FIRST REGULAR SESSION

[PERFECTED]

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 95

95TH GENERAL ASSEMBLY

0461L.02P D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal section 354.535, RSMo, and to enact in lieu thereof seven new sections relating to insurance co-payments for prescription drugs.

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

Section A. Section 354.535, RSMo, is repealed and seven new sections enacted in lieu thereof, to be known as sections 354.535, 376.387, 376.388, 376.389, 376.1460, 376.1462 and 376.1464 to read as follows:

354.535. 1. If a pharmacy, operated by or contracted with by a health maintenance organization, is closed or is unable to provide health care services to an enrollee in an emergency, a pharmacist may take an assignment of such enrollee's right to reimbursement, if the policy or contract provides for such reimbursement, for those goods or services provided to an enrollee of a health maintenance organization. No health maintenance organization shall refuse to pay the pharmacist any payment due the enrollee under the terms of the policy or contract.

2. No health maintenance organization, conducting business in the state of Missouri, shall contract with a pharmacy, pharmacy distributor or wholesale drug distributor, nonresident or otherwise, unless such pharmacy or distributor has been granted a permit or license from the Missouri board of pharmacy to operate in this state.

3. Every health maintenance organization shall apply the same coinsurance, co-payment and deductible factors to all drug prescriptions filled by a pharmacy provider who participates in the health maintenance organization's network if the provider meets the contract's explicit product cost determination. If any such contract is rejected by any pharmacy provider, the health maintenance organization may offer other contracts necessary to comply with any network

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.

adequacy provisions of this act. However, nothing in this section shall be construed to prohibit the health maintenance organization from applying different coinsurance, co-payment and deductible factors between generic and brand name drugs.

4. **If the co-payment applied by a health maintenance organization exceeds the usual and customary retail price of the prescription drug, enrollees shall only be required to pay the usual and customary retail price of the prescription drug, and no further charge to the enrollee or plan sponsor shall be incurred on such prescription.**

5. Health maintenance organizations shall not set a limit on the quantity of drugs which an enrollee may obtain at any one time with a prescription, unless such limit is applied uniformly to all pharmacy providers in the health maintenance organization's network.

[5.**] 6.** Health maintenance organizations shall not insist or mandate any physician or other licensed health care practitioner to change an enrollee's maintenance drug unless the provider and enrollee agree to such change. For the purposes of this provision, a maintenance drug shall mean a drug prescribed by a practitioner who is licensed to prescribe drugs, used to treat a medical condition for a period greater than thirty days. Violations of this provision shall be subject to the penalties provided in section 354.444. Notwithstanding other provisions of law to the contrary, health maintenance organizations that change an enrollee's maintenance drug without the consent of the provider and enrollee shall be liable for any damages resulting from such change. Nothing in this subsection, however, shall apply to the dispensing of generically equivalent products for prescribed brand name maintenance drugs as set forth in section 338.056, RSMo.

376.387. If the co-payment for prescription drugs applied by a health insurer or health carrier, as defined in section 376.1350, exceeds the usual and customary retail price of the prescription drug, enrollees shall only be required to pay the usual and customary retail price of the prescription drug, and no further charge to the enrollee or plan sponsor shall be incurred on such prescription.

376.388. 1. A pharmacy benefits manager, as defined in section 376.1460, shall remit on a monthly basis to the plan sponsor a summary of each claim submitted by the pharmacy benefits manager to the plan sponsor which shall include the prescription number, the eleven-digit National Drug Code (NDC) number used to calculate the charge to the plan sponsor and the National Drug Code (NDC) used to calculate the reimbursement to the pharmacy for such claim, the quantity and the net amount paid by the plan sponsor to the pharmacy benefits manager.

2. A pharmacy benefits manager shall not:

(1) Automatically enroll or passively enroll the pharmacy in a contract, or modify an existing contract without written affirmation from the pharmacy or pharmacist;

(2) Require that a pharmacy or pharmacist participate in one pharmacy benefits manager contract in order to participate in another contract; or

(3) Discriminate between in-network pharmacies or pharmacists on the basis of co-payments or days of supply unless such pharmacy declines to fill such prescriptions at the price allowed to other in-network pharmacies for such prescription.

3. When an insured presents a prescription to a pharmacy in the pharmacy benefits manager's network, the pharmacy benefits manager shall not reassign such prescription to be filled by any other pharmacy. When the pharmacy benefits manager contacts the prescribing health care practitioner to affirm or modify the original prescription, the affirmed or modified prescription shall be filled at the in-network pharmacy of the patient's choice to which the insured presented the original prescription. This subsection shall not apply to any prescribed specialty drug with a specific formulation.

376.389. 1. A health benefit plan or health care services contract that covers prescription drugs shall not limit, reduce, or deny coverage for any immunosuppressive drug if, prior to the limitation, reduction, or denial of coverage:

(1) Any insured was using the immunosuppressive drug;

(2) Such insured or insureds were covered under the plan or contract; and

(3) The immunosuppressive drug was covered under the plan or contract for such insured individual or individuals.

2. A limitation, reduction, or denial of coverage includes removing an immunosuppressive drug from the formulary or other drug list, imposing new prior authorization or other utilization management tools, or placing the immunosuppressive drug on a formulary tier that increases the patient's cost-sharing obligations or otherwise increases the patient's cost-sharing obligations.

3. Nothing in this section shall prohibit an insurer from making uniform changes in its benefit design that apply to all covered drugs, uniformly removing a drug from the formulary list for all insureds, or increasing cost-sharing obligations merely due to a percentage coinsurance payment that necessarily increases with an increase in the underlying drug prices.

376.1460. 1. As used in sections 376.1460 to 376.1464, the following terms shall mean:

(1) "Health carrier", the same meaning as such term is defined in section 376.1350; except when such health care services are provided, delivered, arranged for, paid for, or reimbursed by the department of social services or the department of mental health;

(2) "Pharmacy benefit manager" or "PBM", a person or entity other than a pharmacy or pharmacist acting as an administrator in connection with pharmacy benefits;

(3) "Switch communication", a communication to a patient or the patient's physician from a health carrier or PBM that recommends a patient's medication be switched by the original prescribing health care professional to a different medication than the medication originally prescribed by the prescribing health care professional. A switch communication shall:

(a) Clearly identify the originally prescribed medication and the medication to which it has been proposed that the patient should be switched;

(b) Explain any financial incentives that may be provided to, or have been offered to, the prescribing health care professional by the health carrier or PBM that could result in the switch to the different drug;

(c) Explain any clinical affects that the proposed medication may have on the patient which are different than those of the originally prescribed medication;

(d) Advise the patient of the right to discuss the proposed change in treatment before such a switch takes place, including a discussion with the patient's prescribing practitioner; and

(e) Explain any cost sharing changes for which the patient is responsible; and

(f) Clearly identify the net change in cost to the health insurance payer, including employers, which will result from the use of the proposed drug in lieu of the originally prescribed medication.

2. Anytime a patient's prescribed medication is recommended to be switched to a medication other than that originally prescribed by the prescribing practitioner, the following communications shall be sent:

(1) A switch communication to the patient; and

(2) Information to the plan sponsor or health carrier utilizing a PBM regarding the recommended medication, shown in currency form, and the cost, shown in currency form, of the originally prescribed medication. Such communication shall include notice of medication switches among plan participants, including any financial incentive the health carrier or PBM may be utilizing to encourage or induce the switch. Information contained in the notification shall be in the aggregate and shall not contain any personally identifiable information.

The provisions of this subsection shall not apply to any substitution made under subsection 2 of section 338.056, RSMo, unless such substitute results in a higher cost to the patient or health insurance payer.

3. The department shall promulgate rules governing switch communications. Such rules shall include, but not be limited to the following:

(1) The manner and form for health carriers and pharmacy benefits managers shall use in switch communications to patients and communications to prescribing practitioners and health insurance payers, including employers;

(2) Procedures for verifying the accuracy of any switch communications from health benefit plans and pharmacy benefit managers to ensure that such switch communications are truthful, accurate, and not misleading based on cost to the patient and plan sponsor, the product package labeling, medical compendia recognized by the MO HealthNet program for the drug utilization review program, and peer-reviewed medical literature, with appropriate references provided;

(3) Except for a substitution due to the Food and Drug Administration's withdrawal of a drug for prescription, a requirement that all switch communications bear a prominent legend on the first page that states: "This is not a product safety notice. This is a promotional announcement from your health care insurer or pharmacy benefit manager about one of your current prescribed medications.".

4. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, 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, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, 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, 2009, shall be invalid and void.

376.1462. 1. Issuing or delivering or causing to be issued or delivered a switch communication that has not been approved and is not in compliance with the requirements of section 376.1460 is punishable by a fine not to exceed twenty-five thousand dollars.

2. Providing a misrepresentation or false statement in a switch communication under section 376.1460 is punishable by a fine not to exceed twenty-five thousand dollars.

3. Any other material violation of section 376.1460 is punishable by a fine not to exceed twenty-five thousand dollars.

376.1464. 1. When medications for the treatment of any medical condition are restricted for use by a health carrier or PBM by a step therapy or fail first protocol, a prescriber shall have access to a clear and convenient process to expeditiously override such restriction from the PBM or health carrier. An override of such restriction shall be expeditiously granted by the health carrier or PBM when:

(1) The prescriber can demonstrate, based on sound clinical evidence, that the preferred treatment required under the step therapy or fail first protocol has been ineffective in the treatment of the covered person's disease or medical condition; or

(2) Based on sound clinical evidence or medical and scientific evidence:

(a) The prescriber can demonstrate that the preferred treatment required under the step therapy or fail first protocol is expected or likely to be ineffective based on the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen; or

(b) The prescriber can demonstrate that the preferred treatment required under the step therapy or fail first protocol will cause or will likely cause an adverse reaction or other harm to the covered person.

2. The duration of any step therapy or fail first protocol shall not be longer than a period of fourteen days when such treatment is deemed clinically ineffective by the prescribing physician. However, when the health carrier or PBM can show, through sound clinical evidence, the originally prescribed medication is likely to require more than two weeks to provide any relief or amelioration to the patient the step therapy or fail first protocol may be extended up to seven additional days.

3. Nothing in this section shall be construed as requiring coverage for any condition which is specifically excluded by the insurance policy or contract and not otherwise required by law.

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