BILL ANALYSIS

C.S.H.B. 1464
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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.H.B. 1464 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.H.B. 1464 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 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, are based on high quality studies, research, and medical practice, be created by an explicit and transparent process that meets certain criteria, and be 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 is required to 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.H.B. 1464 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.H.B. 1464 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 stating that 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.H.B. 1464 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 ORIGINAL AND SUBSTITUTE

While C.S.H.B. 1464 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

INTRODUCED	HOUSE COMMITTEE SUBSTITUTE
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:	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 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) "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 practice guidelines used by a health benefit plan issuer, utilization review organization, or independent review organization to	(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 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 clinical review criteria must be based on:
(1) generally accepted clinical practice guidelines that are:
(A) developed and endorsed by a multidisciplinary panel of experts described by Subsection (b); and
(B) based on high quality studies, research, and medical practice that are:
(i) created by an explicit and transparent process that:
(a) minimizes bias and conflicts of interest;
(b) explains the relationship between treatment options and outcomes;
(c) rates the quality of the evidence supporting the recommendations; and
(d) considers relevant patient subgroups and preferences; and

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

(ii) 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, peer-reviewed publications developed by independent experts with expertise applicable to the relevant health condition.

(b) A multidisciplinary panel of experts

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) This section may not be construed to prohibit:

(1) a health benefit plan issuer from requiring a patient to try an AB-rated generic equivalent drug before providing coverage for the equivalent branded prescription drug; or

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

Sec. 1369.0546. STEP THERAPY PROTOCOL EXCEPTION REQUESTS. (a) A health benefit plan issuer shall establish a process in a user-friendly format

(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 or prescribing provider

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 commissioner by rule shall prescribe the form of the written request.

(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) the drug that is subject to the step therapy protocol was prescribed for the patient's condition while under the

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;

health benefit plan currently in force or a previous health benefit plan and the patient is stable on the drug.

(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.

(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 other health care provider deciding the appeal must consider atypical diagnoses and the needs of atypical patient populations.

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 4201.402, Insurance Code, is amended by amending Subsection (a) and adding Subsection (a-1) to read as follows:

(a) Except as provided by Subsection (a-1), not [~~Not~~] later than the third business day after the date a utilization review agent receives a request for independent review, the agent shall provide to the appropriate independent review organization:

(1) a copy of:

No equivalent provision.

(A) any medical records of the enrollee that are relevant to the review;
(B) any documents used by the plan in making the determination to be reviewed;
(C) the written notification described by Section 4201.359; and
(D) any documents and other written information submitted to the agent in support of the appeal; and
(2) a list of each physician or other health care provider who:
(A) has provided care to the enrollee; and
(B) may have medical records relevant to the appeal.
(a-1) For the independent review of a step therapy protocol exception request described by Section 1369.0546(e), the utilization review agent shall provide the information described by Subsection (a) to the appropriate independent review organization not later than 24 hours after the agent receives the request for independent review.

SECTION 5. Section 4202.003, Insurance Code, is amended to read as follows:
Sec. 4202.003. REQUIREMENTS REGARDING TIMELINESS OF DETERMINATION. (a) Except as provided by Subsection (b), the [~~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,

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

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.	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.
(b) For a review of a step therapy protocol exception request under Section 1369.0546, the standards adopted under Section 4202.002 must require each independent review organization to make the organization's determination not later than: (1) except as provided by Subdivision (2), 72 hours after the organization receives the request that the determination be made; or (2) for a determination of an exception request described by Section 1369.0546(e), 24 hours after the organization receives the request that the determination be made.	
SECTION 6. 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 introduced version.
SECTION 7. This Act takes effect September 1, 2017.	SECTION 6. Same as introduced version.