Notice is hereby given that the Missouri Board of Pharmacy will be meeting at 12:45 p.m. on May 2, 2018 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, 3550 Amazonas Drive, Jefferson City, Missouri at 12:45 p.m. on May 2, 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.
TENTATIVE AGENDA
Missouri Board of Pharmacy
CONFERENCE CALL

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

May 2, 2018
12:45 p.m.
POSTED 4/30/2018

OPEN SESSION AGENDA

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

2. 20 CSR 2220-6.050 (Immunization by Protocol) Final Order of Rulemaking/Review of Public Comments

3. 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.

4. Adjournment
April 6, 2018

Kimberly A. Grinston, JD
Executive Director
Missouri Board of Pharmacy
P.O. Box 625
Jefferson City, MO 65102

E-mail: kimberly.grinston@pr.mo.gov

Re: NACDS Comments re Proposed Rule 20 CSR 2220.6.050, Administration of Vaccines Per Protocol

Dear Director Grinston and Members of the Board:

On behalf of our members that operate approximately 948 pharmacies in the State of Missouri, and in partnership with the Missouri Retailers Association, the National Association of Chain Drug Stores (NACDS) is writing to ask the Board of Pharmacy to make three revisions to its Proposed Rule regarding Administration of Vaccines Per Protocol. We ask the Board to eliminate the requirement to amend vaccine protocols where a pharmacy adds or removes a pharmacist and the requirement to list all non-pharmacy locations for vaccine administration. We also urge the Board to allow pharmacy notification of vaccinations to physicians to be accomplished through submission of records of vaccination to the state vaccine registry.

In Subsection (4)(A)(10) of the Proposed Rule, the Board proposes to require protocols to include the street addresses of any non-pharmacy locations at which the pharmacist may administer vaccines. We ask the Board to delete this requirement and only require that the protocol list the addresses of the pharmacy locations at which vaccines are administered. It is impossible for pharmacies to know, in advance, all of the non-pharmacy locations at which they may be called upon to administer vaccines. During the flu season, they may get calls to administer vaccines at a nursing home or a place of employment. However, they will not know which locations will contact them every year. Accordingly, the Board’s proposed requirement would require amending the protocol each time the pharmacy receives such a call for off-site vaccine administration. This will slow down and hinder pharmacies’ ability to deliver such off-site vaccines and stymie efforts to provide vaccines at convenient locations to Missouri citizens. For this reason, we ask the Board to delete this requirement.

In Subsection (4)(C), the Board proposes to require a protocol to be amended and re-signed by authorizing physician(s) anytime a pharmacist is added. As with the non-pharmacy location address requirement, this proposal will lead to time-consuming amendments throughout the year for pharmacies as pharmacists leave and are replaced...
at various pharmacy locations. Until the protocol is amended, the new pharmacist cannot administer vaccines. This provision also makes it almost impossible for pharmacies to use floating pharmacists to administer vaccines because they would need to amend a protocol each time before a floating pharmacist is used. The better course of action is to recognize that the protocol agreement is between the pharmacy and the authorizing physician(s), allowing any otherwise qualified pharmacist under the employment of the pharmacy to provide vaccines pursuant to the protocol. Accordingly, we ask the Board to make this change.

Finally, in Subsection (6)(E), the Board proposes to allow notification from pharmacists to physicians to occur through any manner provided in the governing protocol, or through a common electronic medication record shared by the physician and the pharmacist. While we have no objection to this requirement, we ask the Board to also allow notification to occur when the pharmacy submits the record of immunization to the state vaccination registry. This is a shared database to which all pharmacists and physicians have access. Accordingly, submission of vaccine records to the registry should accomplish the notification goal of this Subsection. To that end, we ask the Board to allow submission to the state vaccine registry to meet the requirements of Subsection (6)(E).

We thank the Board for the opportunity to share our views on the Proposed Rule on vaccine administration. Our members look forward to implementing a revised version of the Proposed Rule.

Sincerely,

Joel Kurzman
Director, State Government Affairs

CC: David Overfelt, President, Missouri Retailers Association
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 338.220, RSMo 2016, and section 338.010, RSMo Supp. 2017, the Board of Pharmacy adopts a rule as follows:

20 CSR 2220-6.050 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the Missouri Register on March 15, 2018 (43 MoReg. 583-586). 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 three (3) comments on the proposed rule from the National Association of Chain Drug Stores (NACDS).

COMMENT # 1: NACDS suggested amending section (4)(A)(10) to remove the requirement that non-pharmacy immunization sites must be listed in the governing protocol.

RESPONSE AND EXPLANATION OF CHANGE: The Board is willing to consider allowing immunization at other medical care facilities without specific protocol designation (e.g., long-term care facilities). However, section 338.010, RSMo, requires consultation with the Missouri Board of Registration for the Healing Arts (BOHA) to incorporate the suggested change. Accordingly, no changes have been made in response to the suggestion at this time, however, the Board will consult with BOHA for future amendment.

COMMENT # 2: NACDS asked to amend section (4)(C) to remove the requirement that the protocol physician re-sign a protocol when a new pharmacist is added. NACDS alternatively suggested that the rule allow immunization protocols between the physician and pharmacy.

RESPONSE AND EXPLANATION OF CHANGE: After consultation with legal counsel, it appears § 338.010, RSMo, requires a protocol between a physician and the specific pharmacist. As a result, no changes have been made in response to the suggestion.

COMMENT # 3: NACDS suggested amending section (6)(E) to allow reporting to the state vaccination registry in lieu of the proposed notification requirements.

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 suggestion may be reconsidered if legislation is not enacted.
(1) Clinical sites shall be selected which will provide direct care and observational learning experiences to meet the objectives of the course.
(A) Select inter-/professional educational experiences may be utilized to provide learning experiences to meet course and program objectives and outcomes. Clinical personnel with professional licensure or certification in a health-related field may be utilized to augment student learning in their respective areas. Observational/inter-professional experiences [shall] may not exceed twenty percent (20%) of the total clinical program hours. Orientation to the facility does not contribute to the twenty percent (20%).
(D) The ratio of faculty to students in the clinical area shall be designed to promote patient safety and to facilitate student learning with the proper supervision.


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 State Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075, or via email at nursing@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 2200—State Board of Nursing
Chapter 8—Minimum Standards for Approved Veteran’s Bridge Programs of Practical Nursing

PROPOSED AMENDMENT
20 CSR 2200-8.100 Educational Program. The board is amending sections (1) and (5).

PURPOSE: This rule is being amended to reduce unnecessary regulatory restrictions.

(1) General Purpose.

(C) The educational program shall provide planned learning experiences essential to the achievement of the stated philosophy and/or mission and graduate competencies of the program and [shall] demonstrate logical progression.

(5) Syllabus Construction. Syllabi shall be current and available to all faculty, students, and cooperating agencies. Each syllabus shall include:

(H) Clock [or credit] hour requirements related to theory, lab, and clinical instruction. Each syllabus should reflect credit hour requirements for theory, lab, and clinical instruction, if used.


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 State Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075, or via email at nursing@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 2220-6.050 Administration of Vaccines Per Protocol. The board is amending all sections of the rule.

PURPOSE: This amendment eliminates unnecessary restrictions/requirements and updates/clarifies requirements for pharmacists
immunizing by protocol.

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol [authorized by a physician licensed pursuant to Chapter 334, RSMo,] with a Missouri licensed physician who is actively engaged in the practice of medicine. Unless otherwise restricted by the governing protocol, vaccines may be administered at any Missouri licensed pharmacy or at any non-pharmacy location identified in the governing protocol.

(A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with the manufacturer’s guidelines, provided [that a pharmacist shall not administer vaccines] CDC guidelines shall control in the event of a conflict. Vaccines may not be administered to persons under twelve (12) years of age unless otherwise authorized by law.

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

(C) Vaccines must be stored in accordance with CDC guidelines/recommendations and within the manufacturer’s labeled requirements, including, when vaccinating outside of a pharmacy.

(D) A pharmacist may only delegate vaccine administration to an intern pharmacist who has met the qualifications of subsections (3)(B) and (C) of this rule and is working under the direct supervision of a pharmacist qualified to administer vaccines. Proof of an intern’s compliance with subsections (3)(B) and (C) must be maintained by both the supervising pharmacist and the intern pharmacist for a minimum of two (2) years.

(3) Protocol. A provision that allows for termination of the protocol at the request of any party to it at any time.

(4) A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualifications under subsections (4)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines.

(5) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;
2. Time period of the protocol;
3. The identification of the vaccines which may be administered;
4. The identity of the patient or groups of patients to receive the authorized vaccine(s);
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician’s name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street addresses of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

(3) Pharmacist Qualifications. Pharmacists administering vaccines by protocol as authorized by Chapter 338, RSMo, must first file a Notification of Intent (NOI) to administer vaccines with the Missouri Board of Pharmacy. To file an NOI, a pharmacist must—

(A) Hold a current Missouri pharmacist license;
(B) Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification issued by the American Heart Association, the American Red Cross, or an equivalent organization. The qualifying BLS or CPR certification program must have included a live in-person skills assessment; and
(C) Have successfully completed a certificate program in administering vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE or regionally accredited pharmacy or medical school/college or approved by the
Board of Pharmacy. The required certificate program must include a live/in-person training component and include instruction in:

1. Current CDC guidelines and recommendations for vaccines authorized by Chapter 338, RSMo, including recommended immunization schedules;
2. Basic immunology and vaccine protection;
3. Physiology and techniques for vaccine administration, including hands-on training in intramuscular, intradermal, subcutaneous and nasal administration routes, and other common routes of vaccine administration;
4. Pre- and post-vaccine screening or assessment; and
5. Identifying and treating adverse immunization reactions;

(D) Notifications of Intent must be filed on the board’s website or on a form approved by the board.

(4) Protocol Requirements.
(A) In addition to filing a NOI, pharmacists administering vaccines under this rule must first enter into a written protocol with a Missouri licensed physician. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must be renewed annually and include the following:

1. The identity of the participating pharmacist and physician;
2. Time period of the protocol;
3. Authorized vaccines;
4. The patient or groups of patients authorized for vaccination;
5. Allowed routes and anatomic sites of administration;
6. If applicable, authorization to create a prescription for each administration under the physician’s name;
7. Emergency response procedures, including, but not limited to, procedures for handling/addressing adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. The length of time the pharmacist must observe an individual for adverse events following an injection;
9. Procedures for disposing of used and contaminated supplies;
10. The street addresses of any non-pharmacy locations at which the pharmacist may administer vaccines;
11. Record-keeping requirements and any required notification procedures; and
12. A provision allowing termination of the protocol at any time at the request of any party.

(B) The protocol, and any subsequent amendments or alterations, must be reviewed and manually or electronically signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its contents and agree to follow the terms of the protocol. A copy of the protocol must be maintained by both the pharmacist and the authorizing physician for a minimum of eight (8) years after termination of the protocol.

(C) Additional pharmacists or immunization locations may be added to an existing protocol if the amendment is signed and dated by the authorizing physician(s) and, if applicable, any newly added pharmacist(s). Existing pharmacists are not required to re-sign the protocol unless other protocol terms or provisions are changed.

(7) Notification Requirement.
(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include/ The pharmacist shall ensure a record is maintained for each vaccine administered by protocol that includes:

1. The patient’s name, address, and date of birth (of the patient);
2. The date, route, and anatomic site of the administration;
3. The vaccine’s name, dose, manufacturer, lot number, and expiration date (of the vaccine);
4. The name and address of the patient’s primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; The identity of the administering pharmacist or, if applicable, the identity of the administering intern pharmacist and supervising pharmacist; and
6. The nature of any adverse reaction and who was notified, if applicable.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection (6)(A) of this rule are promptly delivered to the pharmacy.

(C)/(B) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Within seventy-two (72) hours after a vaccine is administered, a prescription must be obtained from the authorizing physician for the drug dispensed or a prescription must be created in the physician’s name documenting the dispensing as authorized by protocol. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo., and the rules of the board.

(D)/(C) The records required by this rule shall be maintained as follows:
1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy; and
2. If the vaccine is not being administered on behalf of a pharmacy, all records shall be maintained securely and confidentially by the administering pharmacist at an address that shall be identified in the protocol prior to administering the vaccine; and
3. Prescription records must be maintained as required by Chapter 338, RSMo., and the rules of the board; and

4. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be made available for inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the State Board of Pharmacy, the 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.
(C) In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient’s primary health care provider and authorizing physician, if different, within twenty-four (24) hours after learning of the adverse event or reaction.

(D) A pharmacist administering vaccine(s) shall report the administration to all entities as required by state or federal law.

(E) Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule.

(6) Notification of Immunizations. Pharmacists immunizing by protocol must—

(A) Notify all persons or entities as required by state and federal law;

(B) Notify the protocol physician as required by the governing protocol;

(C) Notify the patient’s primary care provider as required by Chapter 338, RSMo; and

(D) Notify the patient’s primary health care provider and, if different, the protocol physician, within twenty-four (24) hours after learning of any adverse event or reaction experienced by the patient. Adverse events or reactions must also be reported to the Vaccine Adverse Event Reporting System (VAERS) or its successor, within thirty (30) days.

(E) Unless otherwise provided by the governing protocol, notification may be made via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Proof of notification must be maintained in the pharmacist’s records as provided in subsection (5)(B) of this rule.

(7) Notification of Intent Renewal. A Notification of Intent (NOI) to immunize by protocol must be renewed biennially with the immunizing pharmacist’s Missouri pharmacist license. To renew a NOI, pharmacists must—

(A) Have a current healthcare provider cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification that complies with subsection (3)(B) of this rule; and

(B) Have completed a minimum of two (2) hours of continuing education (0.2 CEU) related to administering vaccines or CDC immunization guidelines in a course approved by the Board of Pharmacy or provided by an ACPE accredited continuing education provider within the applicable pharmacist biennial renewal period (November 1 to October 31 of the immediately preceding even numbered years).

(C) The required continuing education (CE) shall be governed by 20 CSR 2220-7.080 and may be used to satisfy the pharmacist’s biennial continuing education requirements. The initial training program required by section (3) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within the applicable pharmacist biennial renewal cycle.


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 enti-