Rules of Department of Economic Development

Division 150—State Board of Registration for the Healing Arts Chapter 5—General Rules

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Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT

Division 150—State Board of Registration for the Healing Arts Chapter 5—General Rules

4 CSR 150-5.010 Amphetamine, Amphetamine-Like Drugs

Editor's Note: On April 14, 1992 the Circuit Court of St. Louis County found that 4 CSR 150-5.010 was void since it exceeded the statutory rulemaking authority granted to the Missouri State Board of Registration for the Healing Arts in 334.125, RSMo.

4 CSR 150-5.020 Nonpharmacy Dispensing

PURPOSE: This rule provides information concerning the general responsibilities of a physician who elects to dispense medications from his/her office or clinic.

- (1) Physicians must provide patients the freedom of choice concerning the source of drugs and devices prescribed during the course of the physician/patient relationship. This means that no physician may require, as a condition of the physician/patient relationship, that the patient only receive drugs dispensed directly from the physician's office. By the same token, a physician cannot require any patient to use the services of any particular pharmacy.
- (2) Physicians must provide appropriate, direct supervision to personnel employed to assist in the dispensing of drugs and devices from the physician's office. It shall be a violation of this rule for any physician to permit the dispensing of medication from his/her clinic or office when that physician is not present unless another physician duly licensed under the provisions of Chapter 334, RSMo is present.
- (3) Physicians who elect to dispense medication must comply with the regulations governing the types of container that may be used to repackage prescription drugs as specified by federal law or rule unless the individual to whom the drug is dispensed gives written authorization for the container to be otherwise
- (4) All drugs dispensed by a physician shall bear a label permanently affixed to the exterior of the drug container which sets forth the following information:
 - (A) The date;
 - (B) The patient's name;

- (C) Complete directions for usage;
- (D) The physician's name and address; and
- (E) The exact name and strength of the drug dispensed and, in the case of a generic drug, the name of the manufacturer or repackager of the drug. It shall be a violation of this rule for a physician to dispense a generic drug and affix to the label any trade name or other identification that would serve to misrepresent the source of the drug.
- (5) Physicians may dispense only to individuals with whom they have established a physician/patient relationship. It shall be a violation of this rule for a physician to dispense medication at the order of any other physician not registered to practice at that same location.
- (6) It is not the intention of this rule to interfere with any recognized system for physician education operated by any accredited medical school located within the borders of Missouri nor is it the intention of this rule to interfere with the individual physician's appropriate use of professional samples nor is it the intention of this rule to interfere in any way with the physician's right to directly administer drugs or medicines to any patient.
- (7) Whenever dispensing takes place, appropriate records shall be maintained. These records must be adequate to show the name of the patient, the name and strength of the drug dispensed, the quantity, the dose, etc. A separate log must be maintained for controlled substance dispensing.

AUTHORITY: section 334.125, RSMo 1986.* Original rule filed May 11, 1984, effective Sept. 14, 1984.

*Original authority 1959.

4 CSR 150-5.030 Physical Therapy, Rehabilitation Services, or Both

PURPOSE: This rule provides information concerning the disclosure of a physician's pecuniary interest in a physical therapy or rehabilitation service as directed by section 334.100.2(21), RSMo.

(1) Pursuant to the authority granted in section 334.100.2(21), RSMo, physicians who have a pecuniary interest in physical therapy or rehabilitation service facilities must disclose that interest to patients who are prescribed either physical therapy or rehabilitation services using the following form:

Missouri state law, 334.100.2(21), RSMo, requires a physician notify the patient or guardian that the physician has a pecuniary (financial) interest in the physical therapy facility in which prescribed treatment is provided, and that physical therapy or rehabilitation services are available to the patient on a competitive basis from other facilities.

| Therefore, I un | nderst | anc | l that Dr | | |
|-----------------|--------|-----|------------|----------|----|
| | _has | a | financial | interest | in |
| | | | _facility. | | |

Further, I understand that I have the right to choose any other physical therapy or rehabilitation services which may be more convenient or competitive.

| Patient/ | Guardiai | n Signati |
|----------|----------|-----------|
| | | |
| | Date | |

This should be retained in the patient's permanent record.

AUTHORITY: sections 334.100.2(21), RSMo Supp. 1990 and 334.125, RSMo 1986.* Original rule filed April 4, 1990, effective Nov. 30, 1990.

*Original authority: 334.100.2(21), RSMo 1939, amended 1945, 1959, 1963, 1974, 1976, 1979, 1981, 1983, 1984, 1986, 1987, 1989, 1990 and 334.125, RSMo 1959.

4 CSR 150-5.100 Collaborative Practice

PURPOSE: This rule defines collaborative practice arrangement terms and delimits geographic areas; methods of treatment; review of services; and drug/device dispensing or distribution pursuant to prescription.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

- (1) For the purpose of these rules, the following definitions shall apply:
- (A) Advanced practice nurse—A registered professional nurse who is also an advanced

practice nurse as defined in section 335.016(2), RSMo;

- (B) Collaborative practice arrangements—refers to written agreements, jointly agreed upon protocols, or standing orders, all of which shall be in writing, for the delivery of health care services; and
- (C) Registered professional nurse—A registered professional nurse as defined in section 335.016(9), RSMo, who is not an advanced practice nurse.

(2) Geographic Areas.

- (A) The collaborating physician in a collaborative practice arrangement shall not be so geographically distanced from the collaborating registered professional nurse or advanced practice nurse as to create an impediment to effective collaboration in the delivery of health care services or the adequate review of those services.
- (B) The use of a collaborative practice arrangement by an advanced practice nurse who provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons shall be limited to practice locations where the collaborating physician, or other physician designated in the collaborative practice arrangement, is no further than fifty (50) miles by road, using the most direct route available, from the collaborating advanced practice nurse if the advanced practice nurse is practicing in federally designated health professional shortage areas (HPSAs). Otherwise, in non-HPSAs, the collaborating physician and collaborating advanced practice nurse shall practice within thirty (30) miles by road of one another. The provision of the above specified health care services pursuant to a collaborative practice arrangement shall be limited to only an advanced practice nurse.
- (C) An advanced practice nurse who desires to enter into a collaborative practice arrangement to provide health care services that include the diagnosis and treatment of acutely or chronically ill or injured persons at a location where the collaborating physician is not continuously present shall practice at the same location with the collaborating physician for a period of at least one (1) calendar month before the collaborating advanced practice nurse practices at a location where the collaborating physician is not present. The provision of the above specified health care services pursuant to a collaborative practice arrangement shall be limited to only an advanced practice nurse.

(3) Methods of Treatment.

(A) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated in a collaborative

- practice arrangement between a collaborating physician and collaborating registered professional nurse or advanced practice nurse shall be within the scope of practice of each professional and shall be consistent with each professional's skill, training, education, and competence.
- (B) The collaborating physician shall consider the level of skill, education, training, and competence of the collaborating registered professional nurse or advanced practice nurse and ensure that the delegated responsibilities contained in the collaborative practice arrangement are consistent with that level of skill, education, training, and competence.
- (C) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall also be consistent with the scope of practice of the collaborating physician
- (D) Guidelines for consultation and referral to the collaborating physician or designated health care facility for services or emergency care that is beyond the education, training, competence, or scope of practice of the collaborating registered professional nurse or advanced practice nurse shall be established in the collaborative practice arrangement.
- (E) The methods of treatment and authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall not be further delegated to any other person except that the individuals identified in sections 338.095 and 338.198, RSMo may communicate prescription drug orders to a pharmacist.
- (F) The methods of treatment, including any authority to administer or dispense drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse shall be delivered only pursuant to a written agreement, jointly agreed-upon protocols, or standing orders that shall describe a specific sequence of orders, steps, or procedures to be followed in providing patient care in specified clinical situations.
- (G) The methods of treatment, including any authority to administer, dispense, or prescribe drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating advanced practice nurse shall be delivered only pursuant to a written agreement, jointly agreed upon protocols, or standing orders that are specific to the clinical conditions treated by the collaborating physician and collaborating advanced practice nurse.

- (H) The collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse or advanced practice nurse shall be signed and dated by the collaborating physician and collaborating registered professional nurse or advanced practice nurse before it is implemented, signifying that both are aware of its content and agree to follow the terms of the collaborative practice arrangement. The collaborative practice arrangement and any subsequent notice of termination of the collaborative practice arrangement shall be in writing and shall be maintained by the collaborating professionals for a minimum of eight (8) years after termination of the collaborative practice arrangement. The collaborative practice arrangement shall be reviewed and revised as needed by the collaborating physician and collaborating registered professional nurse or advanced practice nurse.
- (I) Methods of treatment delegated and authority to administer, dispense, or prescribe drugs shall be subject to the following:
- 1. The physician retains the responsibility for ensuring the appropriate administering, dispensing, prescribing and control of drugs utilized pursuant to a collaborative practice arrangement in accordance with all state and federal statutes, rules, or regulations;
- 2. All labeling requirements outlined in section 338.059, RSMo shall be followed;
- Consumer product safety laws and Class B container standards shall be followed when packaging drugs for distribution;
- All drugs shall be stored according to the *United States Pharmacopeia* (USP) recommended conditions;
- 5. Outdated drugs shall be separated from the active inventory;
- 6. Retrievable dispensing logs shall be maintained for all prescription drugs dispensed and shall include all information required by state and federal statutes, rules, or regulations;
- 7. All prescriptions shall conform to all applicable state and federal statutes, rules, or regulations and shall include the name, address, and telephone number of the collaborating physician and collaborating advanced practice nurse;
- 8. A registered professional nurse shall not, under any circumstances, prescribe drugs;
- 9. An advanced practice nurse shall not, under any circumstances, prescribe controlled substances. The administering or dispensing of a controlled substance by a registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall be accomplished only under the direction and supervision of the collaborating physician, or other physician designated in

the collaborative practice arrangement, and shall only occur on a case-by-case determination of the patient's needs following verbal consultation between the collaborating physician and collaborating registered professional nurse or advanced practice nurse. The required consultation and the physician's directions for the administering or dispensing of controlled substances shall be recorded in the patient's chart and in the appropriate dispensing log. These recordings shall be made by the collaborating registered professional nurse or advanced practice nurse and shall be cosigned by the collaborating physician following a review of the records:

- 10. An advanced practice nurse or registered professional nurse in a collaborative practice arrangement may only dispense starter doses of medication to cover a period of time for seventy-two (72) hours or less with the exception of Title X family planning providers or publicly funded clinics in community health settings that dispense medications free of charge. The dispensing of drug samples, as defined in 21 U.S.C. section 353 (c)(1), is permitted as appropriate to complete drug therapy; and
- 11. The medications to be administered, dispensed, or prescribed by a collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall be consistent with the education, training, competence, and scopes of practice of the collaborating physician and collaborating registered professional nurse or advanced practice nurse.
- (J) When a collaborative practice arrangement is utilized to provide health care services for conditions other than acute self-limited or well defined problems, the collaborating physician, or other physician designated in the collaborative practice arrangement, shall see the patient for evaluation and approve or formulate the plan of treatment for new or significantly changed conditions as soon as is practical, but in no case more than two (2) weeks after the patient has been seen by the collaborating advanced practice nurse or registered professional nurse.
- (K) Nothing in these rules shall be construed to permit medical diagnosis of any condition by a registered professional nurse pursuant to a collaborative practive arrangement.

(4) Review of Services.

(A) In order to assure true collaborative practice and to foster effective communication and review of services, the collaborating physician, or other physician designated in the collaborative practice arrangement, shall be immediately available for consultation to the collaborating registered professional

nurse or advanced practice nurse at all times, either personally or via telecommunications.

- (B) The collaborating physician shall review the work, records, and practice of the health care delivered pursuant to a collaborative practice arrangement at least once every two (2) weeks. This review shall be documented by the collaborating physician. This subsection shall not apply to the situation described in subsection (4)(E) below or during the time the collaborating physician and collaborating advanced practice nurse are practicing together as required in subsection (2)(C) above.
- (C) If a collaborative practice arrangement is used in clinical situations where a collaboadvanced practice nurse provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons, then the collaborating physician shall be present for sufficient periods of time, at least once every two (2) weeks, except in extraordinary circumstances that shall be documented, to participate in such review and to provide necessary medical direction, medical services, consultations, and supervision of the health care staff. In such settings the use of a collaborative practice arrangement shall be limited to only an advanced practice nurse and the physician shall not enter into a collaborative practice arrangement with more than three (3) full-time equivalent advanced practice nurses.
- (D) The collaborating physician and collaborating registered professional nurse or advanced practice nurse shall determine an appropriate process of review and management of abnormal test results which shall be documented in the collaborative practice arrangement.
- (E) In the case of collaborating physicians and collaborating registered professional nurses or advanced practice nurses practicing in settings which provide care to well patients or to those with narrowly circumscribed conditions in public health clinics or community health settings that provide population-based health services limited to immunizations, well child care, human immunodeficiency virus (HIV) and sexually transmitted disease care, family planning, tuberculosis control, cancer and other chronic disease and wellness screenings, services related to epidemiologic investigations and prenatal care, review of services shall occur as needed and set forth in the collaborative practice arrangement. If the services provided in such settings include diagnosis and the initiation of treatment of any other disease or injury, then the provisions of subsection (4)(C) shall apply.
- (F) The process and documentation of review shall be on file and maintained in the collaborative practice setting.

- (G) The Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Nursing separately retain the right and duty to discipline their respective licensees for violations of any state or federal statutes, rules, or regulations regardless of the licensee's participation in a collaborative practice arrangement.
- (5) Population-Based Public Health Services. (A) In the case of the collaborating physicians and collaborating registered professional nurses or advanced practice nurses practicing in association with public health clinics that provide population-based health services limited to immunizations, well child care, HIV and sexually transmitted disease care, family planning, tuberculosis control, cancer and other chronic disease and wellness screenings, services related to epidemiologic investigations and related treatment, and prenatal care, the geographic areas, methods of treatment and review of services shall occur as set forth in the collaborative practice arrangement. If the services provided in such settings include diagnosis and initiation of treatment of disease or injury not related to

AUTHORITY: sections 334.104.3, RSMo 1994 and 334.125, RSMo Supp. 1997.* Original rule filed Jan. 29, 1996, effective Sept. 30, 1996. Amended: Filed April 1, 1998, effective Oct. 30, 1998.

population-based health services, then the

provisions of sections (2), (3), and (4) above

shall apply.

*Original authority: 334.104.3, RSMo 1993 and 334.125, RSMo 1959, amended 1993, 1995.