**House** _____ **Amendment NO.**____

**Offered By**

_____ _____

AMEND House Committee Substitute for Senate Substitute for Senate Bill No. 608, Page 4, Section 208.800, Line 3, by inserting after all of said section and line the following:

"376.2029. The legislature declares it a matter of public interest:

(1) That patients be exempt from step therapy protocols if inappropriate or otherwise not in the best interest of the patient;

(2) That patients, through their health care providers, have access to a fair, transparent, and independent process for requesting an exception to a step therapy protocol if the patient's health care provider deems such exception appropriate; and

(3) That patients and health care providers receive a timely determination from health carriers and health benefit plans on requests for an exception to a step therapy protocol.

376.2030. As used in sections 376.2030 to 376.2036, the following terms mean:

(1) "Emergency medical condition", the same meaning as such term is defined in section 376.1350;

(2) "Health benefit plan", the same meaning as such term is defined in section 376.1350;

(3) "Health care provider", the same meaning as such term is defined in section 376.1350;

(4) "Health carrier", the same meaning as such term is defined in section 376.1350;

(5) "Step therapy override exception determination", a determination as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's preferred prescription drug. Such determination shall be based on a review of the patient's or health care provider's request for an override, along with supporting rationale and documentation;

(6) "Step therapy override exception request", a written or electronic request from a patient's health care provider for the step therapy protocol to be overridden in favor of immediate coverage of the health care provider's preferred prescription drug. The manner and form of the request shall be disclosed to the patient and health care provider as provided under section 376.2034;

(7) "Step therapy protocol", a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient are to be prescribed and covered by a health carrier or health benefit plan;

(8) "Utilization review organization", an entity that conducts utilization review other than an insurer or health carrier performing utilization review for its own health benefit plans.

376.2034. 1. If coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health benefit plan, or utilization review organization via a step therapy protocol, a patient and his or her health care provider shall have access to a readily accessible process to request a step therapy override exception determination. A health carrier,

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health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process shall be disclosed to the patient and health care provider, which shall include the necessary documentation needed to process such request and be made available on the health carrier plan or health benefit plan website.

2. A step therapy override exception request shall be expeditiously granted if:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient;

(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;

(3) The patient has tried the step therapy required prescription drug while under his or her current or previous health insurance or health benefit plan, and the use of such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) The patient has tried a prescription drug in the same therapeutic class as the step therapy required prescription drug or with a similar mechanism of action that would generally possess a comparable potency. Pharmacy drug samples shall not be considered trial and failure of a preferred prescription drug in lieu of trying the step therapy required prescription drug; or

(5) The step therapy required prescription drug is not in the best interest of the patient based on medical necessity.

3. The health carrier, health benefit plan, or utilization review organization may request relevant documentation from the health care provider to support the override exception request, including the results of any clinical evaluation or evidence that the patient has tried the step therapy required prescription drug and the use of such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

4. Upon granting a step therapy override exception request, the health carrier, health benefit plan, or utilization review organization shall authorize dispensation of and coverage for the prescription drug prescribed by the patient's treating health care provider, provided such drug is a covered drug under such policy or plan.

5. (1) The health carrier, health benefit plan, or utilization review organization shall:

(a) Acknowledge receipt of a step therapy override exception request and indicate if relevant supporting documentation is needed within one business day of receipt of the request;

(b) If supporting documentation is not needed, grant or deny the step therapy override exception request within three business days of receipt of the request; and

(c) If supporting documentation is needed, grant or deny the step therapy override exception request within three business days of receipt of the supporting documentation.

(2) If an emergency medical condition exists, a health carrier, health benefit plan, or utilization review organization shall:

(a) Acknowledge receipt of a step therapy override exception request and indicate if relevant supporting documentation is needed within one business day of receipt of the request;

(b) If supporting documentation is not needed, grant or deny the step therapy override exception request within one business day of receipt of the request; and

(c) If supporting documentation is needed, grant or deny the step therapy override exception request within one business day of receipt of the supporting documentation.

(3) If an insurer, health plan, or utilization review organization does not grant or deny the step therapy override exception request within the time allotted under this subsection, the step therapy override exception request shall be deemed granted.

(4) If an insurer, health plan, or utilization review organization denies a step therapy override exception request, the insurer, health benefit plan, or utilization review organization shall

provide notification of the denial and a detailed explanation of the reason for the denial to the patient and health care provider. Such detailed explanation shall include the clinical rationale that supports the denial of the step therapy override exception request, if applicable. Upon denial of a step therapy override exception request, the requesting health care provider, on behalf of the patient, shall be given an opportunity to request a reconsideration of the denial as provided under section 376.1365.

6. This section shall not be construed to prevent:

(1) A health carrier, health benefit plan, or utilization review organization from requiring a patient to try an A/B rated generic equivalent or other branded prescription drug prior to providing coverage for the requested branded prescription drug; or

(2) A health care provider from prescribing a prescription drug he or she determines is medically appropriate.

376.2036. 1. The director of the department of insurance, financial institutions and professional registration shall grant a health carrier, health benefit plan, or utilization review organization a waiver from the provisions of sections 376.2030 to 376.2036 if the health carrier, health benefit plan, or utilization review organization demonstrates to the director by actual experience, which is certified by an independent member of the American Academy of Actuaries, over any consecutive twenty-four-month period that compliance with sections 376.2030 to 376.2036 has independently increased the cost of its health insurance policies or health benefit plans by an amount that results in an increase in premium costs to the health carrier, health benefit plan, or utilization review organization greater than the medical inflation rate for such twenty-four-month period. The data provided in support of the waiver and certified by the independent actuary shall demonstrate that the increased costs are attributable to the provisions of sections 376.2030 to 376.2036.

2. The provisions of sections 376.2030 to 376.2036 shall apply only to health insurance policies and health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2018.

3.Notwithstanding any law to the contrary, the department of insurance, financial institutions and professional registration shall promulgate any regulations necessary to enforce sections 376.2030 to 376.2036. 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, 2016, shall be invalid and void."; and

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