BILL ANALYSIS

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C.S.S.B. 1922
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Committee Report (Substituted)

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 recipient's ability to maintain reasonable functional ability.

- Require 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.

Committee Substitute

The substitute will:

- Clarify step therapy protections to ensure they are not overly broad, but can still be used to protect patients from unnecessary step therapy protocols;

- Ensure information necessary for continuity of care is shared between MCOs when patients move from one health plan to another;

- Clarify what confidential information can be shared and the process for sharing that information;

- Require MCOs to post their preferred drug lists on their websites in a searchable format so prior authorization requirements and clinical edits are clear;

- Require MCOs to allow a client to continue accessing a drug that receives a prior authorization requirement or step therapy protocol for a 90-day period;

- Require MCOs to deny a provider's step therapy exemption request within 72 hours of receiving the request, at which point the exemption will be auto-approved;

- Require MCOs to establish clear procedures for prior authorizations and step therapy protocols, to respond to requests for prior authorization or step therapy within 24 hours, and to provide a 72-hour emergency supply of drugs if a response is not given within 24 hours;

- Require clear information related to national drug codes to reduce the administrative burdens on providers;

- Ensure that MCOs can negotiate supplemental rebates that are currently negotiated by the state; and

- Require MCOs to report the number of prescriptions dispensed, percentage of prescriptions needing prior authorization and step therapy, and exceptions granted for those requests.

C.S.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 2 (Sections 533.054 and 533.057, Government Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. (a) Amends Section 533.005(a), Government Code, as follows:

(a) Requires that a contract between a managed care organization (MCO) and the Health and Human Services Commission (HHSC) for the MCO to provide health care services to recipients contain:

(1) through (19) makes no changes to these subdivisions;

(20) a requirement that the MCO develop and submit to HHSC, before the MCO begins to provide health care services to recipients, a comprehensive plan that describes how the MCO's provider network complies with the provider access standards established under Section 533.0061, as added by Chapter 1272 (S.B. 760), Acts of the 84th Legislature, Regular Session, 2015, rather than under Section 533.0061. Makes conforming changes.

(21) makes a conforming change;

(22) makes no changes to this subdivision;

(23) subject to Subsection (a-1) (relating to providing that certain requirements do not apply, and prohibits them from being enforced, on and after August 31, 2018), a requirement that the MCO develop, implement, and maintain an outpatient pharmacy benefit plan for its enrolled recipients:

(A) through (C) makes no changes to these paragraphs;

(D) for purposes of which the MCO may negotiate with and collect rebates from labelers and manufacturers, as those terms are defined by Section 531.070 (Supplemental Rebates), that are associated with pharmacy products on the MCO's formulary, rather than may not negotiate or collect rebates associated with pharmacy products on the vendor drug program formulary.

(E) through (K) makes no changes to these paragraphs.

(24) through (26) makes no changes to these subdivisions.

(b) Effective date, this section: September 1, 2018.

SECTION 2. 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 an MCO that contracts with 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 in written or electronic form or by telephone to the recipient's MCO an exception request for a step therapy protocol required by the recipient's MCO.

(c) Requires that an MCO review and, if clinically appropriate, grant an exception request under Subsection (b) if the request includes a statement by the prescribing provider 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 under Subsection (b) before 72 hours after the MCO receives the request.

(e) Provides that the request, if a statement described by Subsection (c) also states that the prescribing provider reasonably believes that denial of the exception 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 MCO receives the request.

(f) Prohibits an MCO from requiring a prescribed provider to submit a subsequent exception request under Subsection (b) for a drug for treatment of a recipient's condition for which the MCO has already granted an exception to a step therapy protocol for the recipient unless the MCO's medical director determines that the drug for treatment under the previously granted exception request will likely cause physical or mental harm to the recipient.

Sec. 533.054. CONTINUITY OF CARE. (a) 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.

(b) Requires the executive commissioner of HHSC (executive commissioner) by rule or HHSC in its contracts with MCOs, to promote continuity for care for recipients who transfer to a managed care plan offered by an MCO from a managed care plan offered by another MCO, to:

(1) require an MCO that offers the managed care plan from which a recipient transfers enrollment to provide to the MCO that offers the

managed care plan to which the recipient transfers enrollment the prescription drug information necessary to promote the recipient's continuity of care to the extent allowed by law; and

(2) establish an electronic process that facilitates the transfer of the information described by Subdivision (1) between MCOs.

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, subject to Subsections (c), (d), and (e), 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).

(d) Requires that a legislative request for information described by Subsection (a) be accompanied by a detailed description of the legislative purpose of the request. Prohibits HHSC from releasing information that is confidential under 42 U.S.C. Section 1396r-8(b)(3)(D) unless the legislative request for information is accompanied by a written certification from certain legislative entities certifying that the legislative purpose for the request is within the exception to confidentiality described by 42 U.S.C. Section 1396r-8(b)(3)(D)(iv).

(e) Prohibits HHSC from disclosing information described by Subsection (a) until each legislative recipient of the information signs a nondisclosure agreement acknowledging that the information is subject to, and the recipient agrees to comply with, the confidentiality provisions in 42 U.S.C. Section 1396r-8(b)(3)(D) and Section 531.071 (Confidentiality of Information Regarding Drug Rebates, Pricing, and Negotiations). Requires that the nondisclosure agreement also contain an acknowledgment of applicable civil and criminal penalties for improper disclosure.

Sec. 533.056. PREFERRED DRUG LIST; SEARCHABLE DATABASE OF PREFERRED DRUGS AND RESTRICTIONS. (a) 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.

(b) Requires that an MCO maintain on the MCO's Internet website a searchable database to allow a provider to perform a search certain information. Requires that an MCO make reasonable efforts to ensure that the database contains current information.

Sec. 533.057. PRIOR AUTHORIZATION AND STEP THERAPY PROTOCOLS FOR CERTAIN PRESCRIPTION DRUGS. (a) Prohibits an MCO, except as provided by Subsection (b), from requiring prior authorization or a step therapy protocol for prescription drugs that, as determined by the executive commissioner by rule or HHSC in a contract with an MCO, 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, provided that the prior authorization requirement is not solely based on the drug manufacturer's package insert.

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

(d) Requires an MCO to ensure that a drug prescribed before the MCO implements a prior authorization requirement or step therapy protocol for that drug is not subject to the prior authorization requirement or step therapy protocol until the expiration of a period of at least 90 days beginning on the date the prior authorization requirement or step therapy protocol is implemented, as specified by the MCO.

(e) Authorizes an MCO, notwithstanding Subsection (a), to require prior authorization for a prescription drug for patient safety purposes, including a drug that is clinically contraindicated.

Sec. 533.058. PRIOR AUTHORIZATION PROCEDURES. Requires that each MCO establish a procedure for prior authorizations, including step therapy protocols, to ensure compliance with 42 U.S.C. Section 1396r-8(d)(5). Requires that the procedure ensure that certain requirements are met.

Sec. 533.059. REDUCING ADMINISTRATIVE BURDENS ASSOCIATED WITH NATIONAL DRUG CODES. (a) Requires that an MCO ensure that a prescribing provider is not required to provide the national drug code number on a prescription for a generic equivalent of a prescribed drug, except as required by federal law.

(b) Requires HHSC and each MCO, as soon as practicable after receiving notice from the Centers for Medicare and Medicaid Services (CMMS) that a national drug code number for a rebate-eligible prescription drug has been changed or newly added to a list of rebate-eligible prescription drugs maintained by CMMS or a prescription drug that been removed from that list, to provide notice of the change, addition, or removal to providers by updating HHSC's or the MCO's electronic database of national drug code numbers for rebate-eligible prescription drugs, as applicable.

Sec. 533.060. ANNUAL REPORT. Requires that each MCO annually report to HHSC the total number of prescriptions dispensed to recipients enrolled in a managed care plan offered by the MCO, the percentage of prescription drugs described by Subdivision (1) for which prior authorization was required, the percentage of prescription drugs described by Subdivision (1) for which a step therapy protocol was required, and the number of exceptions and appeals sought and granted for prior authorizations, step therapy protocols, and other formulary requests.

SECTION 3. 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. Prohibits HHSC or an MCO from changing a prior authorization requirement or step therapy protocol for a prescription drug to which that section applies until HHSC has completed the study.

SECTION 4. 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 5. Effective date, except as otherwise provided by this Act: September 1, 2017.