SUBJECT: Revising step therapy protocol requirements for a health benefit plan

COMMITTEE: Insurance — committee substitute recommended

VOTE: 9 ayes — Phillips, Muñoz, R. Anderson, Gooden, Oliverson, Paul, Sanford, Turner, Vo

0 nays

WITNESSES: For — Ann Bass; Sheldon Metz; (*Registered, but did not testify*: Blake Hutson, AARP Texas; Audra Conwell, Alliance of Independent Pharmacists of Texas; Jim Arnold, American Cancer Society Cancer Action Network; Joel Romo, American Diabetes Association; Denise Rose, AstraZeneca; Christine Bryan, Clarity Child Guidance Center; Chase Bearden, Coalition of Texans with Disabilities; Reginald Smith, Communities for Recovery; Jordan Williford, Epilepsy Foundation; Christine Yanas, Methodist Healthcare Ministries of South Texas; Deborah Rosales-Elkins, Greg Hansch, National Alliance on Mental Illness-Texas; Gwendolyn Quintana, National Alliance on Mental Illness-Austin Affiliate Advocacy Committee; Will Francis, National Association of Social Workers-Texas Chapter; Simone Nichols-Segers, National MS Society; Amber Pearce, Pfizer; John Heal, Pharmacy Buying Association d/b/a Texas TrueCare Pharmacies; Adriana Kohler, Texans Care for Children; Dan Hinkle, Texas Academy of Family Physicians; Stephanie Simpson, Texas Association of Manufacturers; Michael Grimes, Texas College of Emergency Physicians; Bradford Shields, Texas Federation of Drug Stores; Thomas Kowalski, Texas Healthcare and Bioscience Institute; Duane Galligher, Texas Independent Pharmacies Association; Clayton Stewart, Texas Medical Association; Rachael Reed, Texas Ophthalmological Association; BJ Avery, Texas Optometric Association; Tommy Lucas, Texas Optometric Association; David Reynolds, Texas Osteopathic Medical Association; Clayton Travis, Texas Pediatric Society; Justin Hudman, Texas Pharmacy Association; Jenna Courtney, Texas Radiological Society; Bonnie Bruce, Texas Society of Anesthesiologists; Greg Herzog, Texas Society of Gastroenterology and Endoscopy and Texas Neurology Society; Price Ashley, Texas Society of

Pathologists; Hilda Correa; Carol Daley)

Against — None

On — Michael Harrold, Express Scripts; Melodie Shrader, Pharmaceutical Care Management Association; Abigail Stoddard, Prime Therapeutics; (*Registered, but did not testify*: Wendy Wilson, Prime Therapeutics; Jamie Walker, Texas Department of Insurance)

BACKGROUND: Step therapy is a coverage rule for certain health benefit plans with prescription benefits that requires a patient to first try one or more similar, lower cost drugs before the plan will cover the prescribed drug. Interested observers contend that health insurance plans' exception criteria and appeal procedures for step therapy may not be sufficiently consistent or accessible for patients and prescribing health providers.

DIGEST: CSHB 1464 would require a health benefit plan issuer to establish a user-friendly process through which a provider could request an exception from a health plan's required step therapy protocol. A step therapy protocol is defined as a protocol that required an enrollee to use a prescription drug or sequence of prescription drugs other than the drug that the enrollee's physician recommended for the enrollee's treatment before the health plan would provide coverage for the recommended drug.

The bill would require the exception request process to be readily accessible to a patient and prescribing provider in the health benefit plan's formulary document and otherwise. To make a request, the prescriber would submit a written request to the health plan issuer on a standardized form prescribed by the commissioner of insurance.

Under the bill, a health plan issuer would be required to grant a request for an exception to the step therapy protocol if the request included the prescribing provider's written statement and supporting documentation stating that:

- the drug required under the step therapy protocol was

contraindicated, would likely cause a physical or mental adverse reaction, or was expected to be ineffective based on the known clinical characteristics of the patient and the drug regimen;

- the patient had previously discontinued taking the protocol-required drug, or another drug in the same pharmacologic class or with the same mechanism of action, while covered by a health plan, because the drug was not effective, had diminished effect, or there was an adverse event;
- the protocol-required drug was not in the best interest of the patient, based on clinical appropriateness or other reasons specified in the bill; or
- the patient had been prescribed the drug, was stable on the drug, and the change in the patient's prescription drug regimen required by the step therapy protocol was expected to be ineffective or cause harm to the patient based on certain characteristics specified in the bill.

The health plan issuer would have 72 hours to deny a received exception request before the request would be considered granted. If the exception request stated that the prescribing provider reasonably believed the denial could result in probable death or serious harm, the exception request would be considered granted after 24 hours. Denial of an exception request would be considered an adverse determination that could be appealed. Health care providers deciding the appeal would be required to take into consideration atypical diagnoses and the needs of atypical patient populations.

A health plan issuer that required a step therapy protocol before providing coverage for a prescription drug would be required to establish, implement, and administer the step therapy protocol in accordance with clinical review criteria, as defined by the bill, that were readily available to the health care industry. The health benefit plan issuer would be required to take into account the needs of atypical patient populations and diagnoses in establishing the clinical review criteria. The bill would define the term "clinical review criteria" and would specify what the criteria would include.

The bill would require 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 time frame.

The bill would take effect September 1, 2017, and would apply only to a health benefit plan that was delivered, issued for delivery, or renewed on or after January 1, 2018.

NOTES: A companion bill, SB 680 by Hancock, was reported favorably by the House Insurance Committee on May 2.