

HOUSE _____ AMENDMENT NO. _____

Offered By _____

AMEND House Committee Substitute for Senate Bill No. 284, Page 12, Section 338.055, Line 99, by inserting after all of said section and line the following:

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

(1) Allow for the physician to review the patient's current medication list and medication history information as well as view all the medications available to the physician for the patient's condition;

(2) Have the ability to electronically adjudicate prior authorization and step therapy protocols. An electronic prior authorization process for allowing approval of an exception to the plan formulary or other restriction shall be available, so long as adjudication occurs within forty-eight hours from the time the prescription drug order is received; and

(3) Minimize interference between physician and patient through a neutral and open platform, except that information about the availability of a generic drug may be communicated. A generic drug is identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

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

3. The board of pharmacy shall promulgate rules regarding such an electronic prior authorization process and 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, 2011, shall be invalid and void.”; and

Further amend said bill, Page 13, Section 338.330, Line 38, by inserting after all of said section and line the following:

1 “376.388. 1. A pharmacy benefit manager shall not:
2 (1) Automatically enroll or passively enroll a pharmacy in a contract or modify an existing
3 contract without affirmation from the pharmacy or pharmacist;
4 (2) Require that a pharmacy or pharmacist participate in one pharmacy benefit manager
5 contract in order to participate in another contract; or
6 (3) Discriminate between in-network pharmacies or pharmacists on the basis of
7 copayments or days of supply unless such pharmacy declines to fill such prescriptions at the price
8 allowed to other in-network pharmacies for such prescription.
9 2. When an insured presents a prescription to a pharmacy in the pharmacy benefit
10 manager's network, the pharmacy benefit manager shall not reassign such prescription to be filled
11 by any other pharmacy. When the pharmacy benefit manager contacts the prescribing health care
12 practitioner to affirm or modify the original prescription, the affirmed or modified prescription
13 shall be filled at the in-network pharmacy of the patient's choice to which the insured presented
14 the original prescription.
15 376.1460. 1. As used in sections 376.1460 to 376.1464, the following terms shall mean:
16 (1) "Health carrier", the same meaning as such term is defined in section 376.1350, except
17 when such health care services are provided, delivered, arranged for, paid for, or reimbursed by
18 the department of social services or the department of mental health;
19 (2) "Pharmacy benefit manager" or "PBM", a person or entity other than a pharmacy or
20 pharmacist acting as an administrator in connection with pharmacy benefits;
21 (3) "Switch communication", a communication to a patient or the patient's physician from
22 a health carrier or PBM that recommends a patient's medication be switched by the original
23 prescribing practitioner to a different medication than the medication originally prescribed by the
24 prescribing practitioner. A switch communication shall:
25 (a) Clearly identify the originally prescribed medication and the medication to which it
26 has been proposed that the patient should be switched;
27 (b) Explain any financial incentives that may be provided to, or have been offered to, the
28 prescribing practitioner by the health carrier or PBM that could result in the switch to the different
29 medication;
30 (c) Explain any clinical effects that the proposed medication may have on the patient
31 which are different than those of the originally prescribed medication;
32 (d) Advise the patient of the right to discuss the proposed change in treatment before such
33 a switch takes place, including a discussion with the patient's prescribing practitioner;
34 (e) Explain any cost sharing changes for which the patient is responsible; and
35 (f) Clearly identify the net change in cost to the health insurance payer, including
36 employers, which will result from the use of the proposed medication in lieu of the originally

1 prescribed medication.

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

5 (1) A switch communication to the patient and the patient's physician; and

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

12
13 The provisions of this subsection shall not apply to any substitution made under subsection 2 of
14 section 338.056, unless such substitute results in a higher cost to the patient or health insurance
15 payer.

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

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

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

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

34 5. (1) A PBM owes a fiduciary duty to a covered entity and shall discharge that duty in
35 accordance with the provisions of state and federal law.

36 (2) A PBM shall perform its duties with care, skill, prudence, and diligence and in

1 accordance with the standards of conduct applicable to a fiduciary in an enterprise of like
2 character and with like aims.

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

6 6. Any rule or portion of a rule, as that term is defined in section 536.010 that is created
7 under the authority delegated in this section shall become effective only if it complies with and is
8 subject to all of the provisions of chapter 536, and, if applicable, section 536.028. This section
9 and chapter 536 are nonseverable and if any of the powers vested with the general assembly
10 pursuant to chapter 536, to review, to delay the effective date, or to disapprove and annul a rule
11 are subsequently held unconstitutional, then the grant of rulemaking authority and any rule
12 proposed or adopted after August 28, 2011, shall be invalid and void.

13 376.1462. 1. Issuing or delivering or causing to be issued or delivered a switch
14 communication that has not been approved and is not in compliance with the requirements of
15 section 376.1460 is punishable by a fine not to exceed twenty-five thousand dollars.

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

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

20 376.1464. 1. When medications for the treatment of any medical condition are restricted
21 for use by a health carrier or PBM by a step therapy or fail first protocol, a prescriber shall have
22 access to a clear and convenient process to request an override for such restriction from the PBM
23 or health carrier. An override of such restriction shall be expeditiously granted by the health
24 carrier or PBM when the prescriber can demonstrate:

25 (1) Based on sound clinical evidence, that the preferred treatment required under the step
26 therapy or fail first protocol has been ineffective in the treatment of the covered person's disease
27 or medical condition; or

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

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

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

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

1 or amelioration to the patient the step therapy or fail first protocol may be extended up to seven
2 additional days.

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

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

9 376.1466. In order to expedite and provide a more efficient and cost effective process for
10 the preauthorization and step therapy process, every pharmacy benefit manager and health carrier
11 requiring preauthorization or step therapy for a specific medication shall provide a website with a
12 list of the medications which require preauthorization and the process required to comply with the
13 pharmacy benefit manager's or health carrier's policies.”; and

14
15 Further amend said bill by amending the title, enacting clause, and intersectional references
16 accordingly.