

By: Hancock, et al. S.B. No. 680  
(Bonnen of Galveston, Parker, Thompson of Harris, Bernal,  
Villalba, et al.)

Substitute the following for S.B. No. 680:

By: Phillips C.S.S.B. No. 680

A BILL TO BE ENTITLED

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

1 approves payment; or

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

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

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

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

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

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

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

27 (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;

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

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

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

11           Sec. 1369.0546. STEP THERAPY PROTOCOL EXCEPTION REQUESTS.

12           (a) A health benefit plan issuer shall establish a process in a  
13 user-friendly format that is readily accessible to a patient and  
14 prescribing provider, in the health benefit plan's formulary  
15 document and otherwise, through which an exception request under  
16 this section may be submitted by the provider.

17           (b) A prescribing provider on behalf of a patient may submit  
18 to the patient's health benefit plan issuer a written request for an  
19 exception to a step therapy protocol required by the patient's  
20 health benefit plan. The provider shall submit the request on the  
21 standard form prescribed by the commissioner under Section  
22 [1369.304](#).

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

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

1                   (A) is contraindicated;

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

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

7                   (2) the patient previously discontinued taking the  
8 drug required under the step therapy protocol, or another  
9 prescription drug in the same pharmacologic class or with the same  
10 mechanism of action as the required drug, while under the health  
11 benefit plan currently in force or while covered under another  
12 health benefit plan because the drug was not effective or had a  
13 diminished effect or because of an adverse event;

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

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

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

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

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

27                   (B) the patient:

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

4                   (ii) is stable on the drug; and

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

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

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

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

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

25           (a-2) An adverse determination under Section 1369.0546 is  
26 entitled to an expedited appeal. The physician or, if appropriate,  
27 other health care provider deciding the appeal must consider

1 atypical diagnoses and the needs of atypical patient populations.

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

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

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

16 (A) a review of a health care service provided to  
17 a person with a life-threatening condition eligible for workers'  
18 compensation medical benefits, the eighth day after the date the  
19 organization receives the request that the determination be made;  
20 or

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

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

27 (A) the 15th day after the date the organization

1 receives the information necessary to make the determination; or

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

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

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