MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

March 7, 2018
3:00 p.m.

Notice is hereby given that the Missouri Board of Pharmacy will be meeting at 3:00 p.m. on November 15, 2017 via conference call. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3605 MO Blvd, Jefferson City, Missouri at 3:00 p.m. on March 7, 2018.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes pursuant to Section 610.021(1), (13) and (14) and section 324.001.8, RSMo. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

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

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

March 7, 2018
3:00 p.m.

OPEN SESSION AGENDA

1. Call to Order: Christian Tadrus, PharmD, President

2. Roll Call

3. Approval of Minutes
   a. December 19, 2017

4. Final Orders of Rulemaking
   a. 20 CSR 2220-2.085 (Electronic Prescriptions and Medication Orders)
   b. 20 CSR 2220-6.040 (Administration by Prescription Order)
      1. CVS Health Comments
      2. Missouri Academy of Family Physicians Comments

5. General Administration Report
   a. Budget Update
   b. 2018 Legislation
   c. Strategic Planning Meeting Date
   d. Future Meeting Dates/Times

6. SB 1068

7. The Board may go into closed session at any point during the meeting and all
   votes, to the extent permitted by law, pertaining to and/or resulting from this
   closed meeting will be closed under Section 610.021(1), (5), (7), and (14) and
   under Section 324.001.8, and .9 RSMo. The Board will return to open session at
   the conclusion of discussion on closed session items.

8. Adjournment
The Missouri Board of Pharmacy met via conference call in open session during the times and dates stated in the following minutes. The meeting was called to order by President Christian Tadrus at approximately 1:33 p.m. on December 19, 2017. Each item in the minutes is listed in the order discussed.

**Board Members Present**
Christian Tadrus, PharmD, President
Douglas Lang, R.Ph., Vice-President
Barbara Bilek, PharmD, Member
Christina Lindsay, PharmD, President
Pamela Marshall, R.Ph., Member
Anita Parran, Public Member

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Jennifer Luebbert, Administrative Coordinator
Sarah Decker, Compliance Coordinator

**Others Present**
Curtis Thompson, General Counsel

PRESIDENT CHRISTIAN TADRUS CALLED THE MEETING TO ORDER AT APPROXIMATELY 1:33 P.M. AND ROLL CALL WAS TAKEN.

**ITEM #3  NON-RESIDENT PHARMACY RULE**

**DISCUSSION:** Executive Director Kimberly Grinston reported the public rule comment period has closed; One comment was received from the Accreditation Commission for Health Care (ACHC) asking the Board to recognize ACHC as an inspection entity for sterile compounders. Board members expressed concerns with recognizing a specific third-party vendor, however, Board members agreed qualified third-party entities could perform a satisfactory inspection. Board discussion held; Board consensus to accept an inspection by a Board approved entity. **A motion was made by Pamela Marshall, seconded by Douglas Lang, to approve the final order of rulemaking with a modification to section (2)(G) that allows “a similar inspection by an entity approved by the Board.”** Motion passed 5:0:0:0 by roll call vote as follows:
ITEM #4  NABP Recommendation of the Task Force on the Regulation of Telepharmacy Practice

DISCUSSION: Board consensus to table until April; No discussion held.

ITEM #5  SB 501 Review of Proposed Changes to 19 CSR 30-20.100 (Pharmacy Services and Medication Management)

DISCUSSION: Kimberly Grinston presented proposed language from the Missouri Hospital Association (MHA) that would allow remote technician supervision and “tech-check-tech” in hospital pharmacies regulated by the Missouri Department of Health and Senior Services (DHSS). Board members expressed concerns regarding fragmenting technician regulatory requirements based on practice setting. The following additional Board discussion was held:

• Pamela Marshall suggested the proposed MHA rule could be used as a vehicle to incorporate minimum technician training standards.
• Barbara Bilek indicated she is not opposed to the concept and noted the proposal could benefit and possibly expand hospital services, especially for critical access hospitals. However, Ms. Bilek expressed concerns regarding the lack of specific supervision requirements and the proper pharmacist to technician ratio.
• Anita Parran supported the enhanced technician training proposal but noted the higher standard should be applicable to all practice settings.
• Douglas Lang suggested remote technician supervision can be safely performed but noted the presented language did not address items such as required policies/procedures, pharmacist responsibilities, pharmacist-in-charge (PIC) responsibilities, minimum practice requirements and allowed technician duties. Tom Glenski reported the language appears to rely on CMS’ federal Conditions of Participation but questioned if the Conditions of Participation adequately address Mr. Lang’s concerns.
• Christina Lindsay stated the Board should be willing to work with MHA and DHSS but expressed concerns with officially supporting the proposal given multiple concepts have not been addressed.
• Christian Tadrus expressed concerns with creating standards of practice that are inconsistent, not well-defined and difficult to enforce. Mr. Tadrus supported the discussion but suggested the proposal may be misaligned with the purported goal.

Board consensus to issue a letter to DHSS, approved by the Board President, expressing the aforementioned concerns and offering to assist DHSS with developing the appropriate regulatory approach.

ITEM # 6  Executive Director Updates
DISCUSSION: Kimberly Grinston presented the proposed “Red Tape” rule amendments included in the agenda. Mrs. Grinston noted only minor changes have been made to comply with the Governor’s Executive Order but noted more substantive changes may be appropriate in the future. Board discussion held; Douglas Lang asked if substantive rule changes could be made to the same rules at a later time. Kimberly Grinston reported the agencies have been told additional rule amendments would be accepted. A motion was made by Barbara Bilek, seconded by Christina Lindsay, to approve the proposed rule amendments and rescissions included in the Board agenda. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes       Christina Lindsay – yes

ITEM # 7   Future Meeting Dates/Topics

DISCUSSION: Kimberly Grinston asked if an electronic Board member survey/comment tool would be a helpful way to gather rule comments prior to Board meetings. Barbara Bilek added the electronic survey might unintentionally add to Board member review time; Douglas Lang questioned if the survey would add additional work for Board staff. Board consensus to try a test survey for the February meeting and then evaluate potential benefit.

MOTION TO CLOSE 2:49 P.M.

At 2:49 p.m., Pamela Marshall made a motion, seconded by Barbara Bilek, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes       Christina Lindsay – yes

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 3:51 p.m.

MOTION TO ADJOURN

At approximately 3:51 p.m., a motion was made by Pamela Marshall, seconded by Anita Parran, to adjourn the December 19, 2017, open session conference call meeting. Motion passed 3:0:0:2 by roll call vote as follows:

Anita Parran – yes       Christina Lindsay –absent

Missouri Board of Pharmacy
Open Minutes - Conference Call
December 19, 2017
Page 3 of 4
The meeting was adjourned.

__________________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
Via Electronic Mail

February 14, 2018

Kimberly Grinston JD
Executive Director
Missouri Board of Pharmacy
3605 Missouri Boulevard
Jefferson City, MO 65102
pharmacy@pr.mo.gov

Re: 20 CSR 2220-6.040 Administration by Medical Prescription Order comments proposed amendment

Dear Director Grinston,

I am writing to you in my capacity as Pharmacy Regulatory Affairs Director for CVS Health and its family of pharmacies located across the country. CVS Health appreciates the opportunity to submit comments on the Missouri Board of Pharmacy ("Board") proposed amended rule concerning 20 CSR 2220-6.040 Administration by Medical Prescription Order and would like to thank the Board for their constant vigilance to continuously improve regulations that enhance patient care and guide the practice of pharmacy in Missouri.

Through our integrated offerings across the spectrum of pharmacy care, we are uniquely positioned to provide greater access to care and engage patients in behaviors that improve their health. CVS Health provides multiple points of care to patients via our retail, mail, infusion, long-term-care, specialty pharmacies and MinuteClinics.

CVS Health appreciates the work accomplished by the Board to update and clarify requirements for pharmacists administering medication by prescription order. Attached please find a document with comments in red font.

Recordkeeping is a key component associated with the practice of pharmacy. While it is important that Board requested records are retrieved timely we feel that a twenty four hour window be provided so that the pharmacist can continue to service patients and obtain the needed records during a time that would not interfere with patient care. In addition many patients may not have a primary care provider and therefore language was updated to compensate for this patient population. As pharmacists move forward and
practice at the top of their license, medication administration will be a normal part of their pharmacy practice setting. We feel that notification should not be required during pharmacist’s licensure renewal.

CVS Health appreciates the opportunity to submit comments for 20 CSR 2220-6.040 Administration by Medical Prescription Order. If you have any questions, please contact me directly at 614-572-9008.

Best regards,

[Signature]

John Long RPh, MBA

Enclosures: 1
PROPOSED AMENDMENT

The board is amending the purpose statement, sections (1)–(6), replacing section (7), and adding new section (8).

PURPOSE: This amendment updates and clarifies requirements for pharmacists administering medication by prescription order.

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

(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) [The] Except as otherwise provided by law, a pharmacist may not delegate [the] medication administration to another person, except to [a] an intern pharmacist [intern] who has met the qualifications under subsections [(3)(B), (C), and (E)] and is working under the direct supervision of a pharmacist [qualified] who has met the qualifications to administer drugs pursuant to a medical prescription order. Proof of an intern’s compliance with subsections (3)(B)–(E) must be maintained by both the supervising pharmacist and the intern pharmacist for a minimum of two (2) years.

(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 healthcare 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 an in-person skills assessment;

(C) Successfully complete a certificate program in [the administration of drugs] medication administration and emergency procedures accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE or regionally accredited pharmacy or medical school/college or [a similar health authority or professional body] approved by [the State] Board of Pharmacy. [The certificate program must cover all routes of administration the pharmacist utilizes;] The required training program must provide instruction in—

1. Administration techniques, including 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) 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; and

(E) Proof of compliance with this section must be maintained for a minimum of two (2) years.


(A) [A pharmacist shall administer drugs] Medication must be administered in compliance with all applicable state and federal laws, including applicable Vaccine Information Statements and informed consent requirements. Except as otherwise authorized by law, vaccines must also be administered in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer’s guidelines.

[(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, including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. The manual shall be reviewed annually and be available for inspection by the State Board of Pharmacy or authorized representative.]

(B) Pharmacists must have a current and accurate written policy and procedure manual covering all aspects of administering drugs by medical prescription order, including:

1. Drug administration procedures;
2. Authorized routes of administration;
3. Drug storage;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal and disposal of used/contaminated supplies;
6. Identifying and handling acute adverse events or immunization reactions, including anaphylactic reactions; and

7. Recordkeeping and notification procedures and requirements.

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

(D) Patients must be asked to 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 for Administration. At a minimum, the medical prescription order from a licensed prescriber must contain at a minimum the following:

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

(E) The date of the original order; and

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

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

(6) 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. Pharmacists administering or supervising administration of medication pursuant to this rule shall ensure the following records are manually or electronically maintained separate from the prescription files of a pharmacy for each administration:

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 name and dose. For vaccines and biologics, the manufacturer, expiration date, and lot number must also be documented and recorded;

4. For vaccines, the name and address of the patient’s primary health care provider, as identified by the patient or an indication that a primary health care provider was not provided;

5. The identity of the administering pharmacist, or if applicable, the administering intern pharmacist and his/her supervising pharmacist; and

6. If applicable, the nature of an adverse reaction and who was notified, if applicable.

(B) All records required by this regulation shall be kept by the pharmacist and 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. for two (2) years from the date of such record. Except as otherwise required by section (3), records must be kept at the pharmacy where the prescription order
is maintained. If not administered on behalf of a pharmacy, records not maintained at a pharmacy may be securely stored at a location designated by the pharmacist. Records maintained at a pharmacy must be produced immediately or within twenty four (24) two (2) hours of a request from the board or the board’s authorized designee. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

[(7) Notification Requirements.

(A) A pharmacist administering drugs pursuant to a medical prescription order shall notify the prescriber within seventy-two (72) hours after administration of the following:

1. The identity of the patient;
2. The identity of the drug 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, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction.

(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.]

(7) Notification Requirements. Pharmacists administering or supervising administration of medication under this rule, shall ensure:

(A) The patient’s primary health care provider, if any, is notified of the following within fourteen (14) days of administering a vaccine:

1. The identity of the patient;
2. The 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) The prescriber is notified within twenty-four (24) hours after learning of an adverse event or reaction experienced by a patient following administration. Notification is mandatory and cannot be waived;

(C) Any notifications required by state and federal law are properly completed and documented; and
(D) Notifications required by this section may be made electronically or in writing or 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 maintained as required by subsection (6)(B) or electronically retrievable at the request of the board or the board’s authorized designee.

(8) Notification of Intent Refiling. To continue administration, a Notification of Intent to administer drugs by medical prescription order must be refiled with the board biennially along with the pharmacist’s Missouri pharmacist license. To refile, a pharmacist must meet the requirements of subsection (3)(B) above.


PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri State Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.
February 14, 2018

Missouri State Board of Pharmacy
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102

To Whom It May Concern:

On behalf of the Missouri Academy of Family Physicians, I would like to thank you for the opportunity to submit the following comments related to changes in the proposed rules as published in the January 16, 2018, Missouri Register:

**Title 20, Division 2220, Chapter 6, (6) Record Keeping, Paragraph 4**
Delete the added language "...or an indication that a primary health care provider was not provided". If a patient is receiving the immunization with a specific order for a specific patient, the order must have originated from a "provider, prescriber, or physician". There is no need to allow the provision that the ordering "provider, prescriber, or physician" not be notified.

**Title 20, Division 2220, Chapter 6, (7) Notification Requirements, Paragraph (A)**
It is unreasonable to allow two weeks for the notification to occur. During that time, a patient may be seen in a physician’s office, emergency department, or hospital, and additional immunizations unnecessarily provided. The current 72-hour notification is more than adequate. Many times, the physician is not notified at all.

**Title 20, Division 2220, Chapter 6, (7) Notification Requirements, Paragraph (C)**
Consider language that compels the pharmacist to be certain that the immunization is recorded in the state immunization registry at the time of administration to prevent duplicate and unnecessary immunizations.

Again, the Missouri Academy of Family Physicians greatly appreciates your willingness to consider our perspective as these rules are crafted. Please feel free to contact the Missouri Academy office if additional information is needed.

Sincerely,

[Signature]
Kathleen Eubanks-Meng, DO
Chair
Title 20—DEPARTMENT OF INSURANCE,  
FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 6—Pharmaceutical Care Standards

PROPOSED RULE

ORDER OF RULEMAKING

By the authority vested in the Missouri Board of Pharmacy under sections 338.140, and 338.280, RSMo 2016 and section 330.010.1, RSMo Supp. 2017, the Board of Pharmacy adopts a rule as follows:

20 CSR 2220-6.040 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the Missouri Register on January 16, 2018 (43 MoReg. 86-88). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the Code of State Regulations.

SUMMARY OF COMMENTS: The Board received six (6) comments in response to the proposed rule.

COMMENT # 1: CVS Health asked the Board to amend section (6)(B) to allow production of required records within twenty-four (24) hours of a request from the Board or the Board’s designee in lieu of the proposed two (2) hours.

RESPONSE AND EXPLANATION OF CHANGE:

COMMENT # 2: CVS Health suggested modifying section (7)(A) to clarify that notification to the patient’s primary health care provider is only required if a primary health care provider is identified by the patient.

RESPONSE AND EXPLANATION OF CHANGE: The comment is consistent with the Board’s intent. Section (7)(A) has been amended as suggested to provide clarity.

COMMENT # 3: CVS Health suggested the Board delete proposed section (8) which requires biennial filing of a Notification of Intent to administer medication by prescription order.

RESPONSE AND EXPLANATION OF CHANGE: The biennial notification requirement would allow the Board to identify and track pharmacists administering medication by prescription order. Significantly, the proposed amendment aligns the required notification with pharmacy renewals to better accommodate licensees and reduce required filings. No change has been made in response to the comment.

COMMENT # 4: The Missouri Academy of Family Physicians (MAFP) opposed amending section (6)(A)4. which would require that pharmacist administration records include the name and address of the patient’s primary health care provider or an “indication that a primary health care provider was not provided.” MAFP
suggested the amendment is unnecessary because the prescription order must have originated from a provider, prescriber or physician.

RESPONSE AND EXPLANATION OF CHANGE: While the prescription order must originate from an authorized prescriber, the patient may not have a “primary health care provider.” This issue was specifically raised with indigent or uninsured patients that may not be under a healthcare practitioner’s regular care. The proposed amendment was intended to clarify that pharmacy records must clearly identify when a primary health care provider is not designated or identified by the patient. No change has been made in response to the comment.

COMMENT #5: MAFP suggested the Board retain the seventy-two (72) hour prescriber notification requirement.

RESPONSE AND EXPLANATION OF CHANGE: The Board has received complaints from both prescribers and pharmacists indicating the 72-hour notification requirement is burdensome and unnecessary. The Board believes the proposed fourteen (14) day notification will protect the public while reducing unnecessary regulation. The Board also recognizes prescriber notification is not required for other prescription items. No change has been made in response to the comment.

COMMENT #6: MAFP suggested the Board mandate reporting to the state immunization registry to prevent duplicate and unnecessary immunizations.

RESPONSE AND EXPLANATION OF CHANGE: The Board agrees reporting to the state immunization registry would be beneficial for both prescribers and patients. Legislation is currently pending to require ShowMeVax reporting as suggested. Accordingly, no change has been made in response to the comment at this time. However, the Board may reconsider the suggestion if the legislation is not enacted.

20 CSR 2220-6.040 Administration by Medical Prescription Order.

(7) Notification Requirements. Pharmacists administering or supervising administration of medication under this rule, shall ensure:

(A) The patient’s primary health care provider, if any, is notified of the following within fourteen (14) days of administering a vaccine:
   1. The identity of the patient;
   2. The vaccine administered;
   3. The route of administration;
   4. The anatomic site of the administration;
   5. The dose administered; and
   6. The date of administration;
PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Registration for the Healing Arts, PO Box 4, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 751-3166, or via email at healingarts@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2150—State Board of Registration for the Healing Arts
Chapter 7—Licensing of Physician Assistants

PROPOSED RESCISSION

20 CSR 2150-7.136 Request for Waiver. This rule established procedures for individual physician-physician assistant teams to apply for alternate minimum amounts of on-site supervision and maximum distance between the supervising physician and physician assistant.

PURPOSE: The rule is being rescinded since the current statute no longer requires providers to obtain a waiver before practicing thirty (30) to fifty (50) miles apart.


PUBLIC COST: This proposed rescission will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rescission will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rescission with the State Board of Registration for the Healing Arts, PO Box 4, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 751-3166, or via email at healingarts@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

20 CSR 2220-2.085 Electronic [Transmission of Prescription Data] Prescriptions and Medication Orders. The board is amending the title, purpose statement, amending section (1), deleting current section (2), and adding new sections (2) and (3).

PURPOSE: This amendment updates and clarifies requirements for electronic prescriptions.

PURPOSE: This rule establishes [basic guidelines to address new technology for the transmission of prescription data utilizing electronic mediums] guidelines for electronic prescriptions and medication orders.

(1) Definitions.
[(A) Electronic transmission prescription—Includes transmission of both image and data prescriptions.
(B) Electronic image transmission prescription—Any prescription order for which an exact visual image of the order is received by a pharmacy from a licensed prescriber.
(C) Electronic [data transmission] prescription—Any prescription or medication order that is electronically transmitted from a licensed prescriber or the prescriber’s authorized agent (e.g., a facsimile/scan).
(D) Electronic signature—Means a confidential personalized digital key, code, number or other identifier used for secure electronic data transmissions which identifies and authenticates the signatory. Electronic signatures may be sent as part of an electronic transmission prescription to a pharmacy or it may be applied to a hard copy to be provided to the patient.] An exact electronic replica of the prescriber’s
signature or a confidential digital key code, number, or other identifier attached to or logically associated with a record that is executed or adopted by a prescriber with the intent to sign the record.

(12) When a prescription is transmitted to a pharmacy electronically, the following requirements must be met:

(A) The original electronic facsimile transmission (FAX) document or all information from an electronic source must be readily retrievable through the pharmacy computer system;

(B) To maintain confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented including the identification of the pharmacist responsible for the alteration;

(C) In verifying the authenticity of a transmitted prescription, the pharmacist shall ensure the validity of the prescription as to its source of origin. Measures to be considered in authenticating prescription drug orders received via electronic transmission include:
   1. Maintenance of a practitioner’s facsimile number reference or other electronic signature file;
   2. Verification of the telephone number of the originating facsimile equipment;
   3. Telephone verification with the practitioner’s office that the prescription as both written by the practitioner and transmitted by the practitioner or the practitioner’s authorized agent;

4. Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure the transmission was initiated by the prescriber;

(D) At the option of the patient, an electronically produced prescription may be sent to a pharmacy electronically or provided as a hard copy generated from the prescriber’s electronic prescribing system;

(E) Hard copy prescriptions presented to the patient generated from electronic media shall be applied to paper that utilizes security features that will ensure that the prescription is not subject to any form of copying and/or alteration; and

(F) Electronic transmission technology utilized by pharmacy personnel shall not be used to circumvent or violate any provision of state and federal drug laws or the Pharmacy Practice Act and accompanying regulations.

(2) Prescriptions or medication orders may be transmitted to a pharmacy by the prescriber or the prescriber’s authorized agent as an electronic image transmission or an electronic prescription.

(A) Electronic image transmissions and electronic prescriptions must contain all information required by state and federal law, including designation of whether generic substitution is authorized. Electronic image transmissions must be formatted as required by section 338.056, RSMo, and bear the prescriber’s manual or electronic signature.

(B) Controlled substance prescriptions and medication orders must comply with state and federal controlled substance laws and regulations and must be signed in accordance with state and federal law.

(C) A pharmacist shall be responsible for verifying the authenticity of any electronic image transmission or electronic prescription prior to dispensing by taking measures which, in his/her professional judgment, may be necessary to ensure the prescription or medication order was initiated or authorized by the prescriber.

(3) In lieu of a manually signed prescription or medication order, a pharmacist may accept a paper prescription or medication order with an electronic signature if the prescription/medication order is applied to paper that utilizes security features that will detect or otherwise identify if the prescription/medication order is subject to any form of copying and/or alteration.


PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri State Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65020, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

PROPOSED AMENDMENT

20 CSR 2220-6.040 Administration by Medical Prescription Order.

The board is amending the purpose statement, sections (1)–(6), replacing section (7), and adding new section (8).

PURPOSE: This amendment updates and clarifies requirements for pharmacists administering medication by prescription order.

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

(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) [The] Except as otherwise provided by law, a 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) (3)(B)–(E) and is working under the direct supervision of a pharmacist [qualified] who has met the qualifications to administer drugs pursuant to a medical prescription order. Proof of an intern’s compliance with subsections (3)(B)–(E) must be maintained by both the supervising pharmacist and the intern pharmacist for a minimum of two (2) years.

(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 healthcare 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 certification program must have included an in-person skills assessment;
(C) [Successfully complete] 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), provided by an ACPE or regionally accredited pharmacy or medical school/college or [a similar health authority or professional body] approved by [the State] Board of Pharmacy. [The certificate program must cover all routes of administration the pharmacist utilizes;] The required training program must provide instruction in—
1. Administration techniques, including 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] 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; and
(E) Proof of compliance with this section must be maintained for a minimum of two (2) years.

(4) General Requirements.

(A) [A pharmacist shall administer drugs] Medication must be administered in compliance with all applicable state and federal laws, including applicable Vaccine Information Statements and informed consent requirements. Except as otherwise authorized by law, vaccines must also be administered in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer’s guidelines.
[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, including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. The manual shall be reviewed annually and be available for inspection by the State Board of Pharmacy or authorized representative.
(B) Pharmacists must have a current and accurate written policy and procedure manual covering all aspects of administering drugs by medical prescription order, including:
1. Drug administration procedures;
2. Authorized routes of administration;
3. Drug storage;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal and disposal of used/contaminated supplies;
6. Identifying and handling acute adverse events or immunization reactions, including anaphylactic reactions; and
7. Recordkeeping and notification procedures and requirements.

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

(D) Patients must be asked to 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 for Administration. At a minimum, [T]he medical prescription order from a licensed prescriber must [contain at a minimum the following] include:

(A) The name of the licensed prescriber issuing or authorizing the order;
(B) The date of the original order; and
(F) The date or schedule, if any, of each subsequent administration; and.
[If] A statement that the drug is to be administered by a pharmacist.

(6) 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.] Pharmacists administering or supervising administration of medication pursuant to this rule shall ensure the following records are manually or electronically maintained separate from the prescription files of a pharmacy for each administration:
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 medication name and dose. For vaccines and biologics, the manufacturer, expiration date, and lot number must also be documented and recorded;
4. [The] For vaccines, the name and address of the patient’s primary health care provider, as identified by the patient or an indication that a primary health care provider was not provided;
5. [The name or identifiable initials of the administering pharmacist] The identity of the administering pharmacist, or if applicable, the administering intern pharmacist and his/her supervising pharmacist; and
6. [The] If applicable, the nature of an adverse reaction and who was notified, if applicable.

(B) All records required by this regulation [shall] must be kept by the pharmacist [and 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] for two (2) years from the date of such record. Except as otherwise required by section (3), records must be kept at the pharmacy where the prescription order is maintained. If not administered on behalf of a pharmacy, records not maintained at a pharmacy may be securely stored at a location designated by the pharmacist. Records maintained at a pharmacy must be 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 must be
produced within three (3) business days of a board request.

(7) Notification Requirements.
(A) A pharmacist administering drugs pursuant to a medical prescription order shall notify the prescriber within seventy-two (72) hours after administration of the following:
1. The identity of the patient;
2. The identity of the drug 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, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction.
(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.

(7) Notification Requirements. Pharmacists administering or supervising administration of medication under this rule, shall ensure:
(A) The patient’s primary health care provider is notified of the following within fourteen (14) days of administering a vaccine:
1. The identity of the patient;
2. The 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) The prescriber is notified within twenty-four (24) hours after learning of an adverse event or reaction experienced by a patient following administration. Notification is mandatory and cannot be waived;
(C) Any notifications required by state and federal law are properly completed and documented; and
(D) Notifications required by this section may be made electronically or in writing or 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 maintained as required by subsection (6)(B) or electronically retrievable at the request of the board or the board’s authorized designee.

(8) Notification of Intent Refiling. To continue administration, a Notification of Intent to administer drugs by medical prescription order must be refiled with the board biennially along with the pharmacist’s Missouri pharmacist license. To refile, a pharmacist must meet the requirements of subsection (3)(B) above.


PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri State Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.
SECOND REGULAR SESSION

SENATE BILL NO. 1068

99TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATER.

Read 1st time February 28, 2018, and ordered printed.

ADRIANE D. CROUSE, Secretary.

AN ACT

To amend chapter 197, RSMo, by adding thereto one new section relating to pharmacy technicians.

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

Section A. Chapter 197, RSMo, is amended by adding thereto one new section, to be known as section 197.710, to read as follows:

197.710. 1. In addition to other services authorized by law or regulation, a pharmacy technician may perform the functions described in this section if he or she is registered as a pharmacy technician under section 338.013 and the technician complies with all of the requirements of this section, as applicable to the function being performed.

2. Such functions performed under this section shall only be performed in a setting where the delivery of hospital pharmaceutical services is subject to regulation under sections 197.010 to 197.120.

3. A pharmacy technician may verify the final product of another pharmacy technician in order to ensure an accurate and timely supply of pharmaceuticals if the pharmacy technician has:

   (1) A valid certificate issued by the national Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians, or their successor organizations; and

   (2) Documented competency in final product verification as attested to by the director of the pharmacy.

4. A pharmacy technician shall not be authorized under this section to independently verify the accuracy of compounded or repackaged drugs that have not previously been verified by a pharmacist.
5. To act as a pharmacy technician under supervision by visual and auditory means by a licensed pharmacist at a different site, the pharmacy technician shall have:

   (1) A valid certificate issued by the national Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians, or their successor organizations; and

   (2) Documented competency in the assigned responsibilities being performed as attested to by the director of the pharmacy.

6. The director of the pharmacy shall be responsible for developing and implementing standards to ensure adequate supervision of pharmacy technicians at a different site.

7. An intern pharmacist licensed by the board of pharmacy under section 338.035 may also perform any activity authorized for pharmacy technicians under this section.

8. Nothing in this section shall be construed to modify the responsibility of the director of the pharmacy to ensure the safe provision of pharmaceutical services.