

Meeting Notice

Missouri Board of Pharmacy and Missouri State Board of Registration for the Healing Arts Joint Rulemaking Subcommittee

**Conference Call
December 20, 2010 4:00 p.m.
Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109**

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri State Board of Registration for the Healing Arts, 3605 Missouri Blvd., Jefferson City, Missouri 65109, or by calling (573) 751-0098 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

Except to the extent disclosure is otherwise required by law, the Missouri State Board of Registration for the Healing Arts is authorized to 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) and (14) , RSMo, and Chapters 324.001.8 and 324.001.9 RSMo.

The Joint Committee may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

If any member of the public wishes to attend the open portion of the telephone conference call, s/he should be present at the Division of Professional Registration, Executive Conference Room, 3605 Missouri Blvd, Jefferson City, Missouri, at 4:00 p.m. on December 20, 2010.

Please see attached tentative agenda for this meeting.

**TENTATIVE AGENDA
December 20, 2010 4:00 p.m.**

**Missouri Board of Pharmacy
and
Missouri State Board of Registration for the Healing Arts
Joint Rulemaking Subcommittee**

**Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109
Conference Call**

OPEN SESSION

- 1 Call to Order
- 2 Roll Call
- 3 Discussion and Review of Proposed Medication Therapy Services Rules
- 4 The Joint Committee 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), (3), (5), (7), (13) and (14) and under Section 324.001.8. The Board will return to open session at the conclusion of discussion of closed session items.
- 5 Adjournment

DRAFT (10/1/10):

This draft incorporates staff's notes on BOHA's suggested changes. The proposed suggestions have not been formally approved or reviewed by BOHA.

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

20 CSR 2220-6.060 General Provisions

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

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

(A) **“Authorizing Physician(s)”**- The physician identified in the written protocol as authorizing the pharmacist to provide medication therapy services.

(B) **“Board”**- The Missouri State Board of Pharmacy.

(C) **“Board of Healing Arts”**- The Missouri Board of Registration for the Healing Arts.

(D) **“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, and that is required to maintain patient medical records by state or federal law.

(E) **“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.

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(F) **“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 or generic substitutions made pursuant to § 338.056, RSMo.

(G) **“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 this rule.

(H) **“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;

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- 1 (1) "**Protocol**"- A medication therapy protocol, as defined herein.
2
3 (2) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 shall only be deemed
4 applicable to persons/entities under the jurisdiction of the board of pharmacy, as established by
5 Chapter 338, RSMo.

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

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 § 338.010, RSMo.

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

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(2) Applicants for certification shall hold an active Missouri pharmacist license that is not under discipline with the board. Applications shall be submitted on forms provided by the board 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;

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- 1 12. Documenting clinical outcomes;
- 2 13. Interpreting, monitoring, ordering and assessing patient test results, and;
- 3 14. Patient education and counseling.
- 4
- 5 (3) Certificate Renewal. A certificate of medication therapeutic plan authority shall be renewed
- 6 biennially with the certificate holder's Missouri pharmacist license. For purposes of renewal, six
- 7 (6) of the continuing education hours required for renewing the certificate holder's Missouri
- 8 pharmacist license shall be earned in courses/programs related to medication therapy
- 9 management. The continuing education required by this rule shall be governed by the rules of
- 10 the board governing pharmacist continuing education.
- 11
- 12 (4) The board may terminate a pharmacist's certificate of medication therapeutic plan authority
- 13 if the board determines that the pharmacist has violated the terms of a protocol, the requirements
- 14 of Chapter 338, RSMo, and the rules of the board governing medication therapy services or any
- 15 other state or federal drug law.
- 16

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

20 CSR 2220-6.080 Medication Therapy Services By Protocol.

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

(1) Except as otherwise provided herein, a pharmacist who holds a certificate of medication therapeutic plan authority from the board 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 board, and;

(B) Has entered into a written protocol with a Missouri licensed physician that complies with the requirements of 20 CSR 2220-6.080.

(2) **General Requirements.** A pharmacist may only provide medication therapy services 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 section (2)(B) of this section, the prescription order for a medication therapeutic plan shall be valid for no more than one 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 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 section (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.

(D) Medication therapy decisions made by a pharmacist shall be made in the best interests of the patient.

(3) **Authorizing Physician Requirements.**

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

4 (B) The authorizing physician shall be responsible for the oversight of, and accept the
5 responsibility for, the medication therapy services provided by the pharmacist. The authorizing
6 physician shall also consider the level of skill, education, training and competence of the
7 pharmacist and ensure that the activities authorized by the protocol are consistent with the
8 pharmacist's level of skill, education, training and competence.

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

12 (D) The authorizing physician shall review the pharmacist's medication therapy service
13 activities at least once every three (3) months. If the pharmacist is providing medication therapy
14 services for, or on behalf of, a health care entity, the review requirements shall be satisfied if the
15 pharmacist's work and services are reviewed every three (3) months by a clinical care
16 committee, pharmacy and therapeutics committee, or a reviewing body/committee of the health
17 care entity that includes a Missouri licensed physician. The review required by this subsection
18 may be accomplished in person or by electronic means.

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

21 (F) An authorizing physician shall notify the Board of Healing Arts of a written protocol for
22 medication therapy services entered with a pharmacist at each renewal of the authorizing
23 physician's license.

24
25 **(4) Protocol Requirements.**

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

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

- 31 1. The identity and signatures of the authorizing physician and pharmacist;
- 32 2. The effective dates of the protocol;
- 33 3. A statement of clinical conditions, diseases and drugs, or drug categories included in
34 the written protocol and the type of medication therapy services allowed in each case;
- 35 4. A statement of the methods, procedures, decision criteria and plan the pharmacist is to
36 follow when conducting medication therapy services;
- 37 5. Procedures for documenting medication therapy decisions made by the pharmacist and
38 a plan for communication, feedback, and reporting to the authorizing physician concerning
39 specific decisions made;
- 40 6. A mechanism and procedure that allows the authorizing physician to override, rescind,
41 modify or otherwise amend the protocol. All modifications or amendments to the protocol shall
42 be documented in writing, signed and dated by all involved parties prior to the implementation of
43 such modification or amendment. The protocol may be immediately rescinded by the
44 authorizing physician or the pharmacist with or without cause, provided the rescission is
45 documented in writing. If any conflict arises regarding the professional judgment of the

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1 | pharmacist and physician with regard to the subject of the medication therapy services, the
2 | physician has ultimate authority.
3

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1 7. A statement that the pharmacist shall not delegate the provision of medication therapy
2 services to another person. A Missouri licensed intern pharmacist may perform medication
3 therapy services under the direct supervision of a Missouri licensed pharmacist certified to
4 perform medication therapy service by the Board, if the intern pharmacist has graduated from an
5 ACPE accredited pharmacy school/college or is in his/her final year of an ACPE accredited
6 pharmacy school/college. *Note: BOP staff has concerns as to how this would be implemented*
7 *or determined, especially for out-of-state students. Additionally, not all interns are students.*
8 *The Board has a number of intern pharmacists who are licensed pharmacists in other states or*
9 *who may have already graduated from pharmacy school but are licensed as interns to gain*
10 *Missouri's required pharmacy practice hours (i.e.- the pharmacist may be transferring from a*
11 *state that requires fewer practice hours).*

Deleted: A Missouri licensed intern pharmacist may perform medication therapy services under the direct supervision of a Missouri licensed pharmacist certified to perform medication therapy services by the board, provided that any modification to drug therapy or device usage shall only be initiated by the supervising pharmacist.

12 8. A description of any authority granted to the pharmacist to administer any drug or
13 medication including the identification of any such drug, medication or device;

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14 9. A description of drug therapy related patient assessment procedures or testing that
15 may be ordered or performed by the pharmacist, including any authority to order or perform
16 routine or other laboratory testing;

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17 10. Provisions for allowing the pharmacist to access prescription records, patient
18 profiles, patient medical records or other relevant medical information for purposes of providing
19 medication therapy services;

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20 11. A provision for providing the authorizing physician access to patient records for
21 medication therapy services;

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22 12. Provisions establishing a course of action the pharmacist is authorized to follow to
23 address emergency situations, including, but not limited to, anaphylactic or other adverse
24 medication reactions, adverse needle sticks or other adverse events;

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25 13. Criteria for timely communication from the authorizing physician to the pharmacist
26 and from the pharmacist to the authorizing physician, not inconsistent with the provisions of this
27 rule;

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28 14. The notification requirements required by section (5) of this rule, and;

29 15. The method for reviewing the pharmacist's medication therapy work or services by
30 the authorizing physician, as required by 20 CSR 2220-6.080(3)(D).

31 (C) The written protocol shall also include a description of all medication therapy services
32 the pharmacist is authorized to render or provide. Such services may include:

- 33 1. Assessing patient specific data and issues;
- 34 2. Establishing medication therapeutic goals or medication related action plans for
35 identified medical conditions and medication related concerns;
- 36 3. Assessing and addressing adverse reactions and adverse drug events;
- 37 4. Modifying and monitoring medication regimens;
- 38 5. Evaluating treatment progress;
- 39 6. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in
40 medication regimen reviews;
- 41 7. Medication reconciliation;
- 42 8. Drug utilization review;
- 43 9. Applicable state or federal law;
- 44 10. Formulating and documenting personal medication records;
- 45 11. Documenting clinical outcomes;
- 46 12. Interpreting, monitoring and assessing patient test results, and;

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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 otherwise 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:~~

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1. The resident holds a certificate of medication therapeutic plan authority from the Board;

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 Board to perform medication therapy services.

d. The provisions of section (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;

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

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

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

11
12 **(6) Modifying Drug Therapy.** A pharmacist shall be authorized to modify a patient's non-
13 controlled substance medication therapy, subject to the following:

14 (A) If the pharmacist modifies medication therapy and a medication or device is to be
15 dispensed, the pharmacist shall create a prescription for the medication or device modified under
16 the authorizing physician's name. Such prescription may be dispensed by a licensed pharmacy
17 and shall be maintained in the prescription records of the dispensing pharmacy as provided by
18 the rules of the Board.

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

24 (C) The pharmacist shall ~~not modify any controlled substance prescription. A~~
25 ~~prescription from the authorizing physician, shall be required to modify a controlled substance.~~

Deleted: obtain a prescription order from the authorizing physician or other prescriber for dispensing or modifying any controlled substance prescription

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

33
34 **(7) Recordkeeping.**

35 (A) A pharmacist shall document and maintain an adequate patient record of medication
36 therapy services provided to each patient. The records may be maintained in electronic format
37 provided the records are capable of being printed for review by the board of Healing Arts and
38 the board of pharmacy. An adequate and complete patient record shall include documentation of
39 the following:

- 40 1. The identification of the patient, including, name, birthdate, address and telephone
41 number;
- 42 2. The date or date(s) of any patient visit or consultation, including the reason for any
43 such visit/consultation;
- 44 3. Any pertinent assessments, observations or findings;
- 45 4. Any diagnostic testing recommended or performed;

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

3 6. Referrals to the authorizing physician or other health care provider;

4 7. Any contact with the authorizing physician concerning the patient's treatment or
5 medication therapeutic plan;

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

7 9. Any consultation with any other treatment provider for the patient and the results of
8 such consultation.

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

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

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19
20 (8) **Production of Records.** Records maintained at a pharmacy must be produced during an
21 inspection or investigation by the board of pharmacy or Board of Healing Arts, or their
22 authorized representatives, as requested by the respective board or the board's designee.
23 Records not maintained at a pharmacy shall be produced within three (3) business days after a
24 request from the Board and/or its authorized representative. Failure to maintain or produce
25 records as provided by this rule shall constitute grounds for discipline.

26
27 (9) Nothing in this rule shall be construed to permit medical diagnosis of any condition by a
28 pharmacist or the independent issuing of a prescription by a pharmacist.

29
30 (10) A pharmacist shall not violate or practice in a manner inconsistent with the provisions of
31 this rule or a written protocol. Failure to abide by the requirements of this rule or the provisions
32 of a written protocol shall be subject to disciplinary action pursuant to the provisions of Chapter
33 338, RSMo.

34
35 (11) The requirements of this rule shall not apply to the administration of vaccines pursuant to
36 protocol as governed by 20 CSR 2220-6.050 or the administration of medication by protocol as
37 governed by 20 CSR 2220-6.030.

38
39 (12) The Board of Healing Arts and the Missouri Board of Pharmacy separately retain the right
40 and duty to discipline their respective licensees for violations of any state or federal statutes,
41 rules or regulations regardless of the licensee's participation in a protocol agreement.

42
43 (13) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 shall only be deemed
44 applicable to persons/entities under the jurisdiction of the Board, as established by Chapter 338,
45 RSMo.