Missouri Board of Pharmacy  
Hospital Advisory Committee Meeting  

May 4, 2017  
10:00 a.m.  
Missouri Council of School Administrators Conference Center  
3550 Amazonas Drive  
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 Missouri Council of School Administrators Conference Center, 3550 Amazonas Drive, Jefferson City, Missouri at 10:00 a.m. on May 4, 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 the attached tentative agenda for this meeting.
TENTATIVE AGENDA
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

May 4, 2017
10:00 a.m.
Missouri Council of School Administrators Conference Center
3550 Amazonas Drive
Jefferson City, MO 65109

1. Welcome & Introductions
2. Board Updates
3. Department of Health Updates
4. Review of 20 CSR 2220-6.040 Proposed Revisions (Administration by Medical Prescription Order)
5. Class-B Rule Concept Draft
6. Proposed Class-B Guidance Document
8. Bd. of Pharmacy Technician Working Group Update/Review of Working Group suggestions
9. Review of 20 CSR 2220-6.060 – 6.080 (Medication Therapy Services Rules)
10. Remote Supervision of Pharmacy Technicians/Tele-Pharmacy in Class-B Settings
11. Review of Committee Operations (Structure, meetings, scope/authority, membership and officers)
12. Update on Long-Term Care Working Group and discussion of hospital affiliated long-term care issues
13. Future Agenda Topics
14. Future Agenda Meeting/Schedules
15. Public Questions/Comments
16. Adjournment
PROPOSED AMENDMENT

20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy

PURPOSE: The purpose of this rule is to establish minimum standards of operation for Class J: Shared Services Pharmacy, in compliance with House Bill 567 of the 91st General Assembly.

(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions. A Class J Shared Services permit is required if two or more pharmacies are engaged in, or have an arrangement to provide, functions related to the practice of pharmacy for or on behalf of the other pharmacy. These functions may include, but are not limited to: prescription/order receipt, prescription/order clarification or modification, obtaining prescriber authorization, data entry, compounding, dispensing, pharmacist verification, patient counseling, patient profile maintenance, medication therapy services, medication administration, drug utilization review (DUR) and obtaining refill authorization. Both pharmacies participating in the shared services arrangement shall be required to obtain a Class J permit.

(A) Pharmacies may perform or outsource centralized prescription processing services Class-J Shared Services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;

2. Maintain separate licenses with a Class-J classification for each location involved in providing shared services; and

3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order. Either share a common database or allow access to each pharmacy’s electronic medication or prescription records. The access must provide real-time online access to the patient’s complete profile for all pharmacies involved.
(B) There must be record keeping systems between shared service pharmacies with real time on-line access to shared services by both pharmacies. Transfer of prescription information between two (2) pharmacies that are accessing the same real-time, on-line database pursuant to the operation of a shared service pharmacy operation shall not be considered a prescription transfer and, therefore, is not subject to the requirements of 4 CSR 220-2.120.

(B) Class-J pharmacies operating in compliance with this section are exempt from the requirements of 20 CSR 2220-2.120 and 20 CSR 2220-6.030(4) when transferring prescription information between themselves. A Class-J permit is not required to transfer an individual prescription as authorized by 20 CSR 2220-2.120 pursuant to a request by the patient or the patient’s authorized designee.

(C) The parties performing or contracting for centralized prescription processing Class-J shared services shall maintain a detailed written description of all authorized shared services that includes the name, address and permit number(s) of all pharmacies involved. The parties must also maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the following:

1. A description of how the parties will comply with federal and state laws and regulations; Policies and procedures that identify the duties of each pharmacy, including, the pharmacy responsible for drug utilization review, verifying or obtaining prescriber authorization/clarification, prescription/order data entry and verification, patient profile maintenance, medication/prescription labeling and obtaining refill authorization;

2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;

3. The maintenance of a mechanism for tracking the prescription drug or medication order during each step in the process;

4. The provision of adequate security to protect the confidentiality and integrity of patient information;

5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems;

6. Policies and procedures to ensure the safe and appropriate delivery of prescription drugs within the temperature requirements recommended by the manufacturer or the United States Pharmacopeia (USP), given normal and customary delivery times. Medication must be stored and transported in a manner that does not compromise medication integrity or stability; and

7. A designation of the pharmacy responsible for offering patient counseling as required by 20 CSR 2220-2.190 and federal law. For purposes of § 338.059, RSM, the name and address of the pharmacy responsible for offering patient counseling shall be listed on the prescription label.

(D) Compounding may only be performed pursuant to a Class-J pharmacy arrangement pursuant to a patient-specific prescription or in anticipation of a patient-specific prescription as authorized by 20 CSR 2220-2.200 and the rules of the Board.
(E) A Class-J permit is not required for pharmacists performing non-dispensing activities authorized by 20 CSR 2220-6.050 outside of a licensed pharmacy.

(2) A Class J Shared services permit shall not be required if a completed and labeled prescription is delivered from a Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional to the patient on the same premises or physical location as the pharmacy.

   (A) The exemption recognized in this subsection shall only apply if a completed and labeled prescription is delivered to the receiving pharmacy that is ready for administration to the patient, provided that additional manipulation or compounding of the medication may be performed if necessary for proper administration. Medication administered by a pharmacist shall be performed in compliance with all applicable provisions of law.

   (B) The receiving pharmacy must maintain documentation of the medication received, the name and address of the pharmacy providing the medication, the date of receipt and the patient’s name. If additional manipulation or compounding of the medication is performed by the receiving pharmacy, the product must be treated as a prescription by the receiving pharmacy and shall comply with all applicable prescription requirements, including, all record keeping, compounding and labeling requirements.

   (C) The receiving pharmacy shall be responsible for ensuring compliance with all applicable patient counseling requirements.

   (D) For purposes of this rule, administration is defined as applying or introducing medication to the body of a patient, whether by injection, infusion, inhalation, ingestion or other means.

   (E) Notwithstanding any other provision of this rule, licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security and record keeping requirements.

(3) A pharmacy participating in Class-J shared services with a pharmacy that is not under common ownership must notify patients that his/her prescription or medication order was filled or compounded by another pharmacy. Notification must be provided on the prescription or medication container label required by section 338.059, RSMo.

(4) All records required by this rule, including, all policy and procedure manuals, contracts, quality assurance documentation, or other agreements must be maintained for two (2) years and must be made available to the Board or its representative upon request.

3.00.91 Prescriptions dispensed by prescription drug outlets for delivery to consumers in other other outlet settings. When a drug has been dispensed pursuant to prescription order at a prescription drug outlet but has not been delivered to the ultimate consumer at an other outlet, the drug may be returned to stock only at the originating Prescription Drug Outlet, for subsequent redispensing provided that:

a. The prescription drug outlet complies with Board Rules 3.00.90(a), (b), and (c);

b. The storage conditions during the transport of the prescription to and from the other outlet do not in any way compromise the integrity or stability of the drug;

c. No controlled substance prescriptions may be returned to stock; and

d. No compounded or flavored prescription may be returned to stock.
20 CSR 2220-6.040 Administration by Medical Prescription Order

PURPOSE: This rule establishes procedures for pharmacists to administer drugs and devices, medication pursuant to a medical prescription order.

(1) A pharmacist who complies with the provisions of this rule may administer drugs and devices pursuant to a medical prescription order, including vaccines.

(2) Except as otherwise provided by law, Thea pharmacist may not delegate medication administration to another person, except to an intern pharmacist intern who has met the qualifications under of subsections (3)(B), (C), and (E)(4)(B) – (D) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order.

(3) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the Board. To file a Notification of Intent, a pharmacist must—

(A) Hold a current, unrestricted license to practice pharmacy in this state Missouri pharmacist license;

(B) Hold a current provider level cardiopulmonary resuscitation (CPR) certification or Basic Life Support certification issued by the American Heart Association, or the American Red Cross or an equivalent organization. The certificate program must have included a live training component;

(C) Have successfully completed a certificate program in the administration of drugs medication administration and emergency procedures accredited by the Accreditation Council for Pharmacy Education (ACPE) or provided by a governmental entity or a similar health authority or professional body healthcare professional organization or educational institution approved by the State Board of Pharmacy. The certificate program must cover all routes of administration the pharmacist utilizes; To obtain Board approval, the training program must [be taught by qualified instructors/a licensed healthcare professional and] provide instruction in:

1. Administration techniques which must include hands-on training in routes of administration;
2. Drug storage and handling;
3. Informed consent requirements;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal, and;
6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks.

(D) Pharmacists shall maintain proof of compliance with the requirements of this section for a minimum of two (2) years.
(D) Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;

(E) Maintain documentation of the above requirements; and

(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section.

(D) If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist must first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized to administer medication. Documentation of the required training and training date(s) must be maintained at the pharmacy and available to the Board on request.

(4) General Requirements.

(A) Except as otherwise authorized by law, a pharmacist shall administer drugs vaccines in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer’s guidelines. A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) A pharmacist shall have a written policy and procedure manual covering all aspects of the administration of administering drugs by medical prescription order, including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. The manual shall be reviewed annually and must be available for inspection by the State if requested by the Board of Pharmacy or the Board’s authorized representative. At a minimum, the required policies and procedures must include provisions governing:

1. Drug administration procedures, including, authorized routes of administration,
2. Drug storage;
3. Pre- and post- administration assessment and counseling, including, providing vaccine information statements when applicable;
4. Biohazard waste disposal and disposal of used/contaminated supplies;
5. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and
6. Recordkeeping requirements, including, providing notification to the prescriber and primary health care providers, as required by law.

(D) Drugs must be stored within the manufacturer’s labeled requirements at all times, including when performing administrations outside of a pharmacy. Vaccines shall be stored in accordance with CDC guidelines at all times.
Pharmacists shall request that a patient remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

(5) Requirements of Medical Prescription Order. The medical prescription order from a licensed prescriber must contain at a minimum the following:

(A) The name of the licensed prescriber issuing the order;

(B) The name of the patient to receive the drug;

(C) The name of the drug and dose to be administered;

(D) The route of administration;

(E) The date of the original order; and

(F) The date or schedule, if any, of each subsequent administration; and

(G) A statement that the drug is to be administered by a pharmacist.

(6) Record Keeping.

(A) A pharmacist who administers a drug shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy:

1. The name, address, and date of birth of the patient;

2. The date, route, and anatomic site of the administration;

3. The name, dose, manufacturer, lot number, and expiration date of the drug. The lot number shall also be documented and recorded for vaccines and biologics;

4. For vaccines, the name and address of the patient’s primary health care provider, as identified by the patient. The pharmacist shall document in the patient’s immunization record if a primary health care provider is not provided;

5. The name or identifiable initials of the administering pharmacist. If administered by an intern pharmacy, the identity of the intern and supervising pharmacist; and

6. The nature of an adverse reaction and who was notified, if applicable;

7. Documentation of a patient’s refusal or failure to remain in or return to the pharmacy after administering a vaccine to observe any adverse reactions; and

(B) Except for proof of compliance with section (3) of this rule, all records required by this regulation shall be kept by the pharmacist at the pharmacy where the prescription order is maintained and must be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives. Records may be securely stored offsite at a location designated by the pharmacy, provided the records must be produced as required by section (7)(C).
(C) Production of Records. Records required by this rule shall be electronically or physically maintained for two (2) years and shall be readily retrievable for inspection. At a minimum, records maintained at the pharmacy shall be physically or electronically produced immediately or within two (2) hours of a request from the Board or the Board’s authorized designee. Records not maintained at a pharmacy shall be produced within three (3) business days of a Board request.

(7) Notification Requirements.

(A) A pharmacist administering drugs, a vaccine pursuant to a medical prescription order shall notify the prescriber within seventy-two (72) hours patient’s primary health care provider, if provided by the patient, within fourteen (14) days after administration of the following:

1. The identity of the patient;
2. The identity of the drug, vaccine administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) In the event of any adverse event or reaction experienced by the patient following medication administration, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction. Notification shall be mandatory and cannot be waived.

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

(D) Notifications required by this section shall be made electronically or in writing. Alternatively, notifications may be made via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Documentation of the required notifications, including the notification date, must be kept at the pharmacy or other authorized location where the prescription order is maintained.

(8) Notification of Intent Refiling. To continue administration, a Notification of Intent to administer drugs by medical prescription order must be refilled with the Board biennially along with the pharmacist’s Missouri pharmacist license. To refile, a pharmacist must:

(A) Hold a current Basic Life Support certification issued by the American Heart Association or the American Red Cross or an equivalent organization. The certification program must include a live training component; and

(B) Have successfully completed four (4) hours of continuing education (0.4 CEU) related to drugs administration. The required continuing education (CE) shall be governed by 20 CSR 2220-7.080 and may be used to satisfy the pharmacist’s biennial pharmacist renewal CE requirements. The initial training program required by
subsection (3) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within twelve (12) months prior to refiling the pharmacist’s Notification of Intent.


20 CSR 2220-6.040 Administration by Medical Prescription Order

PURPOSE: This rule establishes procedures for pharmacists to administer drugs and devices, including vaccines, pursuant to medical prescription orders.

(1) A pharmacist who complies with the provisions of this rule may administer drugs and devices, including vaccines, pursuant to a medical prescription order.

(2) Definitions. The following definitions shall apply for purposes of this rule:

____ (A) “Health Clinic or Facility”- A clinic or facility under the common control, management, or ownership of the same hospital or hospital system.

____ (B) “Hospital”- A hospital as defined in section 197.020.

____ (C) “Medical Prescription Order”- A lawful order for drugs or devices issued by an authorized practitioner within the scope of his/her professional practice which is to be dispensed or administered to the ultimate user or recipient.

(2)(3) Except as otherwise provided by law, the pharmacist may not delegate the medication administration to another person, except to an intern pharmacist who has met the qualifications under subsections (3)(B), (C), and (E) (4)(B) - (D) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order. The pharmacist and intern shall maintain proof of the intern’s compliance with this subsection.

(3)(4) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the state Board of Pharmacy. To file a Notification of Intent, a pharmacist must—

____ (A) Hold a current, unrestricted license to practice pharmacy in this state;
(B) Hold a current Basic Life Support certification (BLS) issued by the American Heart Association, or the American Red Cross or an equivalent organization. The certificate program must include a live training component.

(C) Successfully complete a certificate program in the administration of drugs accredited by: the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy (1) a continuing education provider accredited by the Accreditation Council for Pharmacy Education (ACPE) or (2) a governmental entity, healthcare professional organization or educational institution approved by the Board. To obtain Board approval, the training program must [be taught by qualified instructors/a licensed healthcare professional and] provide instruction in:—The certificate program must cover a

1. Physiology and techniques for routes of administration which must include hands-on training in all routes of administration the pharmacist utilizes;
2. Drug storage and handling;
3. Informed consent requirements, if applicable;
4. Pre- and post-administration assessment and counseling;
5. Biohazard waste disposal; and
6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks.

(D) Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;

(E) Maintain documentation of the above requirements; and,

(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section. If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist shall first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized
to administer medication. Documentation of the required training shall be maintained at the pharmacy and available to the Board upon request.

(4) (5) General Requirements.

(A) A pharmacist shall administer drugs vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer’s guidelines. In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs by medical prescription order, including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. The manual Policies and procedures shall be reviewed annually by the pharmacist-in-charge. Policies and procedures must be available for inspection by the State Board of Pharmacy or other authorized Board representative. Documentation of the annual review must be maintained in the pharmacy’s records. At a minimum, the required policies and procedures must include provisions governing:

1. Drug administration procedures, including, authorized routes of administration;

2. Drug storage;

3. Pre- and post- administration assessment and counseling, including, providing vaccine information statements when applicable;

4. Biohazard waste disposal and disposal of used/contaminated supplies;

5. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and

6. Recordkeeping requirements, including, providing notification to the prescriber and primary health care providers, as required by law.

(D) Drugs must be stored within the manufacturer’s labeled requirements at all times, including when performing administrations outside of a pharmacy. Vaccines shall be stored in accordance with CDC guidelines at all times.

(E) Pharmacists shall request that a patient remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.
(F) For pharmacists administering drugs in a... policy and procedure review required by this subsection may be performed by the pharmacist-in-charge or by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the ___responsible for reviewing clinical practices.

(5) (6) Requirements of Medical Prescription Order. The medical prescription order from a licensed prescriber an authorized practitioner must contain at a minimum the following:

(A) The name of the licensed prescriber authorized practitioner issuing the order;
(B) The name of the patient to receive the drug;
(C) The name of the drug and dose to be administered;
(D) The route of administration;
(E) The date of the original order; and
(F) The date or schedule, if any, of each subsequent administration; and
(G) A statement that the drug is to be administered by a pharmacist.

(6) (7) Record Keeping.

(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy.

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the drug. The lot number shall be documented and recorded for vaccines and biologics;
4. For vaccines, the name and address of the patient’s primary health care provider, as identified by the patient. The pharmacist shall document in the patient’s immunization record if a patient’s primary health care provider is unknown or not designated by the patient;
5. The name or identifiable initials of the administering pharmacist. If administered by an intern pharmacist, the identity of the intern and the supervising pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable;
7. A patient’s refusal or failure to remain in or return to the pharmacy as requested after vaccine administration to observe any adverse reactions; and
8. Written or electronic documentation that required notifications have been sent.
(B) All records required by this regulation rule shall be kept by the pharmacist at the pharmacy where the prescription order is maintained and must be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives. Records may be securely stored offsite at a location designated by the pharmacy, provided records must be produced as provided in section (7)(C) of this rule.

(C) Production of Records. Records required by this rule shall be maintained either electronically or physically for two (2) years and shall be readily retrievable and subject to inspection by the board of pharmacy or its agents. At a minimum, records maintained at the pharmacy shall be physically or electronically produced immediately or within two (2) hours of a request from the Board or the Board’s authorized designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Board and/or its authorized designee.

(7) (8) Notification Requirements.

(A) A pharmacist administering drugs a vaccine pursuant to a medical prescription order shall notify the prescriber within seventy-two (72) hours patient’s primary health care provider, if provided by the patient, within fourteen (14) days after administration of the following:

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

(B) In the event of any adverse event or reaction experienced by the patient following administration of a drug, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction. The prescriber may not opt out of adverse event notification requirements.

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

(D) Documentation that the required notifications have been sent must be kept at the pharmacy or other authorized location where the prescription order is maintained.
(9) Notification of Intent Refiling. A Notification of Intent to administer drugs by medical prescription order shall be refiled with the state board of pharmacy biennially along with the pharmacist’s Missouri pharmacist license. To refile, a pharmacist must:

(A) Hold a current Basic Life Support certification issued by the American Heart Association or the American Red Cross or an equivalent organization. The certification program must include a live training component; and

(B) Have successfully completed four (4) hours of continuing education (0.4 CEU) related to drugs administration. The required continuing education (CE) shall be governed by the rules of the state Board of Pharmacy governing pharmacist CE and may be used to satisfy the pharmacist’s biennial pharmacist renewal CE requirements. The initial training program required by subsection (4) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within twelve (12) months prior to refileing the pharmacist’s Notification of Intent.

(10) Administration in a Hospital or a Health Clinic or Facility—Pharmacists administering medication under the jurisdiction of the Board on behalf of a hospital or a health clinic or facility shall comply with the requirements of this rule with the following exceptions:

(A) A pharmacist shall be deemed in compliance with the requirements of sections (7) and (8) of this rule if the pharmacist administers drugs for or on behalf of a hospital or a hospital clinic or facility in compliance with this section and the administration is lawfully recorded in a patient medical record that is required to be maintained by the hospital or the hospital clinic or facility pursuant to state or federal law.

(B) In lieu of completing a certificate program in the administration of drugs as required by section (4) of this rule, pharmacists administering in a hospital or a hospital clinic or facility shall be trained in administration and meet all competency, training and evaluation requirements required by the hospital or hospital clinic or facility and the Missouri Department of Health and Senior Services (DHSS). At a minimum, pharmacist administration training must be similar to or include the training components identified in section (4)(C).

(C) A pharmacist shall administer vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention.
(CDC). In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

(E) The policy and procedure review required by section (5) may be performed by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the hospital responsible for reviewing clinical practices. Required policies and procedures may be maintained in or included with the governing hospital’s approved policies, procedures or protocols.

(F) This section is only applicable to pharmacy services under the jurisdiction of the Board and is not applicable to hospital pharmacy services or pharmacist medication administration under the jurisdiction of the Department of Health and Senior Services.


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 requirements 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---

(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 an external or implanted medical delivery device that is programmed by a healthcare professional.; and

(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.
MISSOURI BOARD OF PHARMACY

CLASS-B HOSPITAL PHARMACY GUIDANCE

*** THIS DRAFT HAS NOT BEEN REVIEWED OR APPROVED BY THE BOARD AND MAY NOT REFLECT THE BOARD’S CURRENT POSITION/ GUIDANCE***
CLASS-B
Hospital Pharmacy Guidance

This guidance document is being provided by the Missouri Board of Pharmacy to provide compliance information for Class-B Hospital pharmacies. **This guidance is not applicable to pharmacy services regulated by and under the jurisdiction of the Missouri Department of Health and Senior Services (DHSS).**

OVERVIEW

In 2014, the Missouri General Assembly enacted SB 808 which officially established a Class-B Hospital pharmacy permit for pharmacies located in Missouri licensed hospitals and also hospital clinics and facilities. Prior to the new law, only Missouri licensed hospitals were eligible for a Class B permit. As healthcare delivery models have evolved, Missouri hospitals indicated pharmacy services were increasingly being delivered via hospital owned clinics or satellite pharmacies that were not part of the licensed hospital. The Board was informed its general pharmacy rules conflicted or hindered compliance with accreditation and other reimbursement requirements, particularly for clinics/facilities not engaged in traditional “prescription” dispensing.

The Board subsequently convened a Hospital Pharmacy Advisory Group comprised of hospital representatives to assist the Board in addressing these concerns. The Advisory Group recommended establishing a single Class-B permit class for both hospitals and hospital related clinics and facilities along with enhanced distribution/dispensing standards for Class-B pharmacies under common control or ownership.

SB 808 was subsequently enacted which officially established the current Class-B Hospital Pharmacy permit classification. SB 808 also:

- Created additional dispensing and distribution allowances for Class-B pharmacies;
- Granted DHSS and the Board of Pharmacy authority to collaborate on rules governing medication distribution and medication therapy services performed by a pharmacist at or within a hospital. This allowance does not change DHSS’ current jurisdiction over hospital pharmacy but allows the agencies to collaborate on rulemaking, and
- Established a standing Hospital Advisory Committee to advise the Board. The Advisory Committee consists of hospital representatives designated by DHSS, the Missouri Hospital Association, the Missouri Society of Health System
Pharmacists and the Missouri Pharmacy Association and a Board appointed pharmacist with experience in hospital pharmacy.

**CLASS-B PERMIT REQUIREMENTS**

Section 338.220, RSMo, defines a “Class-B Hospital Pharmacy” as:

- A pharmacy owned, managed, or operated by a hospital as defined by § 197.020, or
- A hospital clinic or facility under common control, management or ownership of the same hospital or hospital system [§ 338.165.1(3); § 338.220.6].

Eligible clinics/facilities may be located within a Missouri licensed hospital or separately operated at an offsite location. For example, offsite facilities such as infusion clinics, physician clinics, long-term care facilities, ambulatory surgical centers or other healthcare facilities may be licensed as a Class-B pharmacy, provided the clinic/facility meets the common ownership/operation requirements (this list is not exhaustive). The governing hospital or hospital system is not required to be licensed with the Board unless the hospital/hospital system is also providing pharmacy services under the Board’s jurisdiction.

Applicants should consult with legal counsel to determine if a hospital clinic/facility is under “common control, management or ownership of the same hospital or hospital system.” The Board cannot provide legal advice.

Once approved, a Class-B permit will be issued for a specific location/address. Applicants may choose to license all or portions of a building under a Class-B permit (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. For example, a Class-B permit may include drug rooms that are located on different floors within the same building, however, each area and pharmacy activity would be required to comply with Board requirements. A separate Class-B permit would be required for facilities located at different addresses.

Class-B applications and related fees are available on the Board’s website. Note: Applicants must apply for and hold any required classification for specialty pharmacy services regulated by the Board (e.g., Class D-Non-sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).

**CLASS-B LICENSURE FOR MISSOURI HOSPITALS**

Under Chapter 197, RSMo, DHSS has regulatory jurisdiction over pharmacy services provided within the “licensed premises” of a Missouri hospital. A Class-B Hospital Pharmacy permit is not required for hospitals “solely providing services within the practice of
pharmacy under the jurisdiction of, and the licensure granted by” DHSS. [§ 338.220.6, RSMo]. Hospitals solely providing pharmacy services under DHSS’ jurisdiction may choose to be licensed as a Class-B pharmacy although not required.

Section 197.052, RSMo, defines the hospital premises as: “tracts of property which are adjacent but for a common street or highway, as defined in section 300.010, and its accompanying public right-of-way.” DHSS has provided the following examples of facilities considered “adjacent but for a common street or highway” to a hospital:

PHYSICIAN CLINIC

According to DHSS, buildings or areas that do not meet the above definition/requirements would not qualify as part of the hospital’s premises even though the building/area may be:

- Part of the hospital’s campus
- Under the same CMS Certification Number (CCN), or
- Under the same ownership.

Inclusion in the hospital premises is not automatic. Instead, buildings/areas must be officially designated with DHSS as part of the hospital’s license. According to DHSS, this may be done in the hospital’s initial DHSS license application or hospitals may separately notify DHSS to amend their license. Hospitals should contact DHSS to verify that all desired buildings/areas have been properly designated, including any newly added facilities. Pharmacy services provided in buildings/areas that have not been officially included as part of the DHSS licensed hospital premises would be regulated by the Board.

DHSS has advised that the hospital premises may include more than just “inpatient” areas. For example, other hospital areas such as emergency departments, infusion clinics, urgent care facilities, ambulatory surgery centers, physical therapy departments or other “outpatient” service areas may be included, provided the facility or department meets the hospital premises definition above. Note: Additional DHSS regulatory requirements may apply (e.g., DHSS construction standards/life safety code requirements).
Examples of pharmacy services under DHSS jurisdiction would include, but are not limited to:

- Dispensing or distributing medication for use or administration to patients within the same DHSS licensed premises regardless of billing status ("inpatient" vs. "outpatient"). This includes dispensing or distributing to clinics or other hospital departments included within the DHSS licensed premises;
- Compounding medication within the DHSS licensed hospital premises for use or administration within the same licensed premises;
- Counseling or providing other non-dispensing pharmacy services for patients located or receiving treatment within the DHSS licensed hospital premises (e.g., DUR, medication reconciliation, order review/approval);
- Administering medication within the DHSS licensed hospital premises, and
- Initiating, modifying or dosing medication for use or administration within the DHSS licensed hospital premises (a Board Certificate of Medication Therapeutic Plan Authority would still be required as described below).

The Board has jurisdiction over pharmacy services provided outside of the licensed DHSS hospital premises. Examples would include, but are not limited to:

- Dispensing or distributing medication that will be used or administered outside of the DHSS licensed premises (e.g., "take-home" meds)
- Pharmacy services provided under a pharmacy's Class-B permit
- Compounding for use or administration outside of the DHSS licensed hospital premises or compounding medication outside of the DHSS licensed hospital premises regardless of patient location
- Counseling or providing other non-dispensing pharmacy services for patients located or receiving treatment outside of the DHSS licensed hospital premises (DUR, medication reconciliation, order review/approval)
- Administering medication outside of the licensed hospital premises,
- Modifying or initiating drug therapy that will be dispensed, distributed or administered outside of the DHSS licensed premises, and
- Pharmacy services provided at a clinic or facility that is not part of the DHSS licensed hospital premises. This would include any clinic/facility that has not been officially designated with DHSS as part of the hospital's license even if located within the hospital's building or on the hospital campus.

The Board has determined “take home” medication would not include medication 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. ---or-----
The Board has determined “take home” medication would not include medication that is initiated onsite but continued offsite via an external or implanted medical delivery device.
that is programmed by a healthcare professional. Examples would include intrathecal or 5-FU pumps that are started within the DHSS licensed hospital premises. The Board has also determined that medication sent with a patient to be used during an emergency transfer to another facility would not be considered a “take home” medication. These services may be provided under DHSS’ jurisdiction; Board licensure is not required.

Additionally, DHSS rules allow licensed hospitals to send a limited supply of medication home with the patient from the hospital when pharmacy services are not reasonably available. A Board pharmacy permit is not required for these activities as authorized by DHSS rules.

**Dually Regulated Entities**

The Board is aware of dually operating Class-B pharmacies providing pharmacy services under DHSS’ jurisdiction and pharmacy services under the Board’s jurisdiction at the same location. Class-B pharmacies may share pharmacy space with a DHSS regulated hospital; the Board does not require physical separation of facilities or drug inventory. However, proper security must be maintained over drug stock at all times. Additionally, pharmacy services under the Board’s jurisdiction must comply with all applicable Board statutes/rules.

DHSS licensed hospitals may choose to license all or a portion of the hospital as a Class-B pharmacy (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. The Board would only have jurisdiction over and regulate the Class-B pharmacy services.

**Non-Dispensing Activities**

Missouri law authorizes pharmacists to perform non-dispensing activities outside of a Missouri licensed pharmacy. Specifically, 20 CSR 2220-6.055 provides a pharmacist may perform the following activities at a non-pharmacy location:

1. Administering medication or biologicals
2. Obtaining patient history/information
3. Reviewing patient records/medication reconciliation
4. Patient assessment/evaluation
5. Insurance billing and claims

All pharmacists, technicians and interns practicing in Missouri must hold an individual pharmacist, technician or intern license/registration issued by the Board regardless of practice setting. Pharmacist, technicians and interns practicing within a DHSS licensed hospital must be licensed with/registered by the Board.
(6) Drug utilization review
(7) Pharmacy compliance audits/evaluations
(8) Peer review/peer consultations
(9) Managing drug inventory, including purchasing and ordering
(10) Consulting with other health care professionals
(11) Patient referrals

(12) Medication therapy management/medication therapy services, and
(13) Prescription order entry/review, provided a pharmacist can only accept a prescription on the premises of a Missouri licensed pharmacy [§ 338.095.5]

A Class-B pharmacy permit would not be required for allowed non-dispensing activities, unless technicians will be assisting at the non-pharmacy location. If technicians are assisting, a Class-B pharmacy permit is required.

The Board has been asked if pharmacists can maintain or monitor drug storage areas/units that are located in hospital areas/facilities that are not licensed with the Board or located in other unlicensed healthcare facilities such as a private physician’s office, ambulatory surgical center or an infusion clinic. Class-B pharmacies cannot store medication outside of the licensed pharmacy area, except as allowed by 20 CSR 2220-2.900 for automated dispensing systems. However, 20 CSR 2220-6.055 would allow pharmacists to monitor/maintain medication or drug storage areas belonging to other unlicensed entities without a Board pharmacy permit. This would include non-dispensing activities such as checking drug storage, inventorying medication, performing drug utilization reviews, medication reconciliation and counseling patients (this list is not exhaustive).

**SCOPE OF CLASS-B ACTIVITIES**

Once licensed by the Board, sections 338.165.5 and .6, RSMo, grant two new allowances to Class B Hospital pharmacies. Specifically, Class-B Hospital pharmacies may:

1) Dispense medication by prescription or by medication order, and
2) Distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

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1 A Board pharmacy permit would not be required if technicians are only assisting with administering vaccines. 20 CSR 2220-6.055(6).
Dispensing by Prescription/Medication Order

Class-B pharmacies may dispense medication pursuant to a patient-specific prescription or a patient-specific medication order. Prescriptions must comply with all state and federal requirements, including: the required two-line format for Missouri prescribers.

A “medication order” is defined as an order for a legend drug or device that is:

1. 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
2. To be distributed or administered to a patient by a health care practitioner or lawfully authorized designee at a hospital or a “hospital clinic or facility” that is under the “common control, management or ownership of the same hospital or hospital system.” Section 338.165.1, RSMo

Significantly, medication orders can only be used to dispense medication that will be distributed or administered at a hospital or at a qualifying “hospital clinic or facility.” A qualifying hospital clinic or facility could include offsite physician clinics, urgent-care centers, long-term care facilities, infusion clinics, physical therapy units or other healthcare facilities, provided the clinic or facility is under common control, management or ownership of the same hospital or hospital system.

The Board has been asked if a medication order may be used to dispense a self-contained medication therapy course that will be initially administered onsite but later sent home/transferred with a patient to complete/continue administration (e.g., intrathecal and 5-FU pumps). The Board has determined that a medication order may be used in these instances provided administration is initiated onsite of the hospital or a qualifying hospital clinic or facility but continued offsite via a programmed external or implanted medical delivery device. ---or---- The Board has determined that a medication order may be used in these instances provided administration is initiated onsite of the hospital or a qualifying hospital clinic or facility but continued offsite via an external or implanted medical delivery device that is programmed by a healthcare professional.

Medication orders do not have to be in two-line format, however, orders must comply with all state/federal controlled substance requirements. Missouri law is silent on the pharmacist’s authority to perform generic or biosimilar substitution on a medication order. Please consult an attorney for guidance.
**Drug Distribution by Class-B Pharmacies**

Section § 338.165.6 provides a Class B Hospital pharmacy may distribute medication to a “hospital clinic or facility” for patient care or treatment without a Missouri drug distributor license. Once again, a “hospital clinic or facility” is defined as a clinic or facility under common control, management or ownership of the same hospital or hospital system.

Under federal law, a pharmacy may still be required to register with the DEA as a controlled substances distributor if the total dosage units of all controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed by the pharmacy during the previous calendar year.

Significantly, a Class B pharmacy may not distribute compounded preparations to other entities or distribute re-packaged medication to other practitioners without being registered with the FDA.

Licensees distributing non-patient specific medication may also be required to register with the FDA as a section 503(b) drug outsourcer. Licensees should consult with legal counsel to ensure compliance with state and federal law.

**Class-B Labeling Requirements**

Section 338.059, RSMO, provides a written label must be affixed to each prescription container dispensed to a consumer indicating:

1) The date the prescription was filled;
2) A prescription number or other unique identifier;
3) The patient's name;
4) The prescriber's directions for usage;
5) The prescriber's name;
6) The pharmacy's name and address;
7) The exact name and dosage of the drug dispensed, and;
8) If a generic substitution is made, the manufacturer must be identified on the label or in the pharmacy’s records by name or abbreviation. [§ 338.059].

For controlled substance prescriptions issued by an advanced practice registered nurse (APRN) or a physician assistant (PA), the required label must also include the names of the prescribing mid-level practitioner and their supervising or collaborating physician. [ § 195.100, RSMo].

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2 Section 338.059, RSMo, does not apply to internal drug orders for hospital in-patients.
If a unique identifier is used in lieu of a prescription number, the identifier must be able to retrieve the patient’s specific medication order/prescription. Board inspectors have observed instances where a unique identifier could retrieve the patient’s medical record but not the specific medication order/prescription. In some cases, the same identifier was used for multiple patients. Unique identifiers should be formatted to allow retrieval of the specific dispensing record for each individual patient (e.g., a unique identifier/order #).

The Board has been asked about labeling requirements for Class-B pharmacies dispensing medication to a healthcare provider for onsite administration to a patient. The Board understands labeling may be a particular issue for hospital-owned clinics/satellite pharmacies that may not use prescriptions or have software to print a traditional “outpatient” prescription label.

The Board intends on addressing this issue by rule in the future. In the interim, Board Inspectors will not cite Class-B pharmacies for violations of § 338.059’s labeling requirements if:

1) Medication is given to a healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy or within the licensed premises of a DHSS licensed hospital, and

2) The medication/prescription container labeling is accurate and complies with DHSS’ medication labeling requirements [see generally 19 CSR 30-20.100(21) which requires patient name, drug name, strength, expiration date, lot number when applicable and other pertinent information], and

3) The medication/prescription container is not “given to the patient for use/administration” offsite. 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. ---or--- 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 an external or implanted medical delivery device that is programmed by a healthcare professional.

Sterile Compounding

Class-B pharmacies engaged in sterile compounding must also have a Class-H Sterile Compounding pharmacy permit. All sterile compounding for use or administration to patients outside of the DHSS licensed hospital premises must comply with the Board’s sterile compounding rules (20 CSR 2220-2.200, 20 CSR 2220-2.400). Class-B pharmacies may share sterile compounding space/equipment with a DHSS hospital (e.g., the same clean room).

1 Radiopharmaceuticals must also comply with 19 CSR 30-20.100(18)
However, the sterile compounding area will be inspected for compliance with Board requirements.

Licensees are reminded that Class-B pharmacies may only dispense compounded sterile preparations pursuant to a patient-specific prescription or a patient-specific medication order.

Allowed Technician Activities

Generally, a Missouri pharmacy technician registration is required for any person who has independent access to a pharmacy on a routine basis or who assists a pharmacist in the practice of pharmacy. Given the nature of hospital practice, the Board has determined that technician registration is not required for nurses and other healthcare practitioners who access Class-B pharmacy space or drug inventory that is shared with a DHSS regulated hospital pharmacy as part of their non-pharmacy job duties.

Pharmacy technicians may assist in any area of pharmacy practice that does not require the use of professional judgment by a pharmacist. Technicians assisting in Class B pharmacy practice may not work independently and must be under the direct supervision and responsibility of a Missouri licensed pharmacist at all times. All prescriptions prepared or compounded by a technician in a Class-B pharmacy must be finally verified/checkered by a pharmacist, including, reconstituted products.

Medication Therapy Services

Under Missouri law, all pharmacists providing medication therapy services (MTS) must obtain a certificate of medication therapeutic authority from the Board, regardless of practice setting. Licensees should review the Missouri Pharmacy Practice Guide for additional MTS requirements.

As explained in the Practice Guide, an MTS certificate is not required to perform traditional pharmacist functions such as medication reconciliation or medication therapy management. An MTS certificate is only required if a pharmacist will be modifying drug/device therapy which includes:

- Selecting a new, different or additional medication or device (including initiating therapy);
- Discontinuing any current medication/device;
- Selecting a new, different or additional strength, dose, dosage form or dosage schedule;
- Selecting, adding or changing a new or different route of administration.
Generally, pharmacists who are dosing, modifying or initiating medication that will be dispensed, distributed or administered outside of the DHSS licensed premises would be regulated by the Board and required to comply with the Board’s MTS rules and requirements. DHSS would regulate dosing, modifying or initiating medication within the DHSS licensed hospital premises (a Board MT certificate would still be required). Note: This is a general guideline. A determination of DHSS/Board jurisdiction would depend on the specific facts.

The Board has issued the following additional guidance for pharmacists performing MT services under the Board’s jurisdiction:

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The requirements below are applicable to MT services under the Board’s jurisdiction. Please consult DHSS requirements for MT services provided under DHSS jurisdiction.
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1. Pharmacists must have a MT protocol with a Missouri physician that complies with 20 CSR 2220-6.080. A hospital protocol may be used to provide MT services if the protocol includes all information required by 20 CSR 2220-6.080(4) and authorizes the pharmacist to perform the services provided. A separate protocol would not be required. In lieu of individual signatures, 20 CSR 2220-6.080 allows the pharmacist and authorizing physician(s) to sign and date a statement agreeing to be governed by the hospital's protocol.

2. Pharmacists are required to notify the protocol physician within twenty-four (24) hours of modifying drug therapy or within 24-hours of an adverse event, adverse medical reaction or an adverse needle stick. The Board has determined that notifications may be maintained in an electronic medical record (EMR) that is required to be maintained by state or federal law, provided the EMR is accessible to and shared by both the physician and pharmacist.

3. In addition to a MT protocol, pharmacists performing MT services under the Board’s jurisdiction must also have a prescription order from a physician authorizing them to provide MT services for the specific patient. The Board has determined that a protocol approved by a hospital’s clinical care committee, pharmacy and therapeutics committee or an equivalent hospital reviewing body/committee may be used to initiate pharmacist MT services, provided the protocol is not restricted or limited to MT services within the DHSS licensed premises.4 By statute, the prescription order/protocol must be initiated or issued by the physician and not a nurse or physician assistant. [§ 338.010.2]

4. Generally, the authorizing physician must review the pharmacist’s MT services at least once every three (3) months. For pharmacists providing MT services for, or on behalf of, a licensed hospital, the required review may be conducted by the clinical care committee, the pharmacy and therapeutics committee or by an
equivalent hospital reviewing body that includes a Missouri-licensed physician (e.g., the medical staff committee). 4

**Immunization/Administration of Medication**

Pharmacists immunizing or administering medication outside of the DHSS licensed premises must file a Notification of Intent to immunize and/or administer medication by prescription order with the Board and comply with rules 20 CSR 2220-6.040 and 20 CSR 2220-6.050.

Pharmacists immunizing by protocol are required to notify the authorizing protocol physician within seventy-two (72) hours after immunizing and notify the patient's primary care provider within fourteen (14) days after vaccination, if different. Additionally, pharmacists must notify the protocol physician within twenty-four (24) hours of an adverse event/reaction. Pending future Class-B rules, the Board has determined the required notifications may be documented in a common EMR that is accessible to both the pharmacist and physician. Proof of documentation/notice must be produced on inspection or as requested by the Board.

Licensees should review the Missouri Pharmacy Practice Guide for additional immunization/administration compliance information. The Board also has an Immunization/Administration Checklist available online at [http://pr.mo.gov/pharmacists-faq-compliance.asp#immunization](http://pr.mo.gov/pharmacists-faq-compliance.asp#immunization). Pharmacists immunizing or administering medication within the DHSS licensed hospital premises must comply with DHSS requirements.

**Class-J Shared Services**

Class-B pharmacies engaged in shared services with another Board licensed pharmacy must also have a Class-J pharmacy permit, in addition to their Class-B permit. A Class-J permit is required if a pharmacy will be using, or assisting another pharmacy with:

- Filling or refilling a prescription drug order, or
- Performing or assisting in the performing of any function associated with the dispensing process. This would include drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions for another pharmacy.

Pharmacies may participate in a Class-J shared services arrangement if both pharmacies:

1) Have the same owner or have a written contract outlining the shared services to be provided by, and the responsibilities of, each party participating in the contract; and

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4 Note: This allowance would also apply to pharmacists providing MT services for, or on behalf of, a state or federally licensed 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.
2) Maintain separate pharmacy licenses for each shared services location; and
3) Share a common electronic file that allows access to sufficient information necessary or required to fill/refill a prescription drug order. The pharmacies must share a record keeping system that provides real-time, on-line access to shared services by both pharmacies.

Class-J pharmacies must also maintain a policy and procedure manual that describes/includes procedures for: (a) how the parties will comply with state/federal requirements (b) identifying the pharmacist responsible for dispensing and counseling, (c) tracking the prescription drug order during each step in the process, (d) maintaining adequate security to protect the confidentiality and integrity of patient information and (e) maintaining a quality assurance program for pharmacy services that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and resolve identified problems.

Once again, a Class-J permit is required for both pharmacies engaged in shared services. For example, a Class-B chemotherapy infusion pharmacy receives and fills a patient's prescription from a specialty mail order pharmacy (i.e., a manufacturer's indigent program). A Class-J permit would be required for both the Class-B chemotherapy infusion pharmacy and the specialty mail order pharmacy. Pharmacies may add a classification by filing a Pharmacy Classification Change Application with the applicable fee.

Transferring prescription information between Class-J pharmacies in a shared services arrangement that share a real-time, on-line database are not considered “prescription transfers” under, and are not subject to the requirements of, 20 CSR 2220-2.120. Other controlled substance laws may apply.

Record-Keeping

As a licensed pharmacy, Class-B pharmacies must comply with all Board record-keeping requirements applicable to pharmacies. Licensees should review Missouri law and the Missouri Practice Guide for specific requirements. The Board has determined that Class-B pharmacies may maintain dispensing, distribution and administration records in the same electronic or manual system used by the hospital or other hospital clinics/facilities (e.g., a common EMR), provided the records must be readily retrievable on inspection or if requested by the Board.  

5 Controlled substance records must still be separately maintained/retrievable as required by state/federal law.
Future Rules

The Board will be consulting with the Hospital Advisory Committee to develop future Class-B pharmacy rules. Interested parties should monitor the Board’s website for meeting information; public comments are welcomed.

Questions

Questions regarding activities under DHSS’ authority should be addressed to DHSS’ Division of Hospital Licensure and Regulation at (573) 751-6303. Questions regarding the Board’s rules or requirements may be addressed to your Inspector or e-mailed to compliance@pr.mo.gov.
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.
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.
PHARMACY TECHNICIAN
2017 WORKING GROUP RECOMMENDATIONS

In 2016, the Missouri Board of Pharmacy convened the Pharmacy Technician Working Group to review Missouri’s regulation of pharmacy technicians. Working Group members were appointed by the Board President as listed in Attachment A.

The Working Group held five (5) meetings in 2016-2017 on the following dates:
- June 23, 2016
- August 5, 2016
- September 30, 2016
- January 27, 2017
- March 22, 2017

SCOPE OF REVIEW

The Working Group was asked to provide input on the following topics:

1. The current state of technician practice (What activities are technicians currently performing in the various practice settings?)
2. Missouri’s pharmacy technician definition (Is the current definition of a pharmacy technician adequate or sufficiently comprehensive?)
3. Current Board regulation (Are technicians adequately or appropriately regulated?)

The Working Group’s recommendations/comments on each topic area are summarized below.

CURRENT STATE OF TECHNICIAN PRACTICE

The Working Group reviewed and discussed pharmacy technician activities in the following practice settings: (1) retail pharmacy, (2) chain retail pharmacy, (3) mail order pharmacy, (4) hospital and (5) other practice settings (e.g., nuclear, long-term care, sterile compounding).

The Working Group’s discussion revealed technician duties vary significantly based on pharmacy services, technician skill and pharmacy resources/staffing. However, the Working Group unanimously agreed Missouri law does not adequately recognize or address activities that appropriately trained technicians are able to perform. Although pharmacy technicians should not perform any function that requires a pharmacist’s discretion or expertise, the Working Group unanimously agreed Missouri law should allow pharmacy technicians to maximize their capabilities with appropriate pharmacist supervision/oversight.

As further discussed below, the Working Group recommends amending Missouri law to recognize three classifications of pharmacy technicians/personnel: (1) registered pharmacy support staff, (2) registered pharmacy technicians and (3) registered advanced pharmacy technicians. Examples of suggested authorized activities for each classification are included in Attachment C. Note: Attachment C is intended for Board guidance purposes and does not include an exhaustive list of all technician functions. Additional technician functions or duties may exist that are not incorporated in Attachment C.
PHARMACY TECHNICIAN DEFINITION

The current pharmacy technician definition is ambiguous and does not clearly define when registration is required for ancillary staff such as delivery drivers, cashier staff and maintenance personal. Additionally, the registration requirements for individuals having “routine, independent access” to the pharmacy as referenced in 20 CSR 2220-2.090 are likewise unclear.

The Working Group recommends amending Missouri law to recognize three classifications of pharmacy technicians/personnel: (1) registered pharmacy support staff, (2) registered pharmacy technicians and (3) registered advanced pharmacy technicians. Proposed definitions for each classification are included in Attachment B.

CURRENT BOARD REGULATION

Pharmacy practice continues to expand providing increased opportunities for pharmacist clinical services that directly enhance patient care. As the pharmacist’s role expands, Missouri law should be amended to empower properly trained pharmacy technicians to perform expanded pharmacy services under appropriate pharmacist supervision/oversight. While technicians should not be allowed to perform any function that requires a pharmacist’s discretion or expertise, maximizing technician capabilities would allow pharmacists to better allocate their time to direct patient care.

Proper training and education is a necessary component of any expansion of pharmacy technician duties. The Working Group recognizes that several states have adopted a mandatory pharmacy technician certification requirement. Several members of the Working Group cautioned that mandatory certification would not ensure competence and could result in detrimentally impact smaller pharmacies, rural communities and other specialty pharmacies (e.g., nuclear). In contrast, other members suggested certification would help ensure a minimum level of competence and/or knowledge in Missouri’s technician workforce.

After considerable discussion, the Working Group’s consensus recommendations for proposed technician training/education requirements are included in Attachment B.

CONCLUSION

The Working Group extends its appreciation to the Board for an opportunity to assist in this important endeavor. Pharmacy practice continues to evolve in ways that will increase access to care and enhance patient safety. To the extent possible, the Working Group recommends that the Board work with statewide pharmacy groups such as the Missouri Pharmacy Association, the Missouri Retailers Association and the Missouri Society for Health System Pharmacists to pursue any necessary statutory or regulatory changes to implement the proposed recommendations in 2018 or as early as possible.
Working Group Members

Pharmacist Representatives
1) Fred Gattas (Nuclear)
2) Mike Stuart (Independent Pharmacy)
3) Erica Hopkins (Independent Pharmacy)
4) Melody Savley (Independent Pharmacy)
5) Koby Prater (Independent Pharmacy)
6) Ed Alviso (Aetna/Mail Order)
7) Susan Lanctot (Express Scripts)
8) Kristol Chism (Walgreens)
9) Lindsey Wendorff (CVS)
10) Timothy Koch (Wal-Mart)
11) David Wolfrath (Hospital Pharmacy)

Association Representatives
12) Ron Fitzwater (MPA)
13) David Overfelt (Missouri Retailer’s Association)
14) Diane McClaskey (MSHP)
15) Bert McClary (Missouri Hospital Advisory Committee)

Technician Representatives
16) Krista Kippenberger, CPhT
17) Tim Michaelree, (Technician)
18) Susan Pappas (Red Cross Pharmacy)
19) Steve Edwards (Express Scripts)

Advisory Members
20) Jessica Langley (National Healthcareer Association)
21) Miriam Mobley-Smith (PTCB)
22) Kelly Prater (Vatterott)/Veralynn Hilliard***
23) Karen Shaw (Pharm. Tech Program Director, St. Louis College of Health Careers)***
24) Barbara Bilek (Bd. Member)
25) Pam Marshall (Bd. Member)

** Appointed but did not attend***
## WORKING GROUP PROPOSED RECOMMENDATIONS

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<tr>
<th>Classification</th>
<th>Definition</th>
<th>Requirements</th>
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| Registered Pharmacy Support Staff | Any individual with physical access to, or the authority to order legend medication, except for individuals with incidental access to the pharmacy that are under the direct supervision of a Board licensee or registrant. | • Application  
• Criminal history background check |
| Registered Pharmacy Technician | An individual who:  
1. Provides a technical or support role for the practice of pharmacy  
2. Performs any activity that has any effect on the practice of pharmacy or an effect on dispensing/filling prescriptions  
3. Produces or processes prescriptions | • Minimum age of sixteen (16)  
• Application  
• Criminal history background check  
• Complete an employer based training program with minimum training elements established by the Board. |
| Registered Advanced Pharmacy Technician | A pharmacy technician performing advanced technical skills, exercising increased independence or performing a clinical practice support role, as defined by the Board by rule. | • Minimum age of sixteen (16)  
• Application  
• Criminal history background check  
• Pass a NCCA accredited pharmacy technician examination  
• Maintain active CPhT certification.  

In addition to the registered pharmacy technician training, registered pharmacy advanced technicians should also be required to:  
• Complete an accredited pharmacy technician training program, or  
• Complete an employer based training program that includes didactic and experiential training that is focus on the advanced technician skills to be performed.  

***For nuclear pharmacy technicians, successful completion of a certificate nuclear pharmacy technician training program from an ACPE accredited provider would be acceptable. However, an advanced nuclear pharmacy technician registration via certification would not be portable.***
**Additional Recommendations:**

- To prevent workforce interruptions, individuals registered with the Board should be authorized to begin training for a specific technician class once registered with the Board. Pharmacies should be required to maintain a list of all technicians in training for a specific class and the beginning training date.

- All training must be completed within one (1) year. Employers should have discretion to grant a six (6) month extension for good cause. To prevent abuse, technicians who do not complete their training within the required 1 year (or 18 months with an employer extension) should be required to wait a minimum of six (6) months before restarting a training program.

- Future rules/legislation should include a grandfather clause that would allow all currently registered technicians to obtain the registration that corresponds to their current duties. To assist the Board, the enabling rule/legislation could require certification or attestation from a licensed pharmacist that the technician qualifies for the requested classification.
AUTHORIZED TECHNICIAN DUTIES BY CLASSIFICATION

REGISTERED PHARMACY SUPPORT STAFF

Note: Attachment C is intended for guidance purposes and does not include an exhaustive list of all technician functions. Additional technician functions or duties may exist that are not incorporated herein.

1. Patient scheduling
2. General customer service
3. Contacting patient when Rx not picked-up
4. Placing drug orders
5. Providing final drug product to patient
6. Rx delivery (internal & external)
7. Selling PSE products
8. General recordkeeping¹
9. Preparing pharmacy reports for pharmacy review¹
10. Monitoring technician registrations (licensing, discipline)¹
11. Managing technology systems, including, programming, routine database management and billing systems
12. General insurance billing/auditing¹
13. Insurance building auditing with access to the Rx system
14. Adding/updating third party insurance information¹
15. Managing/medication/patient assistance programs (a reg. technician duty if tech is doing more than processing paperwork)

¹ If they have access to the pharmacy.
REGISTERED PHARMACY TECHNICIANS

1. Monitoring Drug Shortages
2. Processing outdate returns
3. Checking/removing outdated/expired meds
4. Maintaining storage/dispensing devices
5. Retrieving medication for dispensing
6. Determining pick-up times
7. Bagging prescriptions
8. Making the offer to counsel
9. Insurance billing/auditing
10. Managing controlled substance systems
11. Managing/medication/patient assistance programs (a support staff/tech duty if just processing paperwork)
12. Following up on missing meds
13. Following up on chart omissions
14. Establishing medication planners for patients
15. Inventory audits
16. Obtaining patient information (other than patient history)
17. Obtaining patient history
18. Prescription data entry & affixing prescription labels
19. Prescription data entry for high risk/ hazardous drugs
20. Counting/preparing prescriptions (new and refill)
21. Inventory
22. Filling first dose (rather than unit doses)
23. Unit dose repackaging
24. Obtaining refill authorization
25. Calling other pharmacies for patient information
26. Requesting/giving transfer information
27. Non-Sterile Compounding
28. Taking/recording verbal prescription information
29. Contacting prescriber for Rx clarification
30. Contacting prescriber for Rx changes
31. Training/Educating support technicians or other registered technicians
32. Obtaining prior authorization
33. Reviewing patient charts to identify medication allergies for RPh follow-up
34. Gathering patient data for drug use evaluations
35. Establishing patient medication planners
36. Preparing clinical monitoring information
REGISTERED ADVANCED PHARMACY TECHNICIANS

1. Dispensing final prescriptions from a remote location/Working under remote supervision

2. Chemo/nuclear preparation or preparation of hazardous injectables

3. Sterile compounding

4. Training/educating an advanced technician

5. Remote video monitoring or remote supervision by a pharmacist

6. Checking other tech pharmacy activities (tech-check-tech)

7. Blood pressure checks

8. Monitoring IV med rates

9. Medical records screening (for RPh intervention based on screening criteria)

10. Medical history assessment/Patient Screening

11. Point-of-Care Testing

12. Conducting or reviewing quality improvement/compliance programs

Technicians are not currently authorized to perform this activity, however, the Working Group recommends including this item as an advanced technician function if allowed by the Board in the future. The activity has been included for Board guidance purposes only and does not constitute an official Working Group recommendation that the practice be allowed.
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 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 2220-6.070 Certificate of Medication Therapeutic 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 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 post-graduate 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;
7. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
8. Medication reconciliation;
9. Drug utilization review;
10. Applicable state or federal law;
11. Formulating and documenting personal medication records;
12. Documenting clinical outcomes;
13. Interpreting, monitoring, ordering, and assessing patient test results; and
(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.


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 review 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 ordered 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 be responsible for the oversight of the medication therapy services provided by the pharmacist that are authorized by protocol. The authorizing physician shall also 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 three (3) 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 blood-clotting products.

(1) Definitions. The following definitions are hereby adopted and applicable to this rule:

(A) “Bleeding disorder,” a medical condition characterized by a deficiency or absence of one (1) or more essential blood-clotting components in the human blood, including all forms of hemophilia, acquired hemophilia, von Willebrand’s disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood-clotting. As defined by section 338.400, RSMo, “bleeding disorder” does not include a bleeding condition secondary to another medical condition or diagnosis, except for acquired hemophilia;

(B) “Blood-clotting product,” a medicine approved for distribution by the federal Food and Drug Administration (FDA) that is used for the treatment and prevention of symptoms associated with bleeding disorders, including, but not limited to, recombinant and plasma derived factor products, von Willebrand factor products, antifibrinolytics, bypass products for patients with inhibitors, prothrombin complex concentrates, and activated prothrombin complex concentrates. Except as otherwise provided by section 338.400, RSMo, a “blood-clotting product” does not include medical products approved solely for the treatment or prevention of side effects of a blood-clotting drug or medication;
(C) “Established patient,” For purposes of section 338.400, RSMo, and this rule, an “established patient” shall be defined as a bleeding disorder patient that has been dispensed a legend blood-clotting product by the pharmacy on more than three (3) occasions in a single calendar year; and

(D) “Pharmacy,” an entity engaged in the practice of pharmacy as defined in section 338.100, RSMo, that provides blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders.

(2) General Requirements. All Missouri licensed pharmacists and pharmacy permit holders shall comply with the following requirements when dispensing blood-clotting factor concentrates:

(A) Prescriptions for blood-clotting factor concentrates shall be dispensed as written or authorized by the prescribing physician, in accordance with state and federal law. No changes or substitutions shall be made unless approved by the prescriber. If the pharmacy has received prescriber authorization to change or substitute the blood-clotting factor concentrate originally prescribed, the patient or the patient’s designee shall be notified and counseled regarding the change or substitution prior to dispensing via the preferred contact method identified by the patient or designee pursuant to subsection (2)(E);

(B) If requested by the patient or the patient’s designee, the pharmacy shall ship and deliver blood-clotting factor concentrates to the patient or the patient’s designee as prescribed within two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations. Nonemergency situations shall include, but may not be limited to, routine prophylaxis requests. Appropriate cold chain management and packaging practices must be used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements;

(C) Patients must be provided with a designated pharmacy contact telephone number for reporting problems with a delivery or product on each dispensing at no cost to the patient;

(D) Unless otherwise authorized by the patient or the patient’s designee, the pharmacy shall contact the patient for authorization to dispense prior to shipping a refill of any blood-clotting product to the patient. The date of patient authorization shall be documented in the pharmacy’s prescription records;

(E) Barring extenuating circumstances, prescriptions for blood clotting factor concentrates shall be dispensed within plus or minus ten percent (10%) of prescribed assays, or as otherwise authorized or directed by the prescriber; and

(F) Recalls or Withdrawals. Prior to dispensing any blood clotting factor concentrate, the pharmacy shall ask the patient or the patient’s designee to designate a preferred contact method for receiving notifications in the event of a recall or withdrawal of the concentrate dispensed or any related ancillary infusion equipment and supplies dispensed by the pharmacy. The preferred contact method shall be documented with the patient information required by 20 CSR 2220-2.190(2).
1. Notice of concentrate or ancillary infusion equipment and supplies recalls and withdrawals shall be provided to the patient via the patient’s preferred contact method within twenty-four (24) hours of receipt of a recall or withdrawal notification from the manufacturer or any state or federal entity that requires or recommends patient notification. The pharmacy shall also notify the prescribing physician within twenty-four (24) hours of such recall or withdrawal and shall obtain a prescription for an alternative product if a new or amended prescription is required to dispense or deemed necessary and appropriate by the prescriber.

2. If attempts to contact the patient via the preferred contact method are unsuccessful, the pharmacy shall mail notification to the patient or the patient’s authorized designee within the required twenty-four (24) hours or the next business day.

3. The time, date, and method of notification to the patient and prescriber shall be documented in the pharmacy’s records and maintained for two (2) years from the date of recall or withdrawal.

(3) In addition to the provisions of section (2), pharmacies that dispense blood-clotting products to established patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, shall comply with the following standards of care:

(A) The pharmacy shall annually notify the board in writing of the pharmacy’s intent to provide legend blood-clotting products for bleeding disorder patients. Notification shall be made on or before January 31 of each calendar year in a manner and form approved by the board;

(B) The pharmacy shall identify in advance, or make arrangements with, a supplier or suppliers capable of providing all brands, assays, and vial sizes of blood-clotting products approved by the federal FDA, including products manufactured from human plasma and those manufactured from recombinant technology techniques. A list of all designated or identified suppliers shall be maintained at the pharmacy and made available during inspection. This requirement shall not be construed to require a pharmacy to purchase products prior to receiving a valid prescription order;

(C) A pharmacist shall be available twenty-four (24) hours a day, seven (7) days a week, every day of the year, either on-site or on call, to fill prescriptions for blood-clotting products, within the time frames designated by section 338.400, RSMo, and the provisions of this rule;

(D) Pharmacists engaged in dispensing or filling blood-clotting factor concentrates or who provide patient counseling regarding blood-clotting factor concentrates to bleeding disorder patients shall have sufficient knowledge, experience, and training to perform the duties assigned. To ensure continued competency, pharmacists engaged in counseling bleeding disorder patients shall complete four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment or therapy, or blood-clotting disorders or diseases each biennial renewal period. The continuing education required by this rule may be used to satisfy the pharmacist’s continuing education requirements. Proof of compliance with this section shall be maintained at the pharmacy for a minimum of four (4) calendar years and shall be made available during inspection or at the request of the board;
If requested by the patient or the patient’s designee, the pharmacy shall provide for the shipment and delivery of blood-clotting products to the patient or the patient’s designee as prescribed within two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations;

(F) Established patients shall be provided access to blood-clotting products within twelve (12) hours of notification from a physician of the patient’s emergent need for a blood-clotting product. For purposes of this section, determination of an emergent need shall be within the professional medical judgment of the physician. Emergent need requests shall be documented in the pharmacy’s prescription records;

(G) The pharmacy shall provide or have available for purchase containers for the disposal of hazardous waste, including, but not limited to, sharp or equivalent biohazard waste containers;

(H) At a minimum, the pharmacy shall provide or have available for purchase ancillary equipment and supplies required to infuse a blood-clotting therapy product into a human vein, including, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, and cold compression packs. If supplies are depleted, the pharmacy shall restock the required ancillary equipment and supplies in a reasonable amount of time which shall not exceed seven (7) calendar days;

(I) The pharmacy shall have contact information available for a nurse or nursing service or agency with experience in providing infusion related nursing services or nursing services for bleeding disorder patients if such services are not provided by the pharmacy;

(J) If requested by the patient or the patient’s authorized designee, the pharmacist shall explain any known insurance copayments, deductibles, coinsurance payments, or lifetime maximum insurance payment limits. For purposes of complying with this section, the pharmacy may rely on information supplied by the patient’s insurer; and

(K) The pharmacy shall register with the National Patient Notification System, or its successor, to receive recall notification for all products included in the National Patient Notification System. The pharmacy shall maintain current and accurate contact information with the National Patient Notification System.

Pharmacies that provide legend blood-clotting products to treat or prevent symptoms of established bleeding disorder patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, shall develop and follow written policies and procedures to ensure compliance with section 338.400, RSMo, and the provisions of this rule. The pharmacy shall review the policies and procedures on an annual basis and document such review. At a minimum, the pharmacy’s written policies and procedures must include procedures for:

(A) Processing prescriptions for blood-clotting products by pharmacy staff to ensure the timely handling and dispensing of blood-clotting products;

(B) Processing partial fill requests by patients to reduce or eliminate excessive dispensing;

(C) Providing and documenting recall notifications in accordance with this rule;
(D) Transferring, dispensing, refilling, or delivering blood-clotting factor concentrates to established patients in the event of an emergency or disaster;

(E) Notifying patients prior to terminating business or terminating the dispensing of any blood-clotting factor concentrate or prior to a known or an anticipated termination of pharmacy services for a bleeding disorder patient. Notification shall be provided in writing and, when reasonably possible, shall be provided a minimum of seven (7) days prior to any such termination;

(F) Shipping or providing blood-clotting products to the patient within the time frames required herein;

(G) Receiving, processing, and dispensing prescription or dispensing requests for a blood-clotting product to bleeding disorder patients, including procedures for handling and processing physician request indicating a patient’s emergent need for a blood-clotting product;

(H) Ensuring appropriate cold chain management and packaging practices are used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements; and

(I) Handling and processing preauthorization notifications and requests and communicating preauthorization requirements to the patient and applicable prescriber.

(5) This rule shall not be construed to require dispensing without appropriate payment or payment arrangements. If the pharmacy is waiting for authorization, certification, or other action from a third-party payer prior to dispensing, the pharmacy shall notify the patient that the prescription is available for dispensing and explain any alternative payment options. Notification shall be provided as soon as reasonably practicable. At a minimum, however, notification shall be provided to the patient prior to the expiration of the shipping and delivery time frames required by subsection (2)(E), (3)(B), or (3)(F) of this rule.
