

SECOND REGULAR SESSION

# SENATE BILL NO. 918

95TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SCHAEFER.

Read 1st time February 8, 2010, and ordered printed.

TERRY L. SPIELER, Secretary.

4861S.011

## AN ACT

To amend chapter 376, RSMo, by adding thereto four new sections relating to pharmacy benefit managers, with penalty provisions.

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

Section A. Chapter 376, RSMo, is amended by adding thereto four new sections, to be known as sections 376.388, 376.1460, 376.1462, and 376.1464, to read as follows:

**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

38 PBM regarding the recommended medication and the cost, shown in  
39 currency form, of the originally prescribed medication. Such  
40 communication shall include notice of medication switches among plan  
41 participants, including any financial incentive the health carrier or  
42 PBM may be using to encourage or induce the switch. Information  
43 contained in the notification shall be in the aggregate and shall not  
44 contain any personally identifiable information.

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

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

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

62 (1) Procedures for verifying the accuracy of any switch  
63 communications from health carriers and pharmacy benefit managers  
64 to ensure that such switch communications are truthful, accurate, and  
65 not misleading based on cost to the patient and plan sponsor, the  
66 product package labeling, medical compendia recognized by the MO  
67 HealthNet program for the drug utilization review program, and peer-  
68 reviewed medical literature; and

69 (2) Except for a substitution due to the Food and Drug  
70 Administration's withdrawal of a drug for prescription, a requirement  
71 that all switch communications bear a prominent notification on the  
72 first page clearly indicating the switch communication is not a product  
73 safety notice.

74 5. A PBM owes a fiduciary duty to a covered entity and shall

75 discharge that duty in accordance with the provisions of state and  
76 federal law.

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

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

84 6. Any rule or portion of a rule, as that term is defined in section  
85 536.010 that is created under the authority delegated in this section  
86 shall become effective only if it complies with and is subject to all of  
87 the provisions of chapter 536, and, if applicable, section 536.028. This  
88 section and chapter 536 are nonseverable and if any of the powers  
89 vested with the general assembly pursuant to chapter 536, to review, to  
90 delay the effective date, or to disapprove and annul a rule are  
91 subsequently held unconstitutional, then the grant of rulemaking  
92 authority and any rule proposed or adopted after August 28, 2010, shall  
93 be invalid and void.

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

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

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

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

8 (1) Based on sound clinical evidence, that the preferred  
9 treatment required under the step therapy or fail first protocol has

10 been ineffective in the treatment of the covered person's disease or  
11 medical condition; or

12 (2) Based on sound clinical evidence or medical and scientific  
13 evidence, that the preferred treatment required under the step therapy  
14 or fail first protocol:

15 (a) Is likely to be ineffective based on the known relevant  
16 physical or mental characteristics of the covered person and known  
17 characteristics of the drug regimen; or

18 (b) Will likely cause an adverse reaction or other harm to the  
19 covered person.

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

28 3. Nothing in this section shall require the PBM or health carrier  
29 to grant an exception to the step therapy or fail first protocol if the  
30 prescriber fails to meet the requirements in subsection 1 of this section.

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

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