BILL ANALYSIS

C.S.H.B. 3286 By: Klick Health Care Reform, Select Committee Report (Substituted)

BACKGROUND AND PURPOSE

Texans on Medicaid who need prescription medications are subject to the state's Medicaid preferred drug list. This restricts their access to necessary medications and can lead to serious health consequences. Recent managed care contract changes have further limited a managed care organization's (MCO) ability to allow exceptions to the state's preferred drug list. MCOs are now forced to decide between patient care and contract violations. In contrast, patients in the commercial market have access to mandatory exception processes, called step therapy exceptions. Health plans in the private market must grant an exception to their step therapy protocol for a patient who is stable on a drug if the change is expected to be ineffective or cause harm to the patient. This lack of exception protections for Texas Medicaid patients creates barriers to accessing necessary medications. People are often forced off of medications that are working for them, which can lead to serious health consequences. C.S.H.B. 3286 seeks to ensure Medicaid patients have access to necessary medications by adding exception protections to the Texas Medicaid program, which will give Medicaid patients similar mandatory exception processes as patients in the commercial market. The bill also creates a database for providers to check if drugs are on the state's preferred drug list.

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. 3286 amends the Government Code to require a Medicaid managed care organization (MCO) to grant an exception to the preferred drug list adopted by the Health and Human Services Commission (HHSC) for the Medicaid vendor drug program and to establish that the Medicaid MCO is not required to adhere to that list with respect to a Medicaid recipient regarding an outpatient pharmacy benefit plan implemented by the Medicaid MCO under the following circumstances:

- the preferred drug is contraindicated, will likely cause an adverse reaction in or physical
 or mental harm to the recipient, or is expected to be ineffective based on the known
 clinical characteristics of the recipient and the known characteristics of the prescription
 drug regimen;
- the recipient previously discontinued taking the preferred drug at any point in the recipient's clinical history and for any length of time because it was not effective, had a diminished effect, or resulted in an adverse event;

88R 27715-D 23.121.1675

Substitute Document Number: 88R 24363

- the preferred drug is not in the best interest of the recipient, based on clinical appropriateness, because the recipient's use of the drug is expected to cause a significant barrier to the recipient's adherence to or compliance with the recipient's plan of care;
- the recipient was prescribed and is taking a nonpreferred drug in the antidepressant or antipsychotic drug class and the recipient:
 - was prescribed the nonpreferred drug before being discharged from an inpatient facility;
 - o is stable on the nonpreferred drug; and
 - o is at risk of experiencing complications from switching from the nonpreferred drug to another drug;
- the preferred drug is not available for reasons outside of the Medicaid MCO's control, including because the drug is in short supply according to the FDA Drug Shortages Database or the drug's manufacturer has placed the drug on backorder or allocation; or
- the preferred drug is not available at a pharmacy located within a 10-mile radius of the recipient.

The bill requires HHSC to ensure that an Internet-based, searchable database is made available through which a provider may search the applicable preferred drug list adopted by HHSC to easily determine whether a prescription drug or drug class is subject to any prior authorization requirements, clinical edits, or other clinical restrictions and that reasonable efforts are made to ensure the database contains current information.

C.S.H.B. 3286 provides for the delayed implementation of any provision for which an applicable state agency determines a federal waiver or authorization is necessary for implementation until the waiver or authorization is requested and granted.

EFFECTIVE DATE

September 1, 2023.

COMPARISON OF INTRODUCED AND SUBSTITUTE

While C.S.H.B. 3286 may differ from the introduced in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.

While both the introduced and the substitute provide for a Medicaid recipient's ability to obtain an exception to access prescription drugs not otherwise available to the recipient, the bill versions differ in their approaches. The introduced required a Medicaid MCO to establish a process in a user-friendly format through which a step therapy protocol exception request may be submitted by a prescribing provider, whereas the substitute instead requires a Medicaid MCO to grant an exception to HHSC's preferred drug list adopted for the Medicaid vendor drug program with respect to certain recipients. Accordingly, the substitute omits provisions that were in the introduced related to the following:

- the definition of step therapy protocol;
- a requirement regarding who the process must be readily accessible to;
- an authorization for a prescribing provider to submit an exception request for a step therapy protocol required by the recipient's Medicaid MCO on behalf of the recipient;
- a requirement regarding a Medicaid MCO's duty to review and, if clinically appropriate, grant such an exception request that includes a statement by the prescribing provider stating certain facts, including the following:
 - the recipient previously discontinued taking the drug required under the step therapy protocol while enrolled in a managed care plan offered by the recipient's current Medicaid MCO or while enrolled in a managed care plan offered by another Medicaid MCO because the drug was not effective or had a diminished effect or because of an adverse event;

88R 27715-D 23.121.1675

Substitute Document Number: 88R 24363

- the drug is expected to worsen a comorbid condition of the recipient or decrease the recipient's ability to achieve or maintain functional ability in performing daily activities; and
- o the drug was prescribed while the recipient was enrolled in a managed care plan offered by the recipient's current Medicaid MCO or while enrolled in a managed care plan offered by a previous Medicaid MCO and is stable on the drug;
- the time after which a request is considered granted if the Medicaid MCO does not deny the request, and a shortened time frame for a request containing a statement that the prescribing provider reasonably believes that denial makes the death of or serious harm to the recipient probable; and
- a prohibition against a Medicaid MCO requiring a prescribing provider to submit a subsequent exception request for certain drugs.

The substitute includes provisions that were not in the introduced establishing the circumstances under which a Medicaid MCO must grant an exception to the applicable HHSC preferred drug list, including the following circumstances:

- the recipient previously discontinued taking the preferred drug at any point in the recipient's clinical history and for any length of time because the drug was not effective, had a diminished effect, or resulted in an adverse event;
- the recipient was prescribed and is taking a nonpreferred drug in the antidepressant or antipsychotic drug class and the recipient was prescribed the nonpreferred drug before being discharged from an inpatient facility, is stable on the nonpreferred drug, and is at risk of experiencing complications from switching from the nonpreferred drug to another drug;
- the preferred drug is not available for reasons outside of the Medicaid MCO's control, including because the drug is in short supply according to the FDA Drug Shortages Database or the drug's manufacturer has placed the drug on backorder or allocation; and
- the preferred drug is not available at a pharmacy located within a 10-mile radius of the recipient.

Both the introduced and the substitute require a searchable database of preferred drugs and restrictions, but the versions differ in the following manner:

- the substitute omits a provision included in the introduced requiring a Medicaid MCO to distribute current copies of the MCO's preferred drug list by posting the list on the MCO's website; and
- whereas the introduced required a Medicaid MCO to maintain on its website a searchable database through which a provider may search the organizations preferred drug list and to make reasonable efforts to ensure the database contains current information, the substitute requires HHSC to ensure that an Internet-based, searchable database is available through which a provider may search the applicable preferred drug list adopted by HHSC and to ensure that reasonable efforts to ensure the database contains current information.

88R 27715-D 23.121.1675