BILL ANALYSIS

C.S.S.B. 680
By: Hancock
Insurance
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Interested parties contend that health insurance carriers' exemption criteria with regard to prescription drug coverage and appeal procedures are not sufficiently consistent or accessible. C.S.S.B. 680 seeks to address this issue by applying certain reforms relating to step therapy protocols required by a health benefit plan in connection with prescription drug coverage.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

C.S.S.B. 680 amends the Insurance Code to require a health benefit plan issuer that requires a step therapy protocol requiring 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 issuer provides coverage for the recommended prescription drug to establish, implement, and administer the step therapy protocol in accordance with clinical review criteria readily available to the health care industry. The bill requires the plan issuer to take into account the needs of atypical patient populations and diagnoses in establishing the clinical review criteria. The bill requires the clinical review criteria to consider generally accepted clinical practice guidelines that are developed and endorsed by a multidisciplinary panel of experts, based on high quality studies, research, and medical practice, created by an explicit and transparent process that meets certain criteria, and updated at appropriate intervals after a review of new evidence, research, and treatments. The bill authorizes the criteria to be based on peer-reviewed publications developed by independent experts, which may include physicians, with expertise applicable to the relevant health condition if such clinical practice guidelines are not reasonably available. The bill prescribes the methods by which a multidisciplinary panel of experts composed of physicians and, as necessary, other health care providers that develops and endorses such clinical practice guidelines must manage conflicts of interest. The bill excepts from those methods 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 plan issuer or benefit manager regarding drugs or formularies.

C.S.S.B. 680 requires a health benefit plan 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 a step therapy protocol exception request may be submitted by the provider. The bill authorizes a prescribing provider on behalf of a patient to

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 and requires the provider to submit the request on the standard request form for prior authorization of prescription drug benefits prescribed by the commissioner of insurance. The bill specifies the circumstances under which a plan issuer is required to grant such a request.

C.S.S.B. 680 requires the standards adopted by the commissioner of insurance for independent review organizations to require each organization to make the organization's determination for a review of a step therapy protocol exception request within a certain timeframe and establishes that an exception request is considered granted if a health benefit plan issuer does not deny the request before 72 hours after the plan issuer receives the request. The bill establishes that an exception request that states the prescribing provider reasonably believes that denial of the request makes the death of or serious harm to the patient probable 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. The denial of an exception request is an adverse determination for purposes of statutory provisions relating to utilization review agents and is subject to appeal under those statutory provisions that relate to the appeal and independent review of an adverse determination. The bill entitles an adverse determination involving an exception request to an expedited appeal and requires the physician or, if appropriate, other health care provider deciding the appeal to consider atypical diagnoses and the needs of atypical patient populations.

C.S.S.B. 680 applies only to a health benefit plan that is delivered, issued for delivery, or renewed on or after January 1, 2018.

EFFECTIVE DATE

September 1, 2017.

COMPARISON OF SENATE ENGROSSED AND SUBSTITUTE

While C.S.S.B. 680 may differ from the engrossed in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the engrossed and committee substitute versions of the bill.

SENATE ENGROSSED	HOUSE COMMITTEE SUBSTITUTE
SECTION 1. Section 1369.051, Insurance Code, is amended.	SECTION 1. Same as engrossed version.
SECTION 2. Subchapter B, Chapter 1369, Insurance Code, is amended by adding Sections 1369.0545 and 1369.0546 to read as follows:	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.	Sec. 1369.0545. STEP THERAPY PROTOCOLS.
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	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 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

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	(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.	(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.	(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.	(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.	(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.	SECTION 3. Same as engrossed version.
SECTION 4. Section 4202.003, Insurance Code, is amended.	SECTION 4. Same as engrossed version.
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 5. Same as engrossed version.
SECTION 6. This Act takes effect September 1, 2017.	SECTION 6. Same as engrossed version.