SENATE
STATE OF MINNESOTA
NINETIETH SESSION

S.F. No. 2897

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DATE	D-PG	OFFICIAL STATUS
03/01/2018	6247	Introduction and first reading
		Referred to Health and Human Services Finance and Policy
03/29/2018		Comm report: To pass as amended and re-refer to Finance

A bill for an act

relating to health insurance; establishing a step therapy protocol and override for prescription drug coverage; proposing coding for new law in Minnesota Statutes, chapter 62Q.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[62Q.184] STEP THERAPY OVERRIDE.**

Subdivision 1. **Definition.** (a) For purposes of this section, the terms in this subdivision have the meanings given.

(b) "Clinical practice guideline" means a systematically developed statement to assist health care providers and patients in making decisions about appropriate health care services for specific clinical circumstances and conditions.

(c) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by the plan sponsor to determine the medical necessity and appropriateness of health care services.

(d) "Plan sponsor" means a health plan company or a utilization review organization, as defined in section 62M.02, subdivision 21.

(e) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, including self-administered and physician-administered drugs, are medically appropriate for a particular patient and are covered under a health plan.

(f) "Step therapy override" means that the step therapy protocol that is overridden in favor of expeditious coverage of the selected prescription drug of the prescribing health care provider because at least one of the conditions of subdivision 3, paragraph (a), exists.

Subd. 2. **Criteria for step therapy protocols.** (a) Clinical review criteria used by a plan sponsor to establish a step therapy protocol must be based on clinical practice guidelines that:

(1) recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol;

(2) are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

(i) requiring members to disclose a potential conflict of interest with entities, including plan sponsors and pharmaceutical manufacturers, and recuse themselves from voting if they have a conflict of interest;

(ii) using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; and

(iii) offering opportunities for public review and comments;

(3) are based on high quality studies, research, and medical practice;

(4) are created by an explicit and transparent process that:

(i) minimizes biases and conflicts of interest;

(ii) explains the relationship between treatment options and outcomes;

(iii) rates the quality of the evidence supporting recommendations; and

(iv) considers relevant patient subgroups and preferences; and

(5) are continually updated through a review of new evidence, research, and newly developed treatments.

(b) In the absence of clinical guidelines that meet the requirements of paragraph (a), findings in peer-reviewed publications may be substituted.

(c) When establishing a step therapy protocol, the plan sponsor shall also take into account the needs of atypical patient populations and diagnoses.

(d) This subdivision does not require a plan sponsor to establish a new entity to develop clinical review criteria to be used for step therapy protocols.

Subd. 3. **Step therapy override.** (a) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by the plan sponsor through the use of a step therapy protocol, the prescribing health care provider shall have access to a clear, readily accessible, and convenient process to request a step therapy override. The process must be made easily accessible on the plan sponsor's Web site. A plan sponsor may use its existing medical exceptions process to satisfy this requirement. The plan sponsor shall grant an override to the step therapy protocol if at least one of the following conditions exist:

(1) the required prescription drug is contraindicated or will likely cause an adverse patient reaction 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 required prescription drug while under their current or previous health plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) the required prescription drug is not in the best interest of the patient, based on medical necessity; and

(5) the patient has been stable on a prescription drug prescribed by their health care provider for the medical condition under consideration while on a current or previous health plan.

(b) Upon the granting of a step therapy override, the plan sponsor shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider.

(c) The patient, or the prescribing health care provider if designated by the patient, may appeal the denial of a step therapy override by the plan sponsor using the complaint procedure under sections 62Q.68 to 62Q.73.

(d) In a denial of an override request and subsequent appeal, the plan sponsor's decision must specifically state why the step therapy override request did not meet the conditions of paragraph (a) cited by the prescribing health care provider in requesting the step therapy override.

(e) The plan sponsor shall respond to a step therapy override request or an appeal within 72 hours of receipt of the request. In cases where exigent circumstances exist, a plan sponsor shall respond within 24 hours of receipt of the request. If the plan sponsor does not send a

response to the patient or prescribing health care provider if designated by the patient, within the time allotted, the override request or appeal is granted and binding on the plan sponsor.

(f) This subdivision does not prevent:

(1) the plan sponsor from requiring a patient to try an AB-rated generic equivalent prior to providing coverage for the equivalent branded prescription drug; and

(2) a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

EFFECTIVE DATE. This section is effective January 1, 2019.