FIRST REGULAR SESSION

HOUSE COMMITTEE SUBSTITUTE FOR

SENATE SUBSTITUTE FOR

SENATE BILL NO. 457

98TH GENERAL ASSEMBLY

2178H.05C D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal sections 195.070, 334.037, 334.104, 334.747, 338.200, and 354.415, RSMo, and to enact in lieu thereof fourteen new sections relating to health care services.

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

Section A. Sections 195.070, 334.037, 334.104, 334.747, 338.200, and 354.415, RSMo, are repealed and fourteen new sections enacted in lieu thereof, to be known as sections 195.070, 324.023, 334.037, 334.104, 334.747, 338.075, 338.200, 354.415, 374.015, 374.018, 375.1605, 376.379, 376.388, and 376.791, to read as follows:

195.070. 1. A physician, podiatrist, dentist, a registered optometrist certified to administer pharmaceutical agents as provided in section 336.220, or an assistant physician in accordance with section 334.037 or a physician assistant in accordance with section 334.747 in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense controlled substances or he or she may cause the same to be administered or dispensed by an individual as authorized by statute.

2. An advanced practice registered nurse, as defined in section 335.016, but not a certified registered nurse anesthetist as defined in subdivision (8) of section 335.016, who holds a certificate of controlled substance prescriptive authority from the board of nursing under section 335.019 and who is delegated the authority to prescribe controlled substances under a collaborative practice arrangement under section 334.104 may prescribe any controlled substances listed in Schedules III, IV, and V of section 195.017**, and may have restricted authority in Schedule II. Prescriptions for Schedule II medications prescribed by an advanced practice registered nurse who has a certificate of controlled substance prescriptive authority are restricted to only those medications containing hydrocodone**.

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

However, no such certified advanced practice registered nurse shall prescribe controlled substance for his or her own self or family. Schedule III narcotic controlled substance **and Schedule II - hydrocodone** prescriptions shall be limited to a one hundred twenty-hour supply without refill.

3. A veterinarian, in good faith and in the course of the veterinarian's professional practice only, and not for use by a human being, may prescribe, administer, and dispense controlled substances and the veterinarian may cause them to be administered by an assistant or orderly under his or her direction and supervision.

4. A practitioner shall not accept any portion of a controlled substance unused by a patient, for any reason, if such practitioner did not originally dispense the drug.

5. An individual practitioner shall not prescribe or dispense a controlled substance for such practitioner's personal use except in a medical emergency.

324.023. 1. Notwithstanding any law to the contrary, any board or commission established under chapters 330, 331, 332, 334, 335, 336, 337, 338, 340, and 345 may, at its discretion, issue oral or written opinions addressing topics relating to the qualifications, functions, or duties of any profession licensed by the specific board or commission issuing such guidance. Any such opinion is for educational purposes only, is in no way binding on the licensees of the respective board or commission, and cannot be used as the basis for any discipline against any licensee under chapters 330, 331, 332, 334, 335, 336, 337, 338, 340, and 345. No board or commission may address topics relating to the qualifications, functions, or duties of any profession licensed by a different board or commission.

2. The recipient of an opinion given under this section shall be informed that the opinion is for educational purposes only, is in no way binding on the licensees of the board, and cannot be used as the basis for any discipline against any licensee under chapters 330, 331, 332, 334, 335, 336, 337, 338, 340, and 345.

334.037. 1. A physician may enter into collaborative practice arrangements with assistant physicians. Collaborative practice arrangements shall be in the form of written agreements, jointly agreed-upon protocols, or standing orders for the delivery of health care services. Collaborative practice arrangements, which shall be in writing, may delegate to an assistant physician the authority to administer or dispense drugs and provide treatment as long as the delivery of such health care services is within the scope of practice of the assistant physician and is consistent with that assistant physician's skill, training, and competence and the skill and training of the collaborating physician.

2. The written collaborative practice arrangement shall contain at least the following provisions:

(1) Complete names, home and business addresses, zip codes, and telephone numbers of the collaborating physician and the assistant physician;

(2) A list of all other offices or locations besides those listed in subdivision (1) of this subsection where the collaborating physician authorized the assistant physician to prescribe;

(3) A requirement that there shall be posted at every office where the assistant physician is authorized to prescribe, in collaboration with a physician, a prominently displayed disclosure statement informing patients that they may be seen by an assistant physician and have the right to see the collaborating physician;

(4) All specialty or board certifications of the collaborating physician and all certifications of the assistant physician;

(5) The manner of collaboration between the collaborating physician and the assistant physician, including how the collaborating physician and the assistant physician shall:

(a) Engage in collaborative practice consistent with each professional's skill, training, education, and competence;

(b) Maintain geographic proximity; except, the collaborative practice arrangement may allow for geographic proximity to be waived for a maximum of twenty-eight days per calendar year for rural health clinics as defined by P.L. 95-210, as long as the collaborative practice arrangement includes alternative plans as required in paragraph (c) of this subdivision. Such exception to geographic proximity shall apply only to independent rural health clinics, provider-based rural health clinics if the provider is a critical access hospital as provided in 42 U.S.C. Section 1395i-4, and provider-based rural health clinics if the main location of the hospital sponsor is greater than fifty miles from the clinic. The collaborating physician shall maintain documentation related to such requirement and present it to the state board of registration for the healing arts when requested; and

(c) Provide coverage during absence, incapacity, infirmity, or emergency by the collaborating physician;

(6) A description of the assistant physician's controlled substance prescriptive authority in collaboration with the physician, including a list of the controlled substances the physician authorizes the assistant physician to prescribe and documentation that it is consistent with each professional's education, knowledge, skill, and competence;

(7) A list of all other written practice agreements of the collaborating physician and the assistant physician;

(8) The duration of the written practice agreement between the collaborating physician and the assistant physician;

(9) A description of the time and manner of the collaborating physician's review of the assistant physician's delivery of health care services. The description shall include provisions

that the assistant physician shall submit a minimum of ten percent of the charts documenting the assistant physician's delivery of health care services to the collaborating physician for review by the collaborating physician, or any other physician designated in the collaborative practice arrangement, every fourteen days; and

(10) The collaborating physician, or any other physician designated in the collaborative practice arrangement, shall review every fourteen days a minimum of twenty percent of the charts in which the assistant physician prescribes controlled substances. The charts reviewed under this subdivision may be counted in the number of charts required to be reviewed under subdivision (9) of this subsection.

3. The state board of registration for the healing arts under section 334.125 shall promulgate rules regulating the use of collaborative practice arrangements for assistant physicians. Such rules shall specify:

(1) Geographic areas to be covered;

(2) The methods of treatment that may be covered by collaborative practice arrangements;

(3) In conjunction with deans of medical schools and primary care residency program directors in the state, the development and implementation of educational methods and programs undertaken during the collaborative practice service which shall facilitate the advancement of the assistant physician's medical knowledge and capabilities, and which may lead to credit toward a future residency program for programs that deem such documented educational achievements acceptable; and

(4) The requirements for review of services provided under collaborative practice arrangements, including delegating authority to prescribe controlled substances.

Any rules relating to dispensing or distribution of medications or devices by prescription or prescription drug orders under this section shall be subject to the approval of the state board of pharmacy. Any rules relating to dispensing or distribution of controlled substances by prescription or prescription drug orders under this section shall be subject to the approval of the department of health and senior services and the state board of pharmacy. The state board of registration for the healing arts shall promulgate rules applicable to assistant physicians that shall be consistent with guidelines for federally funded clinics. The rulemaking authority granted in this subsection shall not extend to collaborative practice arrangements of hospital employees providing inpatient care within hospitals as defined in chapter 197 or population-based public health services as defined by 20 CSR 2150-5.100 as of April 30, 2008.

4. The state board of registration for the healing arts shall not deny, revoke, suspend, or otherwise take disciplinary action against a collaborating physician for health care services

delegated to an assistant physician provided the provisions of this section and the rules promulgated thereunder are satisfied.

5. Within thirty days of any change and on each renewal, the state board of registration for the healing arts shall require every physician to identify whether the physician is engaged in any collaborative practice arrangement, including collaborative practice arrangements delegating the authority to prescribe controlled substances, and also report to the board the name of each assistant physician with whom the physician has entered into such arrangement. The board may make such information available to the public. The board shall track the reported information and may routinely conduct random reviews of such arrangements to ensure that arrangements are carried out for compliance under this chapter.

6. A collaborating physician shall not enter into a collaborative practice arrangement with more than three full-time equivalent assistant physicians. Such limitation shall not apply to collaborative arrangements of hospital employees providing inpatient care service in hospitals as defined in chapter 197 or population-based public health services as defined by 20 CSR 2150-5.100 as of April 30, 2008.

7. The collaborating physician shall determine and document the completion of at least a one-month period of time during which the assistant physician shall practice with the collaborating physician continuously present before practicing in a setting where the collaborating physician is not continuously present. Such limitation shall not apply to collaborative arrangements of providers of population-based public health services as defined by 20 CSR 2150-5.100 as of April 30, 2008.

8. No agreement made under this section shall supersede current hospital licensing regulations governing hospital medication orders under protocols or standing orders for the purpose of delivering inpatient or emergency care within a hospital as defined in section 197.020 if such protocols or standing orders have been approved by the hospital's medical staff and pharmaceutical therapeutics committee.

9. No contract or other agreement shall require a physician to act as a collaborating physician for an assistant physician against the physician's will. A physician shall have the right to refuse to act as a collaborating physician, without penalty, for a particular assistant physician. No contract or other agreement shall limit the collaborating physician's ultimate authority over any protocols or standing orders or in the delegation of the physician's authority to any assistant physician, but such requirement shall not authorize a physician in implementing such protocols, standing orders, or delegation to violate applicable standards for safe medical practice established by a hospital's medical staff.

10. No contract or other agreement shall require any assistant physician to serve as a collaborating assistant physician for any collaborating physician against the assistant physician's

will. An assistant physician shall have the right to refuse to collaborate, without penalty, with a particular physician.

11. All collaborating physicians and assistant physicians in collaborative practice arrangements shall wear identification badges while acting within the scope of their collaborative practice arrangement. The identification badges shall prominently display the licensure status of such collaborating physicians and assistant physicians.

12. (1) An assistant physician with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in Schedule III, IV, or V of section 195.017**, and may have restricted authority in Schedule II,** when delegated the authority to prescribe controlled substances in a collaborative practice arrangement. **Prescriptions for Schedule II medications prescribed by an assistant physician who has a certificate of controlled substance prescriptive authority are restricted to only those medications containing hydrocodone.** Such authority shall be filed with the state board of registration for the healing arts. The collaborating physician shall maintain the right to limit a specific scheduled drug or scheduled drug category that the assistant physician is permitted to prescribe. Any limitations shall be listed in the collaborative practice arrangement. Assistant physicians shall not prescribe controlled substances for themselves or members of their families. Schedule III controlled substances **and Schedule II - hydrocodone prescriptions** shall be limited to a five-day supply without refill. Assistant physicians who are authorized to prescribe controlled substances under this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include the Drug Enforcement Administration registration number on prescriptions for controlled substances.

(2) The collaborating physician shall be responsible to determine and document the completion of at least one hundred twenty hours in a four-month period by the assistant physician during which the assistant physician shall practice with the collaborating physician on-site prior to prescribing controlled substances when the collaborating physician is not on-site. Such limitation shall not apply to assistant physicians of population-based public health services as defined in 20 CSR 2150-5.100 as of April 30, 2009.

(3) An assistant physician shall receive a certificate of controlled substance prescriptive authority from the state board of registration for the healing arts upon verification of licensure under section 334.036.

334.104. 1. A physician may enter into collaborative practice arrangements with registered professional nurses. Collaborative practice arrangements shall be in the form of written agreements, jointly agreed-upon protocols, or standing orders for the delivery of health care services. Collaborative practice arrangements, which shall be in writing, may delegate to a registered professional nurse the authority to administer or dispense drugs and provide

treatment as long as the delivery of such health care services is within the scope of practice of the registered professional nurse and is consistent with that nurse's skill, training and competence.

2. Collaborative practice arrangements, which shall be in writing, may delegate to a registered professional nurse the authority to administer, dispense or prescribe drugs and provide treatment if the registered professional nurse is an advanced practice registered nurse as defined in subdivision (2) of section 335.016. Collaborative practice arrangements may delegate to an advanced practice registered nurse, as defined in section 335.016, the authority to administer, dispense, or prescribe controlled substances listed in Schedules III, IV, and V of section 195.017**, and Schedule II - hydrocodone**; except that, the collaborative practice arrangement shall not delegate the authority to administer any controlled substances listed in Schedules III, IV, and V of section 195.017**, or Schedule II - hydrocodone** for the purpose of inducing sedation or general anesthesia for therapeutic, diagnostic, or surgical procedures. Schedule III narcotic controlled substance **and Schedule II - hydrocodone** prescriptions shall be limited to a one hundred twenty-hour supply without refill. Such collaborative practice arrangements shall be in the form of written agreements, jointly agreed-upon protocols or standing orders for the delivery of health care services.

3. The written collaborative practice arrangement shall contain at least the following provisions:

(1) Complete names, home and business addresses, zip codes, and telephone numbers of the collaborating physician and the advanced practice registered nurse;

(2) A list of all other offices or locations besides those listed in subdivision (1) of this subsection where the collaborating physician authorized the advanced practice registered nurse to prescribe;

(3) A requirement that there shall be posted at every office where the advanced practice registered nurse is authorized to prescribe, in collaboration with a physician, a prominently displayed disclosure statement informing patients that they may be seen by an advanced practice registered nurse and have the right to see the collaborating physician;

(4) All specialty or board certifications of the collaborating physician and all certifications of the advanced practice registered nurse;

(5) The manner of collaboration between the collaborating physician and the advanced practice registered nurse, including how the collaborating physician and the advanced practice registered nurse will:

(a) Engage in collaborative practice consistent with each professional's skill, training, education, and competence;

(b) Maintain geographic proximity, except the collaborative practice arrangement may allow for geographic proximity to be waived for a maximum of twenty-eight days per calendar year for rural health clinics as defined by P.L. 95-210, as long as the collaborative practice arrangement includes alternative plans as required in paragraph (c) of this subdivision. This exception to geographic proximity shall apply only to independent rural health clinics, provider-based rural health clinics where the provider is a critical access hospital as provided in 42 U.S.C. 1395i-4, and provider-based rural health clinics where the main location of the hospital sponsor is greater than fifty miles from the clinic. The collaborating physician is required to maintain documentation related to this requirement and to present it to the state board of registration for the healing arts when requested; and

(c) Provide coverage during absence, incapacity, infirmity, or emergency by the collaborating physician;

(6) A description of the advanced practice registered nurse's controlled substance prescriptive authority in collaboration with the physician, including a list of the controlled substances the physician authorizes the nurse to prescribe and documentation that it is consistent with each professional's education, knowledge, skill, and competence;

(7) A list of all other written practice agreements of the collaborating physician and the advanced practice registered nurse;

(8) The duration of the written practice agreement between the collaborating physician and the advanced practice registered nurse;

(9) A description of the time and manner of the collaborating physician's review of the advanced practice registered nurse's delivery of health care services. The description shall include provisions that the advanced practice registered nurse shall submit a minimum of ten percent of the charts documenting the advanced practice registered nurse's delivery of health care services to the collaborating physician for review by the collaborating physician, or any other physician designated in the collaborative practice arrangement, every fourteen days; and

(10) The collaborating physician, or any other physician designated in the collaborative practice arrangement, shall review every fourteen days a minimum of twenty percent of the charts in which the advanced practice registered nurse prescribes controlled substances. The charts reviewed under this subdivision may be counted in the number of charts required to be reviewed under subdivision (9) of this subsection.

4. The state board of registration for the healing arts pursuant to section 334.125 and the board of nursing pursuant to section 335.036 may jointly promulgate rules regulating the use of collaborative practice arrangements. Such rules shall be limited to specifying geographic areas to be covered, the methods of treatment that may be covered by collaborative practice arrangements and the requirements for review of services provided pursuant to collaborative

practice arrangements including delegating authority to prescribe controlled substances. Any rules relating to dispensing or distribution of medications or devices by prescription or prescription drug orders under this section shall be subject to the approval of the state board of pharmacy. Any rules relating to dispensing or distribution of controlled substances by prescription or prescription drug orders under this section shall be subject to the approval of the department of health and senior services and the state board of pharmacy. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither the state board of registration for the healing arts nor the board of nursing may separately promulgate rules relating to collaborative practice arrangements. Such jointly promulgated rules shall be consistent with guidelines for federally funded clinics. The rulemaking authority granted in this subsection shall not extend to collaborative practice arrangements of hospital employees providing inpatient care within hospitals as defined pursuant to chapter 197 or population-based public health services as defined by 20 CSR 2150-5.100 as of April 30, 2008.

5. The state board of registration for the healing arts shall not deny, revoke, suspend or otherwise take disciplinary action against a physician for health care services delegated to a registered professional nurse provided the provisions of this section and the rules promulgated thereunder are satisfied. Upon the written request of a physician subject to a disciplinary action imposed as a result of an agreement between a physician and a registered professional nurse or registered physician assistant, whether written or not, prior to August 28, 1993, all records of such disciplinary licensure action and all records pertaining to the filing, investigation or review of an alleged violation of this chapter incurred as a result of such an agreement shall be removed from the records of the state board of registration for the healing arts and the division of professional registration and shall not be disclosed to any public or private entity seeking such information from the board or the division. The state board of registration for the healing arts shall take action to correct reports of alleged violations and disciplinary actions as described in this section which have been submitted to the National Practitioner Data Bank. In subsequent applications or representations relating to his medical practice, a physician completing forms or documents shall not be required to report any actions of the state board of registration for the healing arts for which the records are subject to removal under this section.

6. Within thirty days of any change and on each renewal, the state board of registration for the healing arts shall require every physician to identify whether the physician is engaged in any collaborative practice agreement, including collaborative practice agreements delegating the authority to prescribe controlled substances, or physician assistant agreement and also report to the board the name of each licensed professional with whom the physician has entered into such agreement. The board may make this information available to the public. The board shall track

the reported information and may routinely conduct random reviews of such agreements to ensure that agreements are carried out for compliance under this chapter.

7. Notwithstanding any law to the contrary, a certified registered nurse anesthetist as defined in subdivision (8) of section 335.016 shall be permitted to provide anesthesia services without a collaborative practice arrangement provided that he or she is under the supervision of an anesthesiologist or other physician, dentist, or podiatrist who is immediately available if needed. Nothing in this subsection shall be construed to prohibit or prevent a certified registered nurse anesthetist as defined in subdivision (8) of section 335.016 from entering into a collaborative practice arrangement under this section, except that the collaborative practice arrangement may not delegate the authority to prescribe any controlled substances listed in Schedules III, IV, and V of section 195.017**, or Schedule II - hydrocodone**.

8. A collaborating physician shall not enter into a collaborative practice arrangement with more than three full-time equivalent advanced practice registered nurses. This limitation shall not apply to collaborative arrangements of hospital employees providing inpatient care service in hospitals as defined in chapter 197 or population-based public health services as defined by 20 CSR 2150-5.100 as of April 30, 2008.

9. It is the responsibility of the collaborating physician to determine and document the completion of at least a one-month period of time during which the advanced practice registered nurse shall practice with the collaborating physician continuously present before practicing in a setting where the collaborating physician is not continuously present. This limitation shall not apply to collaborative arrangements of providers of population-based public health services as defined by 20 CSR 2150-5.100 as of April 30, 2008.

10. No agreement made under this section shall supersede current hospital licensing regulations governing hospital medication orders under protocols or standing orders for the purpose of delivering inpatient or emergency care within a hospital as defined in section 197.020 if such protocols or standing orders have been approved by the hospital's medical staff and pharmaceutical therapeutics committee.

11. No contract or other agreement shall require a physician to act as a collaborating physician for an advanced practice registered nurse against the physician's will. A physician shall have the right to refuse to act as a collaborating physician, without penalty, for a particular advanced practice registered nurse. No contract or other agreement shall limit the collaborating physician's ultimate authority over any protocols or standing orders or in the delegation of the physician's authority to any advanced practice registered nurse, but this requirement shall not authorize a physician in implementing such protocols, standing orders, or delegation to violate applicable standards for safe medical practice established by hospital's medical staff.

12. No contract or other agreement shall require any advanced practice registered nurse to serve as a collaborating advanced practice registered nurse for any collaborating physician against the advanced practice registered nurse's will. An advanced practice registered nurse shall have the right to refuse to collaborate, without penalty, with a particular physician.

334.747. 1. A physician assistant with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in schedule III, IV, or V of section 195.017**, and may have restricted authority in Schedule II,** when delegated the authority to prescribe controlled substances in a supervision agreement. Such authority shall be listed on the supervision verification form on file with the state board of healing arts. The supervising physician shall maintain the right to limit a specific scheduled drug or scheduled drug category that the physician assistant is permitted to prescribe. Any limitations shall be listed on the supervision form. **Prescriptions for Schedule II medications prescribed by a physician assistant with authority to prescribe delegated in a supervision agreement are restricted to only those medications containing hydrocodone.** Physician assistants shall not prescribe controlled substances for themselves or members of their families. Schedule III controlled substances **and Schedule II - hydrocodone prescriptions** shall be limited to a five-day supply without refill. Physician assistants who are authorized to prescribe controlled substances under this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include the Drug Enforcement Administration registration number on prescriptions for controlled substances.

2. The supervising physician shall be responsible to determine and document the completion of at least one hundred twenty hours in a four-month period by the physician assistant during which the physician assistant shall practice with the supervising physician on-site prior to prescribing controlled substances when the supervising physician is not on-site. Such limitation shall not apply to physician assistants of population-based public health services as defined in 20 CSR 2150-5.100 as of April 30, 2009.

3. A physician assistant shall receive a certificate of controlled substance prescriptive authority from the board of healing arts upon verification of the completion of the following educational requirements:

(1) Successful completion of an advanced pharmacology course that includes clinical training in the prescription of drugs, medicines, and therapeutic devices. A course or courses with advanced pharmacological content in a physician assistant program accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or its predecessor agency shall satisfy such requirement;

(2) Completion of a minimum of three hundred clock hours of clinical training by the supervising physician in the prescription of drugs, medicines, and therapeutic devices;

(3) Completion of a minimum of one year of supervised clinical practice or supervised clinical rotations. One year of clinical rotations in a program accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or its predecessor agency, which includes pharmacotherapeutics as a component of its clinical training, shall satisfy such requirement. Proof of such training shall serve to document experience in the prescribing of drugs, medicines, and therapeutic devices;

(4) A physician assistant previously licensed in a jurisdiction where physician assistants are authorized to prescribe controlled substances may obtain a state bureau of narcotics and dangerous drugs registration if a supervising physician can attest that the physician assistant has met the requirements of subdivisions (1) to (3) of this subsection and provides documentation of existing federal Drug Enforcement Agency registration.

338.075. 1. All licensees, registrants, and permit holders of the board shall report to the board:

(1) Any final adverse action taken by another licensing state, jurisdiction, or government agency against any license, permit, or authorization held by the person or entity to practice or operate as a pharmacist, intern pharmacist, pharmacy technician, pharmacy, drug distributor, drug manufacturer, or drug outsourcing facility. For purposes of this section, "adverse action" shall include, but is not limited to, revocation, suspension, censure, probation, disciplinary reprimand, or disciplinary restriction of a license, permit, or other authorization or a voluntary surrender of such license, permit, or other authorization in lieu of discipline or adverse action;

(2) Any surrender of a license or authorization to practice or operate as a pharmacist, intern pharmacist, pharmacy technician, pharmacy, drug distributor, drug manufacturer, or drug outsourcing facility while under disciplinary investigation by another licensing state, jurisdiction, or governmental agency, and;

(3) Any exclusion to participate in any state or federally funded health care program such as Medicare, Medicaid, or MO HealthNet for fraud, abuse, or submission of any false or fraudulent claim, payment, or reimbursement request.

2. Reports shall be submitted as provided by the board by rule.

3. The board shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010 that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, and, if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the powers vested with the general assembly pursuant to chapter 536, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of

rulemaking authority and any rule proposed or adopted after August 28, 2015, shall be invalid and void.

338.200. 1. In the event a pharmacist is unable to obtain refill authorization from the prescriber due to death, incapacity, or when the pharmacist is unable to obtain refill authorization from the prescriber, a pharmacist may dispense an emergency supply of medication if:

(1) In the pharmacist's professional judgment, interruption of therapy might reasonably produce undesirable health consequences;

(2) The pharmacy previously dispensed or refilled a prescription from the applicable prescriber for the same patient and medication;

(3) The medication dispensed is not a controlled substance;

(4) The pharmacist informs the patient or the patient's agent either verbally, electronically, or in writing at the time of dispensing that authorization of a prescriber is required for future refills; and

(5) The pharmacist documents the emergency dispensing in the patient's prescription record, as provided by the board by rule.

2. (1) If the pharmacist is unable to obtain refill authorization from the prescriber, the amount dispensed shall be limited to the amount determined by the pharmacist within his or her professional judgment as needed for the emergency period, provided the amount dispensed shall not exceed a seven-day supply.

(2) In the event of prescriber death or incapacity or inability of the prescriber to provide medical services, the amount dispensed shall not exceed a thirty-day supply.

3. Pharmacists or permit holders dispensing an emergency supply pursuant to this section shall promptly notify the prescriber or the prescriber's office of the emergency dispensing, as required by the board by rule.

4. An emergency supply may not be dispensed pursuant to this section if the pharmacist has knowledge that the prescriber has otherwise prohibited or restricted emergency dispensing for the applicable patient.

5. **The determination to dispense an emergency supply of medication under this section shall only be made by a pharmacist licensed by the board.**

6. The board shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are

subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2013, shall be invalid and void.

354.415. 1. The powers of a health maintenance organization include, but are not limited to, the power to:

(1) Purchase, lease, construct, renovate, operate, and maintain hospitals, medical facilities, or both, and their ancillary equipment, and such property as may reasonably be required for the organization's principal office or for such other purposes as may be necessary in the transaction of the business of the organization;

(2) Make loans to a medical group under contract with it in furtherance of its program, or to make loans to any corporation under its control for the purpose of acquiring or constructing medical facilities and hospitals or in the furtherance of a program providing health care services to enrollees;

(3) Furnish health care services through providers which are under contract with, or employed by, the health maintenance organization;

(4) Contract with any person for the performance, on the organization's behalf, of certain functions such as marketing, enrollment, and administration;

(5) Contract with an insurance company licensed in this state, or with a health services corporation authorized to do business in this state, for the provision of insurance, indemnity, or reimbursement against the cost of health care services provided by the health maintenance organization;

(6) Offer, in addition to basic health care services:

(a) Additional health care services;

(b) Indemnity benefits covering out-of-area or emergency services; and

(c) Indemnity benefits, in addition to those relating to out-of-area and emergency services, provided through insurers or health services corporations;

(7) Offer as an option one or more health benefit plans which contain deductibles, coinsurance, coinsurance differentials, or variable co-payments. **Copayments may exceed fifty percent of the total cost of the service except as specifically prohibited under this chapter or chapter 376.** Health benefit plans offered under this section that contain deductibles shall be permitted only when combined with any health savings account or health reimbursement account as described in the Medicare Reform Act, P.L. No. 108-173, Title XII, Section 1201, provided that:

(a) The total out-of-pocket expenses paid for the receipt of basic health services under the plan shall not exceed the annual contribution limits for health savings accounts as determined by the Internal Revenue Service;

(b) The health savings account or health reimbursement account must be funded at a level equal to or greater than the out-of-pocket maximum limits defined for the high deductible health plan; and

(c) A distribution from the health savings account or health reimbursement account to pay a health care provider for a qualified medical expense is made within thirty days of the submission of a claim.

2. Prior to the exercise of any power granted in subdivision (1) or (2) of subsection 1 of this section, involving an amount in excess of five hundred thousand dollars, a health maintenance organization shall file notice, with adequate supporting information, with the director. The director shall disapprove such exercise of power if, in his opinion, it would substantially and adversely affect the financial soundness of the health maintenance organization and endanger its ability to meet its obligations. If the director does not disapprove such exercise of power within sixty days of the filing, it shall be deemed approved.

3. The director may exempt from the filing requirement of subsection 2 of this section those activities having minimal effect.

374.015. 1. For purposes of this section, "insurer" shall mean any person, reciprocal exchange, interinsurer, Lloyds insurer, fraternal benefit society, and any other legal entity engaged in the business of insurance including producers, adjusters and third-party administrators, health services corporations, health maintenance organizations, health carriers, prepaid limited health care service plans, dental, optometric, and other similar health service plans. "Insurer" shall also include all companies organized, incorporated, or doing business under the provisions of chapters 325, 354, and 374 to 385.

2. For purposes of this section, "bulletin" shall mean an informal written communication to inform or educate the insurance industry and the general public about a regulatory topic or issue. A bulletin is informational in nature and is not an evaluation of specific facts and circumstances.

3. Notwithstanding any law to the contrary, the director may at his or her discretion issue bulletins addressing the business of insurance in this state.

4. Bulletins do not have the force or effect of law and shall not be considered statements of general applicability that would require promulgation by rule.

5. Such bulletins shall not be binding on the department or an insurer. The director may revise or withdraw any previously issued bulletin; however such revision or withdrawal shall be prospective in nature. The effective date for such bulletin which was withdrawn or revised shall be ninety days after the date the revision or withdrawal notice is published and, where applicable, shall apply to new policies issued and policies that renew on or after that date.

374.018. 1. For purposes of this section, "no-action letter" shall mean a letter that states the intention of the department to not take enforcement actions under section 374.046 with respect to the requesting insurer, based on the specific facts then presented and applicable law, as of the date a no-action letter is issued.

2. For purposes of this section, "insurer" shall mean all insurance companies organized, incorporated, or doing business under the provisions of chapter 354, 376, 379, or 380.

3. Notwithstanding any law to the contrary, the director may at his or her discretion issue no-action letters addressing the business of insurance in this state.

4. No-action letters shall not be considered statements of general applicability that would require promulgation by rule.

5. Insurers who seek guidance may submit a written request for a no-action letter to the department.

6. An insurer is under an affirmative obligation to make full, true, and accurate disclosure of all information related to the activities for which the no-action letter is requested. Each request shall be accompanied by all relevant supplementary information including, but not limited to, background information regarding the request, policies, procedures, and applicable marketing materials. Each request shall also include complete copies of documents, and shall identify all provisions of law applicable to the request.

7. The insurer requesting the no-action letter shall provide the department with any additional information or documents the department requests for its review of the matter.

8. The insurer may withdraw the request for a no-action letter prior to the issuance of the no-action letter.

9. The department shall act on the no-action letter request within ninety days after it receives all information necessary to complete its review.

10. At the completion of its review of a request for a no-action letter the department shall do one of the following:

(1) Issue a no-action letter;

(2) Decline to issue a no-action letter; or

(3) Take such other action as the department considers appropriate.

11. A no-action letter shall be effective as of the date it is issued.

12. As long as there is no change in any material fact or law or the discovery of a material misrepresentation or omission made by the insurer, the department is estopped from bringing any enforcement action under section 374.046 against the requesting insurer concerning the specific conduct that is the subject of the no-action letter issued by the department. However, this estoppel shall not apply to those enforcement actions related

to the financial condition of the insurer. The determination of materiality shall be in the sole discretion of the director.

13. A no-action letter request shall not be a public record as defined in chapter 610 until the date of issuance by the department of a response to the no-action letter request. The request for a no-action letter and the department's response shall, after the date of issuance by the department, be considered a public record as defined in chapter 610. Upon request of the insurer, information submitted with a request for a no-action letter as required under this section that contains proprietary or trade secret information as defined in sections 417.450 to 417.467 shall not be considered a public record.

375.1605. 1. The provisions of this section shall apply to workers' compensation large deductible policies issued by an insurer subject to delinquency proceedings under this chapter. This section shall not apply to first party claims or to claims funded by a guaranty association net of the deductible unless subsection 3 of this section applies. Large deductible policies shall be administered in accordance with their terms except to the extent such terms conflict with this section.

2. For purposes of this section, the following terms shall mean:

(1) "Collateral", any cash, letters of credit, surety bond, or any other form of security posted by the insured or by a captive insurer or reinsurer to secure the insured's obligation under the large deductible policy to pay deductible claims or to reimburse the insurer for deductible claim payments. Collateral may also secure an insured's obligation to reimburse or pay the insurer as may be required for other secured obligations;

(2) "Commercially reasonable", to act in good faith using prevailing industry practices and making all reasonable efforts considering the facts and circumstances of the matter;

(3) "Deductible claim", any claim, including a claim for loss and defense and cost containment expense, unless such expenses are excluded, under a large deductible policy that is within the deductible;

(4) "Large deductible policy", any combination of one or more workers' compensation policies and endorsements issued to an insured and contracts or security agreements entered into between an insured and the insurer in which the insured has agreed with the insurer to:

(a) Pay directly the initial portion of any claim under the policy up to a specified dollar amount, or the expenses related to any claim; or

(b) Reimburse the insurer for its payment of any claim or related expenses under the policy up to the specified dollar amount of the deductible.

The term "large deductible policy" also includes policies which contain an aggregate limit on the insured's liability for all deductible claims in addition to a per-claim deductible limit. The primary purpose and distinguishing characteristic of a large deductible policy is the shifting of a portion of the ultimate financial responsibility under the large deductible policy to pay claims from the insurer to the insured, even though the obligation to initially pay claims may remain with the insurer. A large deductible shall include any policy with a deductible of fifty thousand dollars or more. Large deductible policies do not include policies, endorsements, or agreements which provide that the initial portion of any covered claim shall be self-insured and further that the insured shall have no payment obligation within the self-insured retention. Large deductible policies also do not include policies that provide for retrospectively rated premium payments by the insured or reinsurance arrangements or agreements, except to the extent such arrangements or agreements assume, secure, or pay the policyholder's large deductible obligations;

(5) "Other secured obligations", obligations of an insured to an insurer other than those under a large deductible policy, such as those under a reinsurance agreement or other agreement involving retrospective premium obligations, the performance of which is secured by collateral that also secures an insured's obligations under a large deductible policy.

3. Unless otherwise agreed by the responsible guaranty association, all large deductible claims which are also "covered claims" as defined by the applicable guaranty association law including those that may have been funded by an insured before liquidation shall be turned over to the guaranty association for handling. To the extent the insured funds or pays the deductible claim pursuant to an agreement by the guaranty fund or otherwise, the insured's funding or payment of a deductible claim will extinguish the obligations, if any, of the receiver or any guaranty association to pay such claim. No charge of any kind shall be made against the receiver or a guaranty association on the basis of an insured's funding or payment of a deductible claim.

4. To the extent a guaranty association pays any deductible claim for which the insurer would have been entitled to reimbursement from the insured, a guaranty association shall be entitled to the full amount of the reimbursement and available collateral as provided for under this section to the extent necessary to reimburse the guaranty association. Reimbursements paid to the guaranty association under this subsection shall not be treated as distributions under section 375.1218 or as early access payments under section 375.1205. To the extent that a guaranty association pays a deductible claim that is not reimbursed either from collateral or by insured payments, or incurred expenses in connection with large deductible policies that are not reimbursed

under this section, the guaranty association shall be entitled to assert a claim for those amounts in the delinquency proceeding. Nothing in this subsection limits any rights of the receiver or a guaranty association that may otherwise exist under applicable law to obtain reimbursement from insureds for claims payments made by the guaranty association under policies of the insurer or for the guaranty association's related expenses such as those affording the guaranty association the right to recover for claims payments made to or on behalf of high net worth insureds or claimants.

5. (1) The receiver shall have the obligation to collect reimbursements owed for deductible claims as provided for herein, and shall take all commercially reasonable actions to collect such reimbursements. The receiver shall promptly bill insureds for reimbursement of deductible claims:

(a) Paid by the insurer prior to the commencement of delinquency proceedings;

(b) Paid by a guaranty association upon receipt by the receiver of notice from a guaranty association of reimbursable payments; or

(c) Paid or allowed by the receiver.

(2) If the insured does not make payment within the time specified in the large deductible policy, or within sixty days after the date of billing if no time is specified, the receiver shall take all commercially reasonable actions to collect any reimbursements owed.

(3) Neither the insolvency of the insurer, nor its inability to perform any of its obligations under the large deductible policy, shall be a defense to the insured's reimbursement obligation under the large deductible policy.

(4) Except for gross negligence, an allegation of improper handling or payment of a deductible claim by the insurer, the receiver, or any guaranty association shall not be a defense to the insured's reimbursement obligations under the large deductible policy.

6. (1) Subject to the provisions of this subsection, the receiver shall utilize collateral when available to secure the insured's obligation to fund or reimburse deductible claims or other secured obligations or other payment obligations. A guaranty association shall be entitled to collateral as provided for in this subsection to the extent needed to reimburse a guaranty association for the payments of a deductible claim. Any distributions made to a guaranty association under this subsection shall not be treated as distributions under section 375.1218 or as early access payments under section 375.1205.

(2) All claims against the collateral shall be paid in the order received and no claim of the receiver including those described in this subsection shall supersede any other claim against the collateral as described in subdivision (4) of this subsection.

(3) The receiver shall draw down collateral to the extent necessary in the event that the insured fails to:

(a) Perform its funding or payment obligations under any large deductible policy;

(b) Pay deductible claim reimbursements within the time specified in the large deductible policy or within sixty days after the date of the billing if no time is specified;

(c) Pay amounts due the estate for preliquidation obligations;

(d) Timely fund any other secured obligation; or

(e) Timely pay expenses.

(4) Claims that are validly asserted against the collateral shall be satisfied in the order in which such claims are received by the receiver.

(5) Excess collateral may be returned to the insured as determined by the receiver after a periodic review of claims paid, outstanding case reserves, and a factor for incurred but not reported claims.

376.379. 1. A health carrier or managed care plan offering a health benefit plan in this state that provides prescription drug coverage shall offer, as part of the plan, medication synchronization services developed by the health carrier or managed care plan that allow for the alignment of refill dates for an enrollee's prescription drugs that are covered benefits.

2. Under its medication synchronization services, a health carrier or managed care plan shall:

(1) Not charge an amount in excess of the otherwise applicable co-payment amount under the health benefit plan for dispensing a prescription drug in a quantity that is less than the prescribed amount if:

(a) The pharmacy dispenses the prescription drug in accordance with the medication synchronization services offered under the health benefit plan; and

(b) A participating provider dispenses the prescription drug;

(2) Provide a full dispensing fee to the pharmacy that dispenses the prescription drug to the covered person.

3. For the purposes of this section the terms "health carrier", "managed care plan", "health benefit plan", "enrollee", and "participating provider" shall have the same meaning as defined in section 376.1350.

376.388. 1. As used in this section, unless the context requires otherwise, the following terms shall mean:

(1) "Contracted pharmacy" or "pharmacy", a pharmacy located in Missouri participating in the network of a pharmacy benefit manager through a direct or indirect contract;

(2) "Health carrier", an entity subject to the insurance laws and regulations of this state that contracts or offers to contract to provide, deliver, arrange for, pay for, or

reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health services, except that such plan shall not include any coverage pursuant to a liability insurance policy, workers' compensation insurance policy, or medical payments insurance issued as a supplement to a liability policy;

(3) "Maximum allowable cost", the per unit amount that a pharmacy benefits manager reimburses a pharmacist for a prescription drug, excluding a dispensing or professional fee;

(4) "Maximum allowable cost list" or "MAC list", a listing of drug products that meet the standard described in this section;

(5) "Pharmacy", as such term is defined in chapter 338;

(6) "Pharmacy benefits manager", an entity that contracts with pharmacies on behalf of health carriers licensed by the department of insurance, financial institutions and professional registration under chapter 376.

2. Upon each contract execution or renewal between a pharmacy benefit manager and a pharmacy or between a pharmacy benefits manager and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization, a pharmacy benefits manager shall, with respect to such contract or renewal:

(1) Include in such contract or renewal the sources utilized to determine maximum allowable cost and update such pricing information at least every seven days; and

(2) Maintain a procedure to eliminate products from the maximum allowable cost list of drugs subject to such pricing or modify maximum allowable cost pricing at least every seven days if such drugs do not meet the standards and requirements of this section in order to remain consistent with pricing changes in the marketplace.

3. A pharmacy benefits manager shall reimburse pharmacies for drugs subject to maximum allowable cost pricing which has been updated to reflect market pricing at least every seven days as set forth in subdivision (1) of subsection 2 of this section.

4. A pharmacy benefits manager shall not place a drug on a maximum allowable cost list unless there are at least two therapeutically equivalent multi-source generic drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers.

5. All contracts between a pharmacy benefits manager and a contracted pharmacy or between a pharmacy benefits manager and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization, shall include a process to

internally appeal, investigate, and resolve disputes regarding maximum allowable cost pricing. The process shall include the following:

(1) The right to appeal shall be limited to fourteen calendar days following the reimbursement of the initial claim; and

(2) A requirement that the pharmacy benefits manager shall respond to an appeal described in this subsection no later than fourteen calendar days after the date the appeal was received by such pharmacy benefits manager.

6. For appeals that are denied, the pharmacy benefits manager shall provide the reason for the denial and identify the national drug code of a drug product that may be purchased by contracted pharmacies at a price at or below the maximum allowable cost.

7. If the appeal is successful, the pharmacy benefits manager shall:

(1) Adjust the maximum allowable cost price that is the subject of the appeal effective on the day after the date the appeal is decided;

(2) Apply the adjusted maximum allowable cost price to all similarly situated pharmacies as determined by the pharmacy benefits manager; and

(3) Allow the pharmacy that succeeded in the appeal to reverse and rebill the pharmacy benefits claim giving rise to the appeal.

8. Appeals shall be upheld if:

(1) The pharmacy being reimbursed for the drug subject to the maximum allowable cost pricing in question was not reimbursed as required in subsection 3 of this section; or

(2) The drug subject to the maximum allowable cost pricing in question does not meet the requirements set forth in subsection 4 of this section.

376.791. 1. The provisions of subdivisions (4) and (5) of subsection 2 of section 376.777 shall not apply to any individual health insurance coverage. The term "individual health insurance coverage" shall have the meaning assigned to it in section 376.450.

2. The director shall promulgate rules and regulations to implement and administer the provisions of this section prior to January 1, 2016. Any rule or portion of a rule, as that term is defined in section 536.010 that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, and, if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the powers vested with the general assembly pursuant to chapter 536, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2015, shall be invalid and void.

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