AN ACT

relating to step therapy protocols required by a health benefit plan in connection with prescription drug coverage.

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

SECTION 1. Section 1369.051, Insurance Code, is amended by amending Subdivision (1) and adding Subdivisions (1-a), (1-b), and (5) to read as follows:

(1) "Clinical practice guideline" means a statement systematically developed by a multidisciplinary panel of experts composed of physicians and, as necessary, other health care providers to assist a patient or health care provider in making a decision about appropriate health care for a specific clinical circumstance or condition.

(1-a) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by a health benefit plan issuer, utilization review organization, or independent review organization to determine the medical necessity and appropriateness or the experimental or investigational nature of a health care service or prescription drug.

(1-b) "Drug formulary" means a list of drugs:

(A) for which a health benefit plan provides coverage;

(B) for which a health benefit plan issuer approves payment; or

(C) that a health benefit plan issuer encourages or offers incentives for physicians to prescribe.

(5) "Step therapy protocol" means a protocol that requires an enrollee to use a prescription drug or sequence of prescription drugs other than the drug that the enrollee's physician recommends for the enrollee's treatment before the health benefit plan provides coverage for the recommended drug.

SECTION 2. Subchapter B, Chapter 1369, Insurance Code, is amended by adding Sections 1369.0545 and 1369.0546 to read as follows:

Sec. 1369.0545. STEP THERAPY PROTOCOLS. (a) A health benefit plan issuer that requires a step therapy protocol before providing coverage for a prescription drug must establish, implement, and administer the step therapy protocol in accordance with clinical review criteria readily available to the health care industry. The health benefit plan issuer shall take into account the needs of atypical patient populations and diagnoses in establishing the clinical review criteria. The clinical review criteria:

(1) must consider generally accepted clinical practice guidelines that are:

(A) developed and endorsed by a multidisciplinary panel of experts described by Subsection (b);

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

(C) created by an explicit and transparent process that:

(i) minimizes bias and conflicts of interest;

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

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

(iv) considers relevant patient subgroups and preferences; and

(D) updated at appropriate intervals after a review of new evidence, research, and treatments; or

(2) if clinical practice guidelines described by Subdivision (1) are not reasonably available, may be based on peer-reviewed publications developed by independent experts, which may include physicians, with expertise applicable to the relevant health condition.

(b) A multidisciplinary panel of experts composed of physicians and, as necessary, other health care providers that develops and endorses clinical practice guidelines under Subsection (a)(1) must manage conflicts of interest by:

(1) requiring each member of the panel's writing or review group to:

(A) disclose any potential conflict of interest, including a conflict of interest involving an insurer, health benefit plan issuer, or pharmaceutical manufacturer; and

(B) recuse himself or herself in any situation in which the member has a conflict of interest;

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

(3) offering an opportunity for public review and comment.

(c) Subsection (b) does not apply to a panel or committee of experts, including a pharmacy and therapeutics committee, established by a health benefit plan issuer or a pharmacy benefit manager that advises the health benefit plan issuer or pharmacy benefit manager regarding drugs or formularies.

Sec. 1369.0546. STEP THERAPY PROTOCOL EXCEPTION REQUESTS. (a) A health benefit plan issuer shall establish a process in a user-friendly format that is readily accessible to a patient and prescribing provider, in the health benefit plan's formulary document and otherwise, through which an exception request under this section may be submitted by the provider.

(b) A prescribing provider on behalf of a patient may submit to the patient's health benefit plan issuer a written request for an exception to a step therapy protocol required by the patient's health benefit plan. The provider shall submit the request on the standard form prescribed by the commissioner under Section 1369.304.

(c) A health benefit plan issuer shall grant a written request under Subsection (b) if the request includes the prescribing provider's written statement, with supporting documentation, stating that:

(1) the drug required under the step therapy protocol:

(A) is contraindicated;

(B) will likely cause an adverse reaction in or physical or mental harm to the patient; or

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

(2) the patient previously discontinued taking the drug required under the step therapy protocol, or another prescription drug in the same pharmacologic class or with the same mechanism of action as the required drug, while under the health

benefit plan currently in force or while covered under another health benefit plan because the drug was not effective or had a diminished effect or because of an adverse event;

(3) the drug required under the step therapy protocol is not in the best interest of the patient, based on clinical appropriateness, because the patient's use of the drug is expected to:

(A) cause a significant barrier to the patient's adherence to or compliance with the patient's plan of care;

(B) worsen a comorbid condition of the patient; or

(C) decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; or

(4)(A) the drug that is subject to the step therapy protocol was prescribed for the patient's condition;

(B) the patient:

(i) received benefits for the drug under the health benefit plan currently in force or a previous health benefit plan; and

(ii) is stable on the drug; and

(C) the change in the patient's prescription drug regimen required by the step therapy protocol is expected to be ineffective or cause harm to the patient based on the known clinical characteristics of the patient and the known characteristics of the required prescription drug regimen.

(d) Except as provided by Subsection (e), if a health benefit plan issuer does not deny an exception request described by Subsection (c) before 72 hours after the health benefit plan issuer receives the request, the request is considered granted.

(e) If an exception request described by Subsection (c) also states that the prescribing provider reasonably believes that denial of the request makes the death of or serious harm to the patient probable, the request is considered granted if the health benefit plan issuer does not deny the request before 24 hours after the health benefit plan issuer receives the request.

(f) The denial of an exception request under this section is an adverse determination for purposes of Section 4201.002 and is subject to appeal under Subchapters H and I, Chapter 4201.

SECTION 3. Section 4201.357, Insurance Code, is amended by adding Subsection (a-2) to read as follows:

(a-2) An adverse determination under Section 1369.0546 is entitled to an expedited appeal. The physician or, if appropriate, other health care provider deciding the appeal must consider atypical diagnoses and the needs of atypical patient populations.

SECTION 4. Section 4202.003, Insurance Code, is amended to read as follows:

Sec. 4202.003. REQUIREMENTS REGARDING TIMELINESS OF DETERMINATION. The standards adopted under Section 4202.002 must require each independent review organization to make the organization's determination:

(1) for a life-threatening condition as defined by Section 4201.002, [~~or~~] the provision of prescription drugs or intravenous infusions for which the patient is receiving benefits under the health insurance policy, or a review of a step therapy protocol exception request under Section 1369.0546, not later than the earlier of the third day after the date the organization receives the information necessary to make the determination or, with respect to:

(A) a review of a health care service provided to

a person with a life-threatening condition eligible for workers' compensation medical benefits, the eighth day after the date the organization receives the request that the determination be made; or

(B) a review of a health care service other than a service described by Paragraph (A), the third day after the date the organization receives the request that the determination be made; or

(2) for a situation other than a situation described by Subdivision (1), not later than the earlier of:

(A) the 15th day after the date the organization receives the information necessary to make the determination; or

(B) the 20th day after the date the organization receives the request that the determination be made.

SECTION 5. The changes in law made by this Act apply only to a health benefit plan that is delivered, issued for delivery, or renewed on or after January 1, 2018. A health benefit plan delivered, issued for delivery, or renewed before January 1, 2018, is governed by the law as it existed immediately before the effective date of this Act, and that law is continued in effect for that purpose.

SECTION 6. This Act takes effect September 1, 2017.

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 680 passed the Senate on April 3, 2017, by the following vote: Yeas 31, Nays 0; and that the Senate concurred in House amendment on May 16, 2017, by the following vote: Yeas 30, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 680 passed the House, with amendment, on May 9, 2017, by the following vote: Yeas 144, Nays 2, one present not voting.

Chief Clerk of the House

Approved:

Date

Governor