**BILL ANALYSIS**

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| Senate Research Center | S.B. 1922 |
| 85R11447 LED-D | By: Schwertner |
|  | Health & Human Services |
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**AUTHOR'S / SPONSOR'S STATEMENT OF INTENT**

The cost of prescription drugs was on a steady rise in the 2000s, prompting the Legislature to intervene. In March 2012, prescription drugs were carved into the managed care organization (MCO) contracts. The decision was made by the 82nd Legislature not only for cost-savings, but also to improve access to care and quality. While the legislature carved the prescription drug benefit into managed care, they did not carve the Vendor Drug Program (VDP) into managed care, which would have given MCOs the ability to fully manage the prescription drug benefit. Instead the state currently requires plans to use a single, uniform state Medicaid formulary instead of their own formularies.

Every state's Medicaid program has a preferred drug list (PDL). The PDL is a list of medications that a Medicaid client can receive without prior authorization. Texas's PDL is currently managed by the Health and Human Services Commission's (HHSC) VDP. Texas statute Sunsets the State's PDL in 2018, at which point the program will default to being carved into managed care. However, with this carve-in, there is a lack of statutory patient protections to ensure there are not unintended consequences of giving MCOs the authority to create their own PDLs.

S.B. 1922 adds the following statutory provisions that will provide patient protections while ensuring prescription drug costs are maintained with timely access to clinically appropriate medications:

* Require MCOs develop and begin using their own PDL beginning September 1, 2018.

* Require MCOs to develop a standard process for requesting an exemption from step therapy and share that process with providers and Medicaid enrollees.
* Prohibit MCOs from requiring a client to repeat step therapy when coming into Medicaid or when moving between plans if the provider can document a reason based on previous step therapy for particular drug.
* Prohibit MCOs from requiring step therapy if a provider can document the drug: is contraindicated; will likely cause an adverse physical or mental reaction; or, is not clinically appropriate because the drug will likely cause a significant barrier to drug adherence, worsen a comorbid condition, or decrease the recipients ability to maintain reasonable functional ability.
* Requires MCOs to deny a providers step therapy exemption request within 72 hours of receiving the request otherwise the exemption is considered granted. MCOs are required to deny a request for step therapy within 24 hours if the provider determines denial of the request makes the death of or serious harm to the recipient probable.
* Require MCOs to allow a client to continue access to a current drug when coming into Medicaid or when moving between plans even when the drug is not preferred for a 90 day period. Allow time for the new health plan to transition a client to a preferred drug or an opportunity to have a provider under the new plan to determine if there is a medical necessity to justify continued use of a non-preferred drug.
* Require MCOs to respond to a request by HHSC for information regarding prescription drug rebate negotiations or a supplemental Medicaid or other rebate agreement, including the rebate amount, rebate percentage, and manufacturer or labeler pricing. This information is not subject to disclosure under the public information act, but is available to individual members, agencies or committees of the legislature.
* Require MCOs to post their PDLs on their website.
* Require MCOs to retain the current protected drug classes as defined by HHSC with the requirement that these protected drugs be available without prior authorization. MCOs would only be prohibited from using a prior authorization for drugs that are being used within the United States Food and Drug Administration approved treatment for illnesses determined to need drug protections.
* Require HHSC to conduct a study evaluating the necessary protected drug classes every 10 years. Require the initial study of the necessary protected drug classes to be conducted by September 1, 2018. After the study determines the drugs that should be protected HHSC will direct MCOs to adjust their prior authorization requirements for the drugs that the study determines need protection.
* Require MCOs to allow for refills for prescriptions that subsequently require prior authorization, but allow MCOs to establish time limits to this availability.

As proposed, S.B. 1922 amends current law relating to prescription drug benefits in the Medicaid managed care program.

**RULEMAKING AUTHORITY**

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 (Section 533.053, Government Code) of this bill.

**SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Chapter 533, Government Code, by adding Subchapter B, as follows:

SUBCHAPTER B. PRESCRIPTION DRUG BENEFITS

Sec. 533.051. DEFINITIONS. Defines "labeler," "manufacturer," "recipient," and "step therapy protocol."

Sec. 533.052. APPLICABILITY OF SUBCHAPTER (a) Provides that this subchapter applies to an outpatient pharmacy benefit plan implemented by a managed care organization (MCO) that contracts with the Health and Human Services Commission (HHSC) to provide health care benefits to recipients.

(b) Provides that, to the extent of a conflict between the requirements for an outpatient pharmacy benefit plan for an MCO's enrolled recipients specified by Sections 533.005(a)(23)(A) (relating to an outpatient pharmacy benefit plan that exclusively employs the vendor drug program formulary and preserves certain abilities of the state), (B) (relating to an outpatient pharmacy benefit plan that adheres to the applicable preferred drug list), and (C) (relating to an outpatient pharmacy benefit plan that includes certain prior authorization procedures and requirements) and the requirements for that plan specified by this subchapter, the requirements specified by Sections 533.005(a)(23)(A), (B), and (C) prevail. Provides that this subsection expires August 31, 2018.

Sec. 533.053. STEP THERAPY PROTOCOL EXCEPTION REQUESTS. (a) Requires that an MCO establish a process in a user-friendly format through which an exception request may be submitted by a prescribing provider. Requires that the process be readily accessible to a recipient who enrolls in or transfers to certain managed care plans and to the provider.

(b) Authorizes a prescribing provider on behalf of a recipient to submit to the recipient's MCO a written request for an exception to a step therapy protocol required by the recipient's MCO. Requires the executive commissioner of HHSC by rule to prescribe the form of the written request.

(c) Requires that an MCO grant a written request under Subsection (b) if the request includes the prescribing provider's written statement stating certain information.

(d) Provides that the request, except as provided by Subsection (e), is considered granted if an MCO does not deny an exception request described by Subsection (b) before 72 hours after the MCO receives the request.

(e) Provides that the request, if a written statement 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 recipient probable, is considered granted if the MCO does not deny the request before 24 hours after the managed care organization receives the request.

Sec. 533.054. CONTINUITY OF CARE. Requires that an MCO provide coverage to a recipient who enrolls in a managed care plan offered by the MCO or transfers to a managed care plan offered by the MCO from a managed care plan offered by another MCO for a prescription drug prescribed for the recipient before the enrollment or transfer for a 90-day period following the date of the enrollment or transfer, regardless of whether the prescription drug is on the MCO's preferred drug list.

Sec. 533.055. ACCESS TO INFORMATION REGARDING PRESCRIPTION DRUG REBATES, PRICING, AND NEGOTIATIONS. (a) Authorizes HHSC to require the submission of and review information obtained or maintained by an MCO regarding prescription drug rebate negotiations or a supplemental Medicaid or other rebate agreement, including the rebate amount, rebate percentage, and manufacturer or labeler pricing.

(b) Provides that information described by Subsection (a) that an MCO submits to HHSC as required by HHSC is confidential and not subject to disclosure under
Chapter 552 (Public Information).

(c) Provides that Subsection (b) does not authorize HHSC to withhold from certain entities for use for legislative purposes information described by Subsection (a) that an MCO submits to HHSC or affect the applicability of Section 552.008 (Information for Legislative Purposes).

Sec. 533.056. PREFERRED DRUG LIST. Requires that an MCO provide for the distribution of current copies of the MCO's preferred drug list by posting the list on the MCO's Internet website.

Sec. 533.057. PRIOR AUTHORIZATION FOR CERTAIN PRESCRIPTION DRUGS. (a) Prohibits an MCO, except as provided by Subsection (b), from requiring prior authorization for prescription drugs that, as determined by HHSC, are used to treat patients with illnesses that are life-threatening, are chronic, and require complex medical management strategies.

(b) Provides that Subsection (a) applies only to a drug that is prescribed for a use approved by the U.S. Food and Drug Administration (FDA). Authorizes an MCO to require prior authorization for a drug prescribed for a use that is not approved by the FDA.

(c) Requires HHSC, once every 10 years, to conduct a study to evaluate and determine the classes of prescription drugs for which prior authorizations are prohibited under Subsection (a).

(d) Requires an MCO to ensure that a drug prescribed before the MCO implements a prior authorization requirement for that drug is not subject to the prior authorization requirement until the earlier of the date the recipient exhausts the prescription, including any authorized refills, or the expiration of a period specified by the MCO.

SECTION 2. Requires HHSC, not later than September 1, 2018, to conduct the initial study required by Section 533.057(c), Government Code, as added by this Act.

SECTION 3. Requires a state agency, if necessary for implementation of a provision of this Act, to request a waiver or authorization from a federal agency, and authorizes delay of implementation until such a waiver or authorization is granted.

SECTION 4. Effective date: September 1, 2017.