338.059, RSMo. Medication given to a Missouri licensed healthcare
practitioner for use or administration to a patient onsite of a Class-B pharmacy or onsite of a
hospital or a hospital clinic or facility may be alternatively labeled with: the patient’s name,
expiration date, lot number and the medication name, strength, quantity and dosage form.

(B) Medication will not be considered to have been dispensed for offsite
use/administration if administration is initiated onsite but continued offsite via a
programmed external or implanted medical delivery device. ---or---- Medication will not
be considered to have been dispensed for offsite use/administration if administration is
initiated onsite but continued offsite via an external or implanted medical delivery device
that is programmed by a healthcare professional.

(C) Labels for compounded medication must also comply with 20 CSR 2220-
2.200 and/or 20 CSR 2220-2.400.

(5) Access by Unlicensed Personnel. Except as otherwise provided in this section,
all individuals assisting a pharmacist in the practice of pharmacy as defined by Chapter 338,
RSMo, must be licensed or registered with the Board or have a pending technician
application submitted to the Board as authorized by § 338.013.3, RSMo.

(A) A licensed healthcare professional not licensed or registered with the Board may
access a dually operated Class-B pharmacy to use pharmacy equipment or to remove non-
controlled medication from shared inventory for use or administration by a licensed
healthcare professional onsite of the Class-B pharmacy or onsite of a hospital or a hospital
clinic or facility. Access by a licensed healthcare professional as authorized by this
subsection may be allowed when a pharmacist is not present if:

1. Access to the pharmacy is manually or electronically documented, including, the
date and time the pharmacy was accessed, the identity of individuals accessing
the pharmacy and the name, strength, quantity and dosage form of medication
removed; and

2. The medication is not dispensed to the patient for offsite use or administration
but will be administered to the patient by a Missouri licensed healthcare
professional onsite of the Class-B pharmacy or onsite of a hospital or hospital
clinic or facility. Medication will not be considered to have been given to the
patient for offsite use/administration if administration is initiated onsite but
continued offsite via a programmed external or implanted medical delivery
device; and ---or---

3. If a filled prescription or medication order is removed, the final product and
affixed label has been previously verified by a pharmacist as required by 20 CSR
2220-2.010.

(B) A pharmacist must promptly review all medication removed by a licensed
healthcare professional when a pharmacist is not present as authorized by this subsection.
The required pharmacist review must be completed on or before the next day the pharmacy
is in operation.

(C) Dually operated Class-B pharmacies shall maintain and follow written
policies and procedures governing access to the pharmacy by unlicensed healthcare
professionals, including, policies and procedures for pharmacist review as required by
subsection (5)(B).

6. Records. Prescription, dispensing, distribution or other pharmacy records must be
maintained as required by Missouri law and the rules of the Board. Unless otherwise
provided by law, records required by this rule must be manually or electronically
maintained for two (2) years and available on inspection or at the request of the Board or
the Board’s authorized designee.

(A) Dispensing, distribution and administration records may be maintained in the
same electronic or manual system used by the hospital or a hospital clinic or facility (e.g., a
common EMR), provided the records must be readily retrievable on inspection or on request by the Board or the Board’s authorized designee.

(B) Notifications to a protocol physician or the patient’s primary care provider required by 20 CSR 2220-6.040 (Administration by Medical Prescription Order), 20 CSR 2220-6.050 (Immunization by Protocol) and 20 CSR 2220-6.080 (Medication Therapy Services by Protocol) may be included in an EMR, provided the EMR is accessible to and shared by both the protocol physician/primary care provider and pharmacist.

(7) This rule shall not be construed to preempt or modify any controlled substance laws or requirements or any law applicable to hospital pharmacy services under the jurisdiction of the DHSS.
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 years of age or older as authorized by rule or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis 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 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 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.


Prior revisions: 1929 § 13140; 1919 § 4712; 1909 § 5764
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 authority to promulgate rules in conjunction with the board governing medication distribution and the provision of medication therapy services 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 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.

(L. 2014 S.B. 754 merged with S.B. 808)
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(6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy technicians shall only be authorized to work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.


20 CSR 2220-6.060 General Provisions

PURPOSE: This rule establishes definitions for 20 CSR 2220-6.060 to 20 CSR 2220-6.080 governing medication therapy services by pharmacists.

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080:

(A) Authorizing physician(s)—The physician identified in the written protocol as authorizing the pharmacist to provide medication therapy services;

(B) Health care entity—For purposes of this rule, a health care entity shall be defined as any 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, and that is required to maintain patient medical records by state or federal law;

(C) Medication therapy protocol—A written agreement between a physician and a pharmacist for the provision of medication therapy services. A medication therapy protocol shall comply with the provisions of 20 CSR 2220-6.080;

(D) Medication therapy services—The designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient’s medication therapy or device usage pursuant to a medication therapy protocol. For purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080, modification shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product, generic substitutions made pursuant to section 338.056, RSMo, or medication therapy management that does not include the initiation or implementation of a modification of medication therapy, as provided herein;

(E) Pharmacy resident—A Missouri-licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists;

(F) Prescription order for medication therapeutic plan—A lawful order that is issued by the authorizing physician within the scope of his/her professional practice for the provision of medication therapy services by a pharmacist for a specific patient, including, patients of a health care entity; and

(G) Protocol—A medication therapy protocol, as defined herein.

(2) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2220-6.080, prior to performing medication therapy services.

20 CSR 2220-6.070 Certificate of Medication Therapy Plan Authority

PURPOSE: This rule establishes procedures for obtaining a certificate of medication therapeutic plan authority, as authorized by section 338.010, RSMo.

(1) A pharmacist shall obtain a certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a modification of a patient’s medication therapy or device usage. Pharmacists with a certificate of medication therapeutic authority shall enter into a written protocol with a Missouri-licensed physician that complies with the requirements of 20 CSR 2220-6.080, prior to performing medication therapy services.

(2) Applicants for certification shall hold an active Missouri pharmacist license. Applications shall be submitted on forms provided by the Missouri State Board of Pharmacy and shall be accompanied by the certificate of medication therapeutic plan authority fee and proof of the applicant—

(A) Holds a doctor of pharmacy (PharmD) degree earned from a school, accredited by the Accreditation Council for Pharmacy Education (ACPE); or

(B) Has successfully completed a postgraduate medication therapy certificate course or program accredited or granted by the APCE, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists, or the American Pharmacists Association; or

(C) Holds a current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators; or

(D) Has completed a post-graduate medication therapy certificate course that, at a minimum, included training in the following areas:

1. Assessing patient specific data and issues;
2. Establishing medication therapeutic goals or medication related action plans for identified medication conditions and medication related concerns;
3. Assessing and addressing adverse reactions and adverse drug events;
4. Modifying and monitoring medication regimens;
5. Improving patient care and outcomes through medication therapy services;
6. Evaluating treatment progress;
(3) Certificate Renewal. A certificate of medication therapeutic plan authority shall be renewed biennially with the certificate holder’s Missouri pharmacist license. For purposes of renewal, six (6) of the continuing education hours required for renewing the certificate holder’s Missouri pharmacist license shall be earned in courses/programs related to medication therapy management. The continuing education required by this rule shall be governed by the rules of the Missouri State Board of Pharmacy governing pharmacist continuing education.

(4) The Missouri State Board of Pharmacy may discipline or terminate a pharmacist’s certificate of medication therapeutic plan authority if the Missouri State Board of Pharmacy determines that the pharmacist has violated the terms of a protocol, the requirements of Chapter 338, RSMo., or rules of the board governing medication therapy services or any other state or federal drug law.


20 CSR 2220-6.080 Medication Therapy Services By Protocol

**PURPOSE**: This rule establishes procedures for the provision of medication therapy services by protocol, as authorized by section 338.010, RSMo.

(1) Except as otherwise provided herein, a pharmacist who holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy shall be authorized to provide medication therapy services in Missouri if the pharmacist—

(A) Holds a current Missouri pharmacist license that is not under discipline with the Missouri State Board of Pharmacy; and

(B) Has entered into a written protocol with a Missouri licensed physician that complies with the requirements of this rule.

(2) General Requirements. A pharmacist may provide medication therapy services only with current certification and as authorized by the protocol and the authorizing physician. A pharmacist providing medication therapy services pursuant to this rule shall comply with the following:

(A) Prior to providing medication therapy services, the pharmacist shall receive a prescription order for a medication therapeutic plan from the authorizing physician for a specific patient which authorizes the pharmacist to perform medication therapy services. Except as otherwise provided in subsection (2)(B) of this rule, the prescription order for a medication therapeutic plan shall be valid for no more than one (1) year and shall include:

1. The patient’s name, address, and date of birth;
2. The date the prescription order for a medication therapeutic plan is issued;
3. The clinical indication for medication therapy services;
4. The length of time for providing medication therapy services, if less than one (1) year; and
5. The authorizing physician’s name and address;

(B) A prescription order for a medication therapeutic plan may be transmitted orally, electronically, or in writing. If an oral prescription order for a medication therapeutic plan is issued, all information required under subsection (2)(A) of this rule shall be documented by the pharmacist and maintained in the patient’s record in accordance with section (7) of this rule;

(C) The pharmacist shall maintain relevant prescription records, patient profiles, patient medical records, or other medical information to determine the services to be rendered; and

(D) In lieu of compliance with 20 CSR 2220-2.018, prescription orders for medication therapy services shall comply with the provisions of this rule, provided the pharmacist shall maintain the prescription order in the patient record required by section (7) of this rule and shall document any change or alteration made to the prescription order based on contact with the prescriber in the applicable patient record.

(3) Authorizing Physician Requirements.

(A) The authorizing physician shall be actively engaged in the practice of medicine in the state of Missouri and shall hold a current and unrestricted Missouri physician license pursuant to Chapter 334, RSMo.

(B) The authorizing physician shall provide the oversight of the medication therapy services provided by the pharmacist that are authorized by protocol. The authorizing physician shall consider the level of skill, education, training, and competence of the pharmacist and ensure that the activities authorized by the protocol are consistent with the pharmacist’s level of skill, education, training, and competence.

(C) The written protocol shall be reviewed and signed by the pharmacist and the authorizing physician at least annually and revised as needed. The authorizing physician and pharmacist shall document the date of the annual review on the written protocol.

(D) The authorizing physician shall review the pharmacist’s medication therapy service activities regularly, but not less than once every three (3) months. If the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, the review requirements shall be satisfied if the pharmacist’s work and services are reviewed every three (3) months by a clinical care committee, pharmacy and therapeutics committee, or a reviewing body/committee of the health care entity that includes a Missouri-licensed physician. The review required by this subsection may be accomplished in person or by electronic means.

(E) The practice location of the authorizing physician shall be no further than fifty (50) miles by road from the pharmacist identified in the written protocol.

(F) An authorizing physician shall notify the Missouri State Board of Registration for the Healing Arts of a written protocol for medication therapy services entered with a pharmacist at each renewal of the authorizing physician’s license.

(4) Protocol Requirements.

(A) The medication therapy services performed by a pharmacist pursuant to the protocol shall be within the authorizing physician’s scope of practice and within the skill, education, training, and competence of both the authorizing physician and the pharmacist.

(B) The written protocol between the authorizing physician and pharmacist shall, at a minimum, include the following:

1. The identity and signatures of the authorizing physician and pharmacist;
2. The effective dates of the protocol;
3. A statement of clinical conditions, diagnoses, diseases, and specific drugs, or drug categories included in the written protocol and the type of medication therapy services allowed in each case;
4. A statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting medication therapy services;
5. Procedures for documenting medication therapy decisions made by the pharmacist and a plan for communication, feedback, and reporting to the authorizing physician concerning specific decisions made;
6. A mechanism and procedure that allows the authorizing physician to override, rescind, modify, or otherwise amend the protocol. All modifications or amendments to the protocol shall be documented in writing, signed, and dated by all involved parties prior to the implementation of such modification or amendment. The protocol may be immediately rescinded by the authorizing physician or the pharmacist with or without cause, provided the rescission is documented in writing. If any conflict arises regarding the professional judgment of the pharmacist and physician with regard to the subject of the medication therapy services, the physician has ultimate authority;
7. A statement that the pharmacist shall not delegate the responsibility of medication therapy services to another person;
8. A description of any authority granted to the pharmacist to administer any drug or medication including the identification of any such drug, medication, or device;
9. A description of drug therapy related patient assessment procedures or testing that may be ordered or performed by the pharmacist, including any authority to order or perform routine or other laboratory testing;
10. Provisions for allowing the pharmacist to access the patient’s medical records for purposes of providing medication therapy services;
11. A provision for providing the authorizing physician access to patient records for medication therapy services provided by the pharmacist for patients of the authorizing physician;
12. Provisions establishing a course of action the pharmacist is authorized to follow to address emergency situations, including, but not limited to, anaphylactic or other adverse medication reactions, adverse needle sticks, or other adverse events;
13. Criteria for timely communication from the authorizing physician to the pharmacist and from the pharmacist to the authorizing physician, not inconsistent with the provisions of this rule;
14. The notification requirements required by section (5) of this rule; and
15. The method for reviewing the pharmacist’s medication therapy work or services by the authorizing physician, as required by subsection (3)(D) of this rule.

(C) The written protocol shall include a description of medication therapy services the pharmacist is authorized to render or provide. Such services may include:
1. Assessing patient-specific data and issues;
2. Establishing medication therapeutic goals or medication related action plans for identified medical conditions and medication related concerns;
3. Assessing and addressing adverse reactions and adverse drug events;
4. Modifying and monitoring medication regimens;
5. Evaluating treatment progress;
6. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
7. Medication reconciliation;
8. Drug utilization review;
9. Formulating and documenting personal medication records;
10. Documenting clinical outcomes;
11. Interpreting, monitoring, and assessing patient test results;
12. Initiation of drug therapy, as authorized by protocol; and
13. Patient education and counseling.

(D) The protocol required by this section shall be signed and dated by the authorizing physician and the pharmacist. If the protocol includes multiple authorizing physicians or participating pharmacists, a separate protocol shall not be required for each physician or pharmacist if all authorizing physicians and pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol.

(E) Any revisions, modifications, or amendments to the protocol must be in writing. The authorizing physician shall promptly notify the pharmacist of any such revision, modification, or amendment and shall maintain documentation of the notification, including the date such notification was made. The authorizing physician may delegate the notification requirements of this subsection to an authorized designee, provided the physician shall be ultimately responsible for compliance with the notification requirements.

(F) A pharmacist shall not be authorized to adjust, change, or modify any controlled substance prescribed for a patient, except as authorized by state or federal law.

(G) The protocol shall be maintained by the authorizing physician and the pharmacist for a minimum of eight (8) years after termination of the protocol. The protocol may be maintained electronically.

(H) A protocol shall automatically and immediately terminate if the pharmacist ceases to maintain an active Missouri pharmacist license, the authorizing physician is deceased, or if the authorizing physician fails to maintain an active, unrestricted Missouri physician license.

(I) Pharmacy Residents. If specifically authorized by the protocol, a pharmacy resident shall be authorized to perform medication therapy services under the written protocol of a Missouri pharmacist in lieu of an individual protocol, if—
1. The resident holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy;
2. The resident is enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists; and
3. The resident is providing medication therapy services under the supervision of a Missouri pharmacist certified by the Missouri State Board of Pharmacy to perform medication therapy services.

(J) The provisions of subsection (4)(I) shall only apply to medication therapy services provided by a pharmacist as part of his/her residency training.

(5) Notification Requirements. A pharmacist shall comply with the following notification requirements:

(A) Within twenty-four (24) hours after learning of an anaphylactic or other adverse medication reaction, adverse needle stick, or other adverse event experienced by a patient, the pharmacist shall notify the patient’s authorizing physician or an authorized designee of the authorizing physician;

(B) The pharmacist shall notify the authorizing physician or an authorized designee of the authorizing physician in the written protocol of any modification of therapy, within twenty-four (24) hours, provided the protocol may include more stringent notification requirements;

(C) A pharmacist shall be deemed in compliance with the notification requirements of this rule if the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, as defined by this rule, and documentation of the notifications required by this section is recorded in a patient medical...
record that is required to be maintained by the health care entity pursuant to state or federal law; and

(D) Notifications required by this section shall be in writing unless otherwise authorized by the authorizing physician.

(6) Modifying Drug Therapy.

(A) A pharmacist may be authorized by protocol to modify a patient’s non-controlled substance medication therapy, subject to the following:

1. If the pharmacist modifies medication therapy and a medication or device is to be dispensed, the pharmacist shall create a prescription for the medication or device modified under the authorizing physician’s name. Such prescription may be dispensed by a licensed pharmacy and shall be maintained in the prescription records of the dispensing pharmacy as provided by the rules of the Missouri State Board of Pharmacy; and

2. If the pharmacist modifies medication therapy or a device, the pharmacist shall document such modification according to section (7) of this rule. Pharmacists providing medication therapy services for patients of a health care entity shall be deemed in compliance with the provisions of this subsection if the modification is documented in a patient medical record that the health care entity is required to maintain under state or federal law.

(B) The pharmacist shall not modify any controlled substance prescription. A prescription from the authorizing physician shall be required to modify a controlled substance.

(C) For purposes of 20 CSR 2220-6.060, 20 CSR 2220-6.070, and 20 CSR 2220-6.080, modification of medication therapy shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product or generic substitutions made pursuant to section 338.056, RSMo.

(7) Record Keeping.

(A) A pharmacist shall document and maintain an adequate patient record of medication therapy services provided to each patient. The records may be maintained in electronic format provided the records are capable of being printed for review by the Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy. An adequate and complete patient record shall include documentation of the following:

1. The identification of the patient, including name, birthdate, address, and telephone number;

2. The date(s) of any patient visit or consultation, including the reason for any such visit/consultation;

3. Any pertinent assessments, observations, or findings;

4. Any diagnostic testing recommended or performed;

5. The name of any medication or device modified and the strength, dose, dosage schedule, dosage form, and route of administration of any medication modified or administered;

6. Referrals to the authorizing physician;

7. Referrals for emergency care;

8. Any contact with the authorizing physician concerning the patient’s treatment or medication therapy services plan;

9. Any informed consent for procedures, medications, or devices; and

10. Any consultation with any other treatment provider for the patient and the results of such consultation.

(B) Pharmacist Record Retention. Except as otherwise provided herein, records required to be maintained by a pharmacist pursuant to this rule shall be maintained securely and confidentially for a minimum of seven (7) years after termination of the protocol unless more stringent requirements are established for record keeping under state or federal law. All records required to be maintained by the pharmacist by this rule shall be maintained by the pharmacist at an address that shall be identified in the written protocol.

(C) Physician Record Retention. Except as otherwise provided herein, records required to be maintained by the authorizing physician pursuant to this rule shall be maintained securely and confidentially for a minimum of seven (7) years after termination of the protocol unless more stringent requirements are established for record keeping pursuant to state or federal law.

(8) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, or their authorized representatives, as requested by the respective board or the board’s designee. Records not maintained at a pharmacy shall be produced within thirty (30) business days after a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(9) Nothing in this rule shall be construed to permit medical diagnosis of any condition by a pharmacist or the independent issuing of a prescription by a pharmacist.

(10) A pharmacist shall not violate or practice in a manner inconsistent with the provisions of this rule or a written protocol. A pharmacist’s failure to abide by the requirements of this rule or the provisions of a written protocol shall be subject to disciplinary action pursuant to the provisions of Chapter 338, RSMo.

(11) The requirements of this rule shall not apply to the administration of vaccines pursuant to protocol as governed by 20 CSR 2220-6.050 or the administration of medication by protocol as governed by 20 CSR 2220-6.040.

(12) The Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy separately retain the right and duty to discipline their respective licensees for violations of any state or federal statutes, rules, or regulations regardless of the licensee’s participation in a protocol agreement.

(13) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Pharmacy and the Missouri State Board of Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334, RSMo.


20 CSR 2220-6.100 Pharmacy Standards for Dispensing Blood-Clotting Products

PURPOSE: This rule implements the provisions of section 338.400, RSMo, and establishes pharmacy standards for dispensing...
This draft has not been approved by the Board and is not being proposed or suggested by Board staff. The included language is intended solely for discussion purposes and to assist the Board in developing a future Class-N rule.

20 CSR 2220-2.850 Class-N Automated Dispensing Systems (Health Care Facilities)

PURPOSE: This rule establishes guidelines for the use of automated dispensing and storage systems.

(1) Definitions.
   (A) Automated Dispensing System: A mechanical/automated system that is used to store, package and dispense medication for patient use or administration. An automated dispensing system does not include a mechanical/automated system used for compounding or administering medication or an automated filling system governed by 20 CSR 2220-2.950.
   (B) Dispense/Dispensing - The provision of medication by a Missouri licensed pharmacy or pharmacist pursuant to a legally valid prescription or medication order for the ultimate user.
   (C) “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 dispensed and labeled by, or loaded into, an automated dispensing system.
   (D) Health Care Facility-
      1. A location other than a pharmacy or a licensed health care facility where healthcare services are provided to patients by a Missouri licensed healthcare practitioner at the same location; 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.
   (E) Licensed Health Care Practitioner- A Missouri licensed healthcare practitioner authorized to prescribe or a Missouri licensed dentist, licensed practical nurse, optometrist, pharmacist, physician, physician assistant, podiatrist, registered nurse, surgeon or veterinarian.
   (F) “Manufacturer Unit of Use Package”- A drug dispensed in the manufacturer’s original and sealed packaging, or in the original and sealed packaging of a repackager registered with the United States Food and Drug Administration (FDA), without additional manipulation or preparation by the pharmacy except for application of the required pharmacy label.
   (G) Medication Order: A medication order as defined by § 338.165.1(5), RSMo.
(2) Authorized Activities. A Class-N automated dispensing system may be operated in a healthcare facility to dispense medication that will be provided or administered to a patient by a licensed healthcare practitioner at or within the healthcare facility. A Class-N automated dispensing system shall not be used to dispense medication that will be used by or administered to the patient outside of the healthcare facility. Medication shall not be deemed to have been dispensed for offsite patient use/administration if administration is initiated onsite of the healthcare facility by a licensed healthcare professional but continued offsite by a parenteral infusion method, including, but not limited to, a subcutaneous, intrathecal or intravenous method or via an implanted device, port, catheter or pump.

(3) Licensure. Applicants for a Class-N pharmacy permit shall submit an application in a form and manner approved by the Board along with the required application fee. The application must identify the address where the automated dispensing system will be operated and shall identify a supervising Missouri licensed pharmacy that is responsible for managing system operations. [Some states mandate that only a licensed pharmacy can apply for an automated dispensing license. Should this be included in Missouri’s rule?]

(A) A Class-N automated dispensing system must successfully pass a Board inspection prior to issuance of the permit. Once approved, a Class-N permit will be issued for the specific location inspected by the Board. A Change of Location application must be filed with the board if the system is moved to a different facility or address. Operation of the system must cease until the Change of Location application has been approved by the board and a new pharmacy permit issued.

(B) A Class-N permit may only be used to perform authorized Class-N pharmacy services. An additional pharmacy permit is required to provide other pharmacy services authorized by Chapter 338, RSMo.

(C) Remodeling plans for a Class-N system must be submitted to the Board in advance for review and approval. Remodeling will be deemed to have occurred if the automated dispensing machine or system is changed or replaced, moved to a different room within the approved facility/site or fastened to a new or different permanent structure than initially approved or if the overall physical security of drugs stored in the system is changed as defined in 20 CSR 2220-2.010. Remodeling plans must be provided to the board office thirty (30) days prior to commencing the proposed change along with an affidavit showing any physical changes to the automated dispensing site, structure or location and the projected remodel completion date.

(D) An Out-of-Business Notification form must be filed with the Board within fifteen (15) days of discontinuing service or closing a Class-N system.
(4) Standards of Operation. Class-N automated dispensing systems must be maintained and operated in compliance with applicable state and federal drug laws, including, all controlled substance and patient confidentiality requirements. The system must be maintained in good working order and must properly and accurately function at all times the system is in operation. A pharmacist shall not be required to be physically present on site when the automated dispensing system is in operation if the system is operated in compliance with this rule.

(A) Except as otherwise authorized by law, medication may only be dispensed from a Class-N automated dispensing system pursuant to a patient-specific prescription or a patient-specific medication order.

(B) Prior to initial operation, the system must be tested by a properly qualified pharmacy designee to ensure the system is functioning properly. Additional testing must occur if any modification to the automated dispensing system occurs that changes or alters the dispensing or electronic verification process. Testing dates and results must be documented in the pharmacy’s system.

(C) All transactions regarding the automated dispensing system must be tracked and documented in writing, including, the placement, removal and dispensing of medication into and out of the system.

(D) Medication stocked in an automated dispensing system must be maintained under proper temperature and storage conditions in compliance with Food and Drug Administration (FDA) requirements and manufacturer guidelines. The system must be equipped with an effective temperature measuring device. At a minimum, temperatures must be recorded and documented daily. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that are reviewed daily or if the system provides alerts of improper temperature deviations that are promptly reviewed by a pharmacist. Documentation of the required temperature review or any temperature alerts must be maintained in the pharmacy’s records or otherwise accessible to the pharmacy.

(E) Controlled substances shall be handled and dispensed in compliance with all state and federal controlled substance laws.

(F) Long Term Care. The provisions of 20 CSR 2220-2.140 shall be applicable to a remote dispensing system used in a long-term care facility for emergency dispensing (e.g., an e-kit). All other long-term care dispensing via an automated dispensing system shall comply with the provisions of this rule.

(5) Except as otherwise provided in section (6), a pharmacist shall review and approve all medication dispensed by the automated dispensing system prior to release. A pharmacist may electronically verify medication contents and labels from a remote location if:
1. The entire dispensing process is fully automated from the time the process is initiated until a completed and properly labeled manufacturer unit of use package or medication container is produced that is ready for dispensing;

2. A pharmacist reviews and verifies the prescription or medication order and the patient/medication information used to initiate the dispensing process prior to dispensing;

3. An electronic verification system is used to verify the correct medication and medication strength, dosage form and quantity have been dispensed; and

4. The pharmacist electronically views and verifies the final medication package or container for accuracy prior to dispensing using video or electronic technology. The pharmacist must be able to view and verify the actual package/container, including, the label and medication contents.

(6) Medication may be removed by a licensed healthcare practitioner from a Class-N automated dispensing system when a pharmacist is not physically present if:

1. The medication will be used or administered as authorized by section (2) of this rule;

2. The identity of the individual healthcare practitioner accessing the system is electronically recorded and verified before dispensing using a password or other unique identifier;

3. A pharmacist reviews and approves the initial prescription or medication order. Subsequent refills/doses may be removed from the automated system for the specific patient without additional pharmacist review/approval of the prescription or medication order, however, any change in the prescription or medication order shall require new approval from a pharmacist;

4. The automated dispensing system uses an electronic verification system to verify the correct medication is dispensed;

5. A pharmacist is available to respond to inquiries in the event of an emergency; and

6. A pharmacist operating on behalf of the pharmacy reviews all medication dispensed by the system and the applicable prescription/medication order on a random basis/sample size/weekly/monthly basis to ensure proper dispensing and compliance with the requirements of the rule. The identity of the reviewing pharmacist, the date of review and the review results must be documented in writing and maintained in the pharmacy’s records for two (2) years.

(C) The final pharmacist prescription/medication order verification requirements of 20 CSR 2220-2.010 shall be deemed satisfied if a pharmacist complies with the requirements of this section.
(7) Labeling. Medication must be 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. Multi-med paks must comply with 20 CSR 2220-2.145 and must be labeled with the following:

1. The name of the patient;
2. A serial number for the patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;
3. The name, strength, physical description or identification and total quantity of each drug product contained therein;
4. The directions for use and cautionary statements if any, contained in the prescription order for each drug product therein;
5. Any storage instructions or cautionary statements required by the official compendia;
6. The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date shall be not later than sixty (60) days from the date of preparation); and
7. Any other information, statements, or warnings required for any of the drug products contained therein.

(8) Stocking Medication. Automated dispensing systems may only be stocked by a Missouri licensed pharmacist or by a Missouri licensed intern pharmacist or registered technician. Individuals authorized to stock medication must be trained on system use and operations as appropriate for the tasks performed. A list of individuals authorized to stock the system must be maintained by the pharmacy and available on request of the Board or the Board’s authorized designee.

A. Medication must be transported to the automated dispensing system in a secure, tamper-evident container. No outdated, expired, misbranded or adulterated medication may be stocked or stored in the system;

B. The pharmacy must maintain a record of all medication stocked into or removed from the system. At a minimum, the pharmacy’s records must maintain written documentation of the date and time medication is stocked into or removed from the system, the identity of individuals stocking or removing medication and the type of medication stocked/removed.

C. Automated dispensing systems may be stocked by an intern pharmacist or a pharmacy technician without a pharmacist present if:

1. 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 prepackaged and labeled. The identity of the verifying pharmacist must be documented in the pharmacy’s records; and
2. An electronic verification system or other mechanical system is used to ensure medication and prepackaged containers/cartridges are correctly stocked or loaded into the system.

(D) Medication may be returned and reused as authorized by 20 CSR 2220-3.040 or as authorized by 20 CSR 2220-2.145 governing multi-med dispensing.

(E) Prepackaging must comply with 20 CSR 2220-2.130

(9) Prescription/Medication Order Records. The pharmacy must maintain records of all prescriptions or medication orders dispensed by the automated dispensing system. Prescriptions must be maintained as required by section 338.100, RSMo, and the rules of the Board. For medication orders, the pharmacy’s records must include the dispensing date, patient name, authorized prescriber and the name, strength, dosage form and quantity of medication dispensed. Except as otherwise required by law, prescription and medication order records may be included in a patient medical record maintained by the healthcare facility, provided the records must be retrievable by the pharmacy on request of the Board or the Board’s authorized designee. Prescriptions and medication orders must be assigned a sequential number or other unique identifier that allows individual retrieval of the dispensing record.

(10) Security. Adequate security systems and procedures must be maintained to prevent unauthorized access to or movement of the automated dispensing system and to prevent medication loss, diversion or theft.

(A) Automated dispensing systems must be securely placed inside of a licensed pharmacy or health care facility. The system must be securely fastened to a permanent structure and shall not be located in or near exit doors or accessible to the public.

(B) Automated dispensing systems must be locked by key, combination or other mechanical or electronic means. The system must consist of a substantially constructed container and shall be maintained and operated in a manner that will prevent system theft, tampering or unauthorized use/access. The system must be equipped with an alarm or other monitoring system that notifies or alerts the pharmacy in the event of a security breach or other unauthorized access.

(C) A written list must be maintained of all individuals or entities authorized to access an automated dispensing system. The pharmacist-in-charge must have authority to assign, initiate, modify and deny access to the automated dispensing system as deemed necessary or appropriate. System access must be promptly terminated or revoked if access authorization is revoked or rescinded.
(D) All access to the automated dispensing system must be manually or electronically documented, including, the date and time the system was accessed, the identity of individuals accessing the system and the name, strength, quantity and dosage form of medication placed in or removed from the system.

(E) Any theft or diversion of or from an automated dispensing system 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.

(F) [The pharmacy must reconcile medication inventory for each automated dispensing system every six ??? months.] A perpetual inventory must be maintained for any automated dispensing system that stocks or provides controlled substances. [ Controlled substance inventory must be reconciled every ?? months.] The required inventory and reconciliation must be documented in writing and retained for two (2) years. Should all inventory have to be reconciled?

(11) Quality Assurance. An initial and ongoing quality assurance program must be operated and established to objectively and systematically monitor the appropriate use and performance of all automated dispensing systems. The quality assurance program must include policies and procedures for detecting, evaluating and documenting system malfunctions and any breach of security.

(A) Quality assurance testing must be conducted [weekly/monthly/every six (6) months] for each automated dispensing system to measure system accuracy and operations. At a minimum, the required testing must include a physical inspection of drugs in the system and testing of the electronic verification system. Retesting must be performed whenever any upgrade or change is made to the system that may affect, alter or change system security, medication release/dispensing or the electronic verification system.

(B) As part of the quality assurance program, a pharmacist must review and investigate any verified or suspected dispensing or labeling error related to the automated dispensing system. The investigation dates and results must be documented in the pharmacy’s records. If a dispensing error is verified or substantiated, operation of the system must immediately cease until the system has been restored to proper functioning.

(C) Quality assurance documentation shall be maintained for two (2) years, including, documentation of quality assurance testing and testing results.
(12) Policies and procedures. The pharmacy shall establish and follow written policies and procedure to ensure the proper, safe, and secure functioning of all automated dispensing systems. Policies and procedures shall be reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy’s records for a minimum of two (2) years. The required annual review shall be documented in the pharmacy’s records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for—

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

(B) Ensuring accurate filling, loading, and stocking of the system;

(C) Monitoring and ensuring accurate dispensing;

(D) Reporting, investigating, and addressing known or suspected errors and system malfunctions;

(E) Testing the accuracy of the automated dispensing system and any accompanying electronic verification system;

(F) Training persons with system access on proper equipment use and operations;

(G) Tracking, documenting and investigating medication errors;

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

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

(J) Preventing unauthorized access to the system, including, assigning, discontinuing, restricting or changing security access as deemed necessary or appropriate;

(K) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;

(M) Maintaining the quality assurance program required by section (10) of this rule;

(N) Securing and accounting for wasted or discarded medications;

(O) Providing any required notifications to the board or other state or federal agency; and

(P) Emergency procedures in the event of a disaster or power outage that affects system functioning, including, procedures for system recovery.
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) “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 dispensing cabinet.

(B) Health Care Facility-

1. The office or practice location of a licensed health care practitioner authorized to prescribe medication in the state of Missouri; 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.

(C) Licensed Health Care Practitioner- A Missouri licensed dentist, licensed practical nurse, optometrist, pharmacist, physician, physician assistant, podiatrist, registered nurse, surgeon or veterinarian or other Missouri licensed healthcare practitioner authorized to prescribe medication.

(2) Authorized Activities. A Missouri licensed pharmacy may operate an automated distribution cabinet (“ADC”) at a health care facility for the purposes of distributing medication to licensed health care practitioners for patient use or administration. ADCs shall not be used to dispense compounded medication or to dispense patient-specific prescriptions or patient-specific medication orders filled/dispensed by the pharmacy. ADCs authorized by this section shall not be available for direct patient or public use.

(A) ADCs must be operated in compliance with all state and federal drug laws, including, all applicable controlled substance laws. The pharmacy shall be responsible for the proper operation of the ADC and must ensure medication is properly and accurately distributed. The pharmacy shall establish and follow written policies and procedures to ensure the proper, safe
and secure functioning of an ADC. Policies and procedures must be reviewed annually by the pharmacist-in-charge.

(B) ADCs must consist of a substantially constructed container that is locked by key, combination or other mechanical or electronic means. Adequate security procedures must be established and followed to prevent unauthorized access and to deter drug theft/diversion.

(C) ADCs must be securely placed within the designated health care facility. ADCs shall not be located in or near exit doors and shall not be accessible to the public. The pharmacy must maintain a current written or electronic list of all locations/addresses where ADCs are located. The list must be maintained at the pharmacy and available on inspection or request of the Board or the Board’s authorized designee.

(D) All access to an ADC must be manually or electronically documented, including, the date and time the ADC was accessed, the identity of individuals accessing the ADC and the name, strength, quantity and dosage form of medication placed in, distributed by or removed by each individual.

(E) Medication must be transported to the ADC in a secure, tamper-evident container. No outdated, expired, misbranded or adulterated medication may be stocked or stored in the system. ADCs may be stocked by an intern pharmacist or a pharmacy technician without a pharmacist present if:

1. The ADC 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 prepackaged and labeled. The identity of the verifying pharmacist must be documented in the pharmacy’s records; and

2. An electronic verification system or other mechanical system is used to ensure medication and prepackaged containers/cartridges are correctly stocked or loaded into the ADC.

(F) Medication must be stored under proper temperature and storage conditions in compliance with Food and Drug Administration (FDA) requirements and manufacturer guidelines. Temperatures must be recorded and documented daily. Repackaging shall comply with all state and federal law, including, 20 CSR 2220-2.130.

(G) Distribution records of all medication stocked in, distributed by or removed from an ADC must be maintained. At a minimum, distribution records must include the identity,
quantity and dosage form of medication received, distributed or removed from an ADC and the
date of receipt, distribution or removal of such medication.

(H) A pharmacist shall review all medication distributed by an ADC on a (monthly/weekly)
basis to ensure proper distribution. The identity of the reviewer, date of review and any
distribution discrepancies or errors shall be documented in writing and maintained in the
pharmacy’s records. Medication inventory must also be reconciled for each ADC every (2-
weeks, month/six (6) months). A perpetual inventory must be maintained for any ADC that
stocks or provides controlled substances.

(I) Unless otherwise exempted by 20 CSR 2220-5.020 or Chapter 338, RSMo, a Missouri
drug distributor license is required if the total amount of medication annually distributed by the
pharmacy via an ADC or otherwise exceeds five-percent (5%) of the pharmacy’s total gross
sales. For purposes of this section, total gross sales shall be 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.

(J) This rule is solely applicable to pharmacies operating an ADC pursuant to this rule.
This rule shall not be construed to prohibit or interfere with the compounding, administering,
prescribing or dispensing of medication by a healthcare practitioner as otherwise authorized by
law.

(K) 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.