FIRST REGULAR SESSION

SENATE BILL NO. 236

96TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SCHAEFER.

Read 1st time February 9, 2011, and ordered printed.

TERRY L. SPIELER, Secretary.

1364S.02I

AN ACT

To amend chapters 338 and 376, RSMo, by adding thereto six new sections relating to pharmacy services, with penalty provisions.

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

Section A. Chapters 338 and 376, RSMo, are amended by adding thereto six new sections, to be known as sections 338.098, 376.388, 376.1460, 376.1462, 376.1464, and 376.1466, to read as follows:

338.098. 1. All prescription drug orders communicated by way of electronic transmission shall:

(1) Be transmitted directly to a pharmacist or pharmacy technician in a licensed pharmacy of the patient's choice with no intervening person having access to the prescription drug order;

(2) Identify the transmitter's phone number or any other suitable means to contact the transmitter for verbal or written confirmation, the time and date of the transmission, and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law;

(3) Be transmitted by an authorized practitioner or the designated agent of the prescriber; and

(4) Be deemed the original prescription drug order, provided it meets the requirements of this subsection.

2. All electronic transmission devices used to communicate a prescription to a pharmacist or pharmacy technician shall:

(1) Allow any legal prescription drug order to be written and entered into the device without interference or limitations prior to submission to a pharmacist or pharmacy technician; and

(2) Allow the prescription to be written through a neutral and

open platform that does not use any means, program, or device, including, but not limited to, advertising, instant messaging, and pop-up messaging, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a health care professional at the point of care.

3. Notwithstanding subdivision (2) of subsection 2 of this section, individuals or entities may show information regarding a plan's formulary so long as:

(1) All covered outpatient drugs and pharmacies, in and out of network, available are readily disclosed to the health care professional;

(2) Nothing is designed to preclude or make more difficult the health care professional's or patient's selection of any particular pharmacy or covered outpatient drug; and

(3) An electronic prior authorization process for allowing approval of an exception to the plan formulary or other restriction is available, providing adjudication occurs within forty-eight hours from the time the prescription drug order is received. The board of pharmacy shall promulgate rules regarding such an electronic prior authorization process.

4. All electronic transmission devices used to communicate a prescription to a pharmacist or pharmacy technician shall be limited to messages to the prescriber and his or her staff that are consistent with the label, substantially supported by scientific evidence, accurate, up-to-date, and fact-based, including a fair and balanced presentation of risks and benefits, and support for better clinical decision-making, such as, alerts to adverse events and access to formulary information. This information must be consistent with the U.S. Food and Drug Administration regulations for advertising pharmaceutical products and not be selectively or competitively pushed to the prescriber. The distribution of such information must not diminish the patient's right to appeal.

5. Nothing in this section shall preclude the use of paper prescriptions.

376.388. 1. A pharmacy benefits manager shall not:

(1) Automatically enroll or passively enroll a pharmacy in a contract, or modify an existing contract without 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 copayments or days of supply unless such pharmacy declines to fill such prescriptions at the price allowed to other in-network pharmacies for such prescription.

2. 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.

376.1460. 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 practitioner to a different medication than the medication originally prescribed by the prescribing practitioner. 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 practitioner by the health carrier or PBM that could result in the switch to the different medication;

(c) Explain any clinical effects 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;

(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 medication in lieu of the originally prescribed medication.

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

(1) A switch communication to the patient; and

(2) Information to the plan sponsor or health carrier using a PBM regarding the recommended medication 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 using 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, unless such substitute results in a higher cost to the patient or health insurance payer.

3. All health carriers and pharmacy benefit managers shall submit the format and language for any switch communication that shall be sent to a patient under this section to the department of insurance, financial institutions and professional registration for approval. The department shall examine the format and language of the switch communication to ensure it meets the criteria for a switch communication as described in this section. The department shall have sixty days to review and issue a statement to the health carrier or PBM regarding compliance with this section. If the department finds noncompliance with this section, the department shall cite specific reasons for such decision.

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

(1) Procedures for verifying the accuracy of any switch communications from health carriers 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; and

(2) 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 notification on the first page clearly indicating the switch communication is not a product safety notice.

5. A PBM owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law.

(1) A PBM shall perform its duties with care, skill, prudence, and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of like character and with like aims.

(2) A PBM shall notify the covered entity in writing of any activity, policy, or practice of the PBM that directly or indirectly presents any conflict of interest with the duties imposed by this section.

6. 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, 2011, 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 request an override for such restriction from the PBM or health carrier. An override of such restriction shall be expeditiously granted by the health carrier or PBM when the prescriber can demonstrate:

(1) 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, that the preferred treatment required under the step therapy or fail first protocol:

(a) Is 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) 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 require the PBM or health carrier to grant an exception to the step therapy or fail first protocol if the prescriber fails to meet the requirements in subsection 1 of this section.

4. 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 covered by law.

376.1466. In order to expedite and provide a more efficient and cost effective process for the preauthorization and step therapy process, every pharmacy benefit manager and health carrier requiring preauthorization or step therapy for a specific medication shall provide a website with a list of the medications which require preauthorization and the process required to comply with the pharmacy benefits manager's or health carrier's policies.

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