BILL ANALYSIS

Senate Research Center
85R14546 PMO-F

C.S.S.B. 680
By: Hancock
Business & Commerce
3/14/2017
Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Step therapy protocols, also known as “fail first” requirements, are used by health insurance companies to review the use of prescription drugs and control costs. A patient may be required to try and fail on lower-cost or older drugs selected by their health plan before coverage is granted for the drug prescribed by the patient’s healthcare provider.

Health insurance carriers’ exemption criteria and appeal procedures are not consistent or accessible, and it may take a patient up to 53 calendar days to complete an appeal for a new prescription. Currently, the only protection health insurance enrollees have regarding step therapy is a prohibition against adding a step therapy protocol to a covered prescription drug mid-plan year.

S.B. 680 ensures step therapy protocols are reasonable and transparent for Texans and their health care providers.

The bill adds language to the Insurance Code directing health insurance carriers using step therapy protocols to:

(1) Ensure step therapy protocols are based on widely accepted clinical guidelines so that medicine—not cost—dictate requirements.

(2) Create a clear and expeditious process to protect patients from being required to try or stay on a step therapy medication if it would create a significant barrier to compliance, worsen a comorbid condition, is contraindicated, or decrease the patient's ability to achieve or maintain reasonable function.

(3) Protect stable patients from being required to try a new medication if step therapy protocols are added at contract renewal.

(4) Prohibit insurers from requiring patients to fail on a prescribed medication more than once, even if the patient switches to a different health insurance company.

(5) Respond to step therapy exemption requests based on an expedited timeline.

The bill also categorizes step therapy exemption denials as adverse determinations and allows patients to access an expedited external review. Four other states have enacted similar legislation. (Original Author’s / Sponsor’s Statement of Intent)

C.S.S.B. 680 amends current law relating to step therapy protocols required by a health benefit plan in connection with prescription drug coverage.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the commissioner of insurance in SECTION 2 (Section 1369.0546, Insurance Code) of this bill.

SECTION BY SECTION ANALYSIS

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

(1) and (1-a) Defines "clinical practice guideline" and "clinical review criteria."

(1-b) Redesignates existing Subdivision (1) as Subdivision (1-b) and makes no further changes to this subdivision.

(5) Defines "step therapy protocol."

SECTION 2. Amends Subchapter B, Chapter 1369, Insurance Code, by adding Sections 1369.0545 and 1369.0546, as follows:

Sec. 1369.0545. STEP THERAPY PROTOCOLS. (a) Requires a health benefit plan issuer (issuer) that requires a step therapy protocol (protocol) before providing coverage for a prescription drug, to establish, implement, and administer the protocol in accordance with clinical review criteria readily available to the health care industry. Requires the issuer to take into account the needs of atypical patient populations and diagnoses in establishing the clinical review criteria. Requires that the clinical review criteria be based on certain generally accepted clinical practice guidelines (guidelines), or authorizes the guidelines, if the guidelines are not reasonably available, to be based on peer-reviewed publications developed by independent experts, including physicians, with expertise applicable to the relevant health condition.

(b) Requires a multidisciplinary panel of experts composed of physicians, and, as necessary, other health care providers that develops and endorses guidelines to manage conflicts of interest by requiring each member of the panel's writing or review group to disclose any potential conflict of interest, including certain conflicts, and recuse himself or herself in any situation in which the member has a conflict of interest; to work, using a methodologist, with writing groups to provide objectivity in data analysis and the ranking of evidence by preparing evidence tables and facilitating consensus; and by offering an opportunity for public review and comment.

(c) Prohibits this section from being construed to prohibit an issuer from requiring a patient to try an AB-rated generic equivalent drug before providing coverage for the equivalent branded prescription drug, unless the AB-rated generic equivalent has been demonstrated to be ineffective on the patient or has caused or is likely to cause an adverse reaction in or physical or mental harm to the patient, or to prohibit a prescribing provider from prescribing a prescription drug that is determined to be medically appropriate.

Sec. 1369.0546. STEP THERAPY PROTOCOL EXCEPTION REQUESTS. (a) Requires an issuer to 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 the provider is authorized to submit an exception request.

(b) Authorizes a prescribing provider, on behalf of a patient, to submit to the patient's issuer a written request for an exception to a protocol required by the patient's health benefit plan (plan). Requires the commissioner of insurance (commissioner) to prescribe, by rule, the form of the written request.

(c) Requires an issuer to grant a written request if the request includes the prescribing provider's written statement stating that the drug required under the protocol meets certain standards; the patient previously discontinued taking the drug required under the protocol, or certain other prescription drugs, while under a certain plan because the drug was not effective or had a diminished effect or because of an adverse event; the drug required under the 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 cause certain negative results; or the drug that is subject

to the protocol was prescribed for the patient's condition and covered while under the plan currently in force or a previous plan and the patient is stable on the drug.

(d) Provides that, except as provided by Subsection (e), if an issuer does not deny an exception request before 72 hours after the issuer receives the request, the request is considered granted.

(e) Provides that, 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 issuer does not deny the request before 24 hours after the issuer receives the request.

(f) Provides that the denial of an exception request is an adverse determination for purposes of Section 4201.002 (Definitions) and is subject to appeal under Subchapters H (Appeal of Adverse Determination) and I (Independent Review of Adverse Determination), Chapter 4201 (Utilization of Review Agents).

SECTION 3. Amends Section 4201.357, Insurance Code, by adding Subsection (a-2), to provide that an adverse determination under Section 1369.0546 is entitled to an expedited appeal and to require the physician or, if appropriate, other health care provider deciding the appeal to consider atypical diagnoses and the needs of atypical patient populations.

SECTION 4. Amends Section 4202.003, Insurance Code, as follows:

Sec. 4202.003. REQUIREMENTS REGARDING TIMELINESS OF DETERMINATION. (a) Requires the standards adopted under Section 4202.002 (Adoption of Standards for Independent Review Organizations) to require each independent review organization to make the organization's determination for a life-threatening condition as defined by Section 4201.002, 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 protocol exception request under Section 1369.0546, not later than the earlier of the third day after the date the organization receives certain information necessary to make the determination.

SECTION 5. Makes application of this Act prospective to January 1, 2018.

SECTION 6. Effective date: September 1, 2017.