By: Schwertner S.B. No. 1922

A BILL TO BE ENTITLED

AN ACT

relating to prescription drug benefits in the Medicaid managed care program.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. (a) Section 533.005(a), Government Code, is amended to read as follows:

(a) A contract between a managed care organization and the commission for the organization to provide health care services to recipients must contain:

(1) procedures to ensure accountability to the state for the provision of health care services, including procedures for financial reporting, quality assurance, utilization review, and assurance of contract and subcontract compliance;

(2) capitation rates that ensure the cost-effective provision of quality health care;

(3) a requirement that the managed care organization provide ready access to a person who assists recipients in resolving issues relating to enrollment, plan administration, education and training, access to services, and grievance procedures;

(4) a requirement that the managed care organization provide ready access to a person who assists providers in resolving issues relating to payment, plan administration, education and training, and grievance procedures;

(5) a requirement that the managed care organization provide information and referral about the availability of educational, social, and other community services that could benefit a recipient;

(6) procedures for recipient outreach and education;

(7) a requirement that the managed care organization make payment to a physician or provider for health care services rendered to a recipient under a managed care plan on any claim for payment that is received with documentation reasonably necessary for the managed care organization to process the claim:

(A) not later than:

(i) the 10th day after the date the claim is received if the claim relates to services provided by a nursing facility, intermediate care facility, or group home;

(ii) the 30th day after the date the claim is received if the claim relates to the provision of long-term services and supports not subject to Subparagraph (i); and

(iii) the 45th day after the date the claim is received if the claim is not subject to Subparagraph (i) or (ii); or

(B) within a period, not to exceed 60 days, specified by a written agreement between the physician or provider and the managed care organization;

(7-a) a requirement that the managed care organization demonstrate to the commission that the organization pays claims described by Subdivision (7)(A)(ii) on average not later than the 21st day after the date the claim is received by the organization;

(8) a requirement that the commission, on the date of a recipient's enrollment in a managed care plan issued by the managed care organization, inform the organization of the recipient's Medicaid certification date;

(9) a requirement that the managed care organization comply with Section 533.006 as a condition of contract retention and renewal;

(10) a requirement that the managed care organization provide the information required by Section 533.012 and otherwise comply and cooperate with the commission's office of inspector general and the office of the attorney general;

(11) a requirement that the managed care organization's usages of out-of-network providers or groups of out-of-network providers may not exceed limits for those usages relating to total inpatient admissions, total outpatient services, and emergency room admissions determined by the commission;

(12) if the commission finds that a managed care organization has violated Subdivision (11), a requirement that the managed care organization reimburse an out-of-network provider for health care services at a rate that is equal to the allowable rate for those services, as determined under Sections 32.028 and 32.0281, Human Resources Code;

(13) a requirement that, notwithstanding any other law, including Sections 843.312 and 1301.052, Insurance Code, the organization:

(A) use advanced practice registered nurses and physician assistants in addition to physicians as primary care

providers to increase the availability of primary care providers in the organization's provider network; and

(B) treat advanced practice registered nurses and physician assistants in the same manner as primary care physicians with regard to:

(i) selection and assignment as primary care providers;

(ii) inclusion as primary care providers in the organization's provider network; and

(iii) inclusion as primary care providers in any provider network directory maintained by the organization;

(14) a requirement that the managed care organization reimburse a federally qualified health center or rural health clinic for health care services provided to a recipient outside of regular business hours, including on a weekend day or holiday, at a rate that is equal to the allowable rate for those services as determined under Section 32.028, Human Resources Code, if the recipient does not have a referral from the recipient's primary care physician;

(15) a requirement that the managed care organization develop, implement, and maintain a system for tracking and resolving all provider appeals related to claims payment, including a process that will require:

(A) a tracking mechanism to document the status and final disposition of each provider's claims payment appeal;

(B) the contracting with physicians who are not network providers and who are of the same or related specialty as

the appealing physician to resolve claims disputes related to denial on the basis of medical necessity that remain unresolved subsequent to a provider appeal;

(C) the determination of the physician resolving the dispute to be binding on the managed care organization and provider; and

(D) the managed care organization to allow a provider with a claim that has not been paid before the time prescribed by Subdivision (7)(A)(ii) to initiate an appeal of that claim;

(16) a requirement that a medical director who is authorized to make medical necessity determinations is available to the region where the managed care organization provides health care services;

(17) a requirement that the managed care organization ensure that a medical director and patient care coordinators and provider and recipient support services personnel are located in the South Texas service region, if the managed care organization provides a managed care plan in that region;

(18) a requirement that the managed care organization provide special programs and materials for recipients with limited English proficiency or low literacy skills;

(19) a requirement that the managed care organization develop and establish a process for responding to provider appeals in the region where the organization provides health care services;

(20) a requirement that the managed care organization:

(A) develop and submit to the commission, before

the organization begins to provide health care services to recipients, a comprehensive plan that describes how the organization'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;

(B) as a condition of contract retention and renewal:

(i) continue to comply 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; and

(ii) make substantial efforts, as determined by the commission, to mitigate or remedy any noncompliance 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;

(C) pay liquidated damages for each failure, as determined by the commission, to comply 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, in amounts that are reasonably related to the noncompliance; and

(D) regularly, as determined by the commission, submit to the commission and make available to the public a report containing data on the sufficiency of the organization's provider network with regard to providing the care and services described

under Section 533.0061(a), as added by Chapter 1272 (S.B. 760), Acts of the 84th Legislature, Regular Session, 2015, and specific data with respect to access to primary care, specialty care, long-term services and supports, nursing services, and therapy services on the average length of time between:

(i) the date a provider requests prior authorization for the care or service and the date the organization approves or denies the request; and

(ii) the date the organization approves a request for prior authorization for the care or service and the date the care or service is initiated;

(21) a requirement that the managed care organization demonstrate to the commission, before the organization begins to provide health care services to recipients, that, subject to 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:

(A) the organization's provider network has the capacity to serve the number of recipients expected to enroll in a managed care plan offered by the organization;

(B) the organization's provider network includes:

(i) a sufficient number of primary care providers;

(ii) a sufficient variety of provider types;

(iii) a sufficient number of providers of

long-term services and supports and specialty pediatric care providers of home and community-based services; and

(iv) providers located throughout the region where the organization will provide health care services; and

(C) health care services will be accessible to recipients through the organization's provider network to a comparable extent that health care services would be available to recipients under a fee-for-service or primary care case management model of Medicaid managed care;

(22) a requirement that the managed care organization develop a monitoring program for measuring the quality of the health care services provided by the organization's provider network that:

(A) incorporates the National Committee for Quality Assurance's Healthcare Effectiveness Data and Information Set (HEDIS) measures;

(B) focuses on measuring outcomes; and

(C) includes the collection and analysis of clinical data relating to prenatal care, preventive care, mental health care, and the treatment of acute and chronic health conditions and substance abuse;

(23) subject to Subsection (a-1), a requirement that the managed care organization develop, implement, and maintain an outpatient pharmacy benefit plan for its enrolled recipients:

(A) that exclusively employs the vendor drug program formulary and preserves the state's ability to reduce

waste, fraud, and abuse under Medicaid;

(B) that adheres to the applicable preferred drug list adopted by the commission under Section 531.072;

(C) that includes the prior authorization procedures and requirements prescribed by or implemented under Sections 531.073(b), (c), and (g) for the vendor drug program;

(D) for purposes of which the managed care organization:

(i) may [~~not~~] negotiate with and [~~or~~] collect rebates from labelers and manufacturers, as those terms are defined by Section 531.070, that are associated with pharmacy products on the managed care organization's [~~vendor drug program~~] formulary; and

(ii) may not receive drug rebate or pricing information that is confidential under Section 531.071;

(E) that complies with the prohibition under Section 531.089;

(F) under which the managed care organization may not prohibit, limit, or interfere with a recipient's selection of a pharmacy or pharmacist of the recipient's choice for the provision of pharmaceutical services under the plan through the imposition of different copayments;

(G) that allows the managed care organization or any subcontracted pharmacy benefit manager to contract with a pharmacist or pharmacy providers separately for specialty pharmacy services, except that:

(i) the managed care organization and

pharmacy benefit manager are prohibited from allowing exclusive contracts with a specialty pharmacy owned wholly or partly by the pharmacy benefit manager responsible for the administration of the pharmacy benefit program; and

(ii) the managed care organization and pharmacy benefit manager must adopt policies and procedures for reclassifying prescription drugs from retail to specialty drugs, and those policies and procedures must be consistent with rules adopted by the executive commissioner and include notice to network pharmacy providers from the managed care organization;

(H) under which the managed care organization may not prevent a pharmacy or pharmacist from participating as a provider if the pharmacy or pharmacist agrees to comply with the financial terms and conditions of the contract as well as other reasonable administrative and professional terms and conditions of the contract;

(I) under which the managed care organization may include mail-order pharmacies in its networks, but may not require enrolled recipients to use those pharmacies, and may not charge an enrolled recipient who opts to use this service a fee, including postage and handling fees;

(J) under which the managed care organization or pharmacy benefit manager, as applicable, must pay claims in accordance with Section 843.339, Insurance Code; and

(K) under which the managed care organization or pharmacy benefit manager, as applicable:

(i) to place a drug on a maximum allowable

cost list, must ensure that:

(a) the drug is listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, has an "NR" or "NA" rating or a similar rating by a nationally recognized reference; and

(b) the drug is generally available for purchase by pharmacies in the state from national or regional wholesalers and is not obsolete;

(ii) must provide to a network pharmacy provider, at the time a contract is entered into or renewed with the network pharmacy provider, the sources used to determine the maximum allowable cost pricing for the maximum allowable cost list specific to that provider;

(iii) must review and update maximum allowable cost price information at least once every seven days to reflect any modification of maximum allowable cost pricing;

(iv) must, in formulating the maximum allowable cost price for a drug, use only the price of the drug and drugs listed as therapeutically equivalent in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book;

(v) must establish a process for eliminating products from the maximum allowable cost list or modifying maximum allowable cost prices in a timely manner to

remain consistent with pricing changes and product availability in the marketplace;

(vi) must:

(a) provide a procedure under which a network pharmacy provider may challenge a listed maximum allowable cost price for a drug;

(b) respond to a challenge not later than the 15th day after the date the challenge is made;

(c) if the challenge is successful, make an adjustment in the drug price effective on the date the challenge is resolved, and make the adjustment applicable to all similarly situated network pharmacy providers, as determined by the managed care organization or pharmacy benefit manager, as appropriate;

(d) if the challenge is denied, provide the reason for the denial; and

(e) report to the commission every 90 days the total number of challenges that were made and denied in the preceding 90-day period for each maximum allowable cost list drug for which a challenge was denied during the period;

(vii) must notify the commission not later than the 21st day after implementing a practice of using a maximum allowable cost list for drugs dispensed at retail but not by mail; and

(viii) must provide a process for each of its network pharmacy providers to readily access the maximum allowable cost list specific to that provider;

(24) a requirement that the managed care organization and any entity with which the managed care organization contracts for the performance of services under a managed care plan disclose, at no cost, to the commission and, on request, the office of the attorney general all discounts, incentives, rebates, fees, free goods, bundling arrangements, and other agreements affecting the net cost of goods or services provided under the plan;

(25) a requirement that the managed care organization not implement significant, nonnegotiated, across-the-board provider reimbursement rate reductions unless:

(A) subject to Subsection (a-3), the organization has the prior approval of the commission to make the reduction; or

(B) the rate reductions are based on changes to the Medicaid fee schedule or cost containment initiatives implemented by the commission; and

(26) a requirement that the managed care organization make initial and subsequent primary care provider assignments and changes.

(b) This section takes effect September 1, 2018.

SECTION 2. Chapter 533, Government Code, is amended by adding Subchapter B to read as follows:

SUBCHAPTER B. PRESCRIPTION DRUG BENEFITS

Sec. 533.051. DEFINITIONS. In this subchapter:

(1) "Labeler" and "manufacturer" have the meanings assigned by Section 531.070.

(2) "Recipient" means a Medicaid recipient.

(3) "Step therapy protocol" means a protocol that requires a recipient to use a prescription drug or sequence of prescription drugs other than the drug that the recipient's physician recommends for the recipient's treatment before a managed care organization provides coverage for the recommended drug.

Sec. 533.052. APPLICABILITY OF SUBCHAPTER. (a) This subchapter applies to an outpatient pharmacy benefit plan implemented by a managed care organization that contracts with the commission to provide health care benefits to recipients.

(b) To the extent of a conflict between the requirements for an outpatient pharmacy benefit plan for a managed care organization's enrolled recipients specified by Sections 533.005(a)(23)(A), (B), and (C) and the requirements for that plan specified by this subchapter, the requirements specified by Sections 533.005(a)(23)(A), (B), and (C) prevail. This subsection expires August 31, 2018.

Sec. 533.053. STEP THERAPY PROTOCOL EXCEPTION REQUESTS. (a) A managed care organization shall establish a process in a user-friendly format through which an exception request under this section may be submitted by a prescribing provider. The process must be readily accessible to:

(1) a recipient who enrolls in a managed care plan offered by the managed care organization or transfers to a managed care plan offered by the managed care organization from a managed care plan offered by another managed care organization; and

(2) the provider.

(b) A prescribing provider on behalf of a recipient may

submit in written or electronic form or by telephone to the recipient's managed care organization an exception request for a step therapy protocol required by the recipient's managed care organization.

(c) A managed care organization shall review and, if clinically appropriate, grant an exception request under Subsection (b) if the request includes a statement by the prescribing provider stating that:

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

(A) is contraindicated;

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

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

(2) the recipient previously discontinued taking the drug required under the step therapy protocol:

(A) while enrolled in a managed care plan offered by the recipient's current managed care organization or while enrolled in a managed care plan offered by another managed care organization; and

(B) because the drug was not effective or had a diminished effect or because of an adverse event;

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

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

(B) worsen a comorbid condition of the recipient; or

(C) decrease the recipient's ability to achieve or maintain reasonable functional ability in performing daily activities; or

(4) the drug that is subject to the step therapy protocol was prescribed for the recipient's condition while enrolled in a managed care plan offered by the recipient's current managed care organization or while enrolled in a managed care plan offered by a previous managed care organization and the recipient is stable on the drug.

(d) Except as provided by Subsection (e), if a managed care organization does not deny an exception request under Subsection (b) before 72 hours after the managed care organization receives the request, the request is considered granted.

(e) If a statement described by Subsection (c) also states that the prescribing provider reasonably believes that denial of the exception request makes the death of or serious harm to the recipient probable, the request is considered granted if the managed care organization does not deny the request before 24 hours after the managed care organization receives the request.

(f) A managed care organization may not require a prescribing provider to submit a subsequent exception request under Subsection (b) for a drug for treatment of a recipient's condition

for which the managed care organization has already granted an exception to a step therapy protocol for the recipient unless the managed care organization'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) A managed care organization shall provide coverage to a recipient who enrolls in a managed care plan offered by the managed care organization or transfers to a managed care plan offered by the managed care organization from a managed care plan offered by another managed care organization 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 managed care organization's preferred drug list.

(b) To promote continuity of care for recipients who transfer to a managed care plan offered by a managed care organization from a managed care plan offered by another managed care organization, the executive commissioner by rule or the commission in its contracts with managed care organizations shall:

(1) require a managed care organization that offers the managed care plan from which a recipient transfers enrollment to provide to the managed care organization 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 managed care organizations.

Sec. 533.055. ACCESS TO INFORMATION REGARDING PRESCRIPTION DRUG REBATES, PRICING, AND NEGOTIATIONS. (a) The commission may require the submission of and review information obtained or maintained by a managed care organization 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) Subject to Subsections (c), (d), and (e), information described by Subsection (a) that a managed care organization submits to the commission as required by the commission is confidential and not subject to disclosure under Chapter 552.

(c) Subsection (b) does not:

(1) authorize the commission to withhold from individual members, agencies, or committees of the legislature for use for legislative purposes information described by Subsection (a) that a managed care organization submits to the commission; or

(2) affect the applicability of Section 552.008.

(d) The commission may not release 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 affidavit from the requestor providing a detailed description of the legislative purpose for the request and describing how the request is within the exception to confidentiality described by 42 U.S.C. Section 1396r-8(b)(3)(D)(iv).

(e) The commission may not disclose 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. The nondisclosure agreement must also contain an acknowledgement of applicable civil and criminal penalties for improper disclosure.

Sec. 533.056. PREFERRED DRUG LIST; SEARCHABLE DATABASE OF PREFERRED DRUGS AND RESTRICTIONS. (a) A managed care organization shall provide for the distribution of current copies of the managed care organization's preferred drug list by posting the list on the managed care organization's Internet website.

(b) A managed care organization shall maintain on the managed care organization's Internet website a searchable database to allow a provider to search the managed care organization's preferred drug list and easily determine whether a prescription drug or drug class is subject to any prior authorization requirements, clinical edits, or other clinical restrictions. A managed care organization shall 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) Except as provided by Subsection (b), a managed care organization may not require prior authorization or a step therapy protocol for prescription drugs that, as determined by the executive commissioner by rule or by the commission in a contract with a managed care organization, are used to treat patients with illnesses that:

(1) are life-threatening;

(2) are chronic; and

(3) require complex medical management strategies.

(b) Subsection (a) applies only to a drug that is prescribed for a use approved by the United States Food and Drug Administration. A managed care organization may require prior authorization for a drug prescribed for a use that is not approved by the United States Food and Drug Administration, provided that the prior authorization requirement is not solely based on the drug manufacturer's package insert.

(c) Once every 10 years, the commission shall 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) A managed care organization shall ensure that a drug prescribed before the managed care organization 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 managed care organization.

(e) Notwithstanding Subsection (a), a managed care organization may require prior authorization for a prescription drug for patient safety purposes, including a drug that is clinically contraindicated.

Sec. 533.058. PRIOR AUTHORIZATION PROCEDURES. Each managed

care organization shall establish a procedure for prior authorizations, including step therapy protocols, to ensure compliance with 42 U.S.C. Section 1396r-8(d)(5). The procedure must ensure that:

(1) a prior authorization requirement for a drug is not imposed before the drug has been submitted for review to the managed care organization's drug utilization review board or pharmacy and therapeutics committee;

(2) a response to a request for prior authorization will be provided by telephone or other telecommunications device not later than 24 hours after the request is made; and

(3) a 72-hour supply of a covered prescribed drug will be provided in an emergency or if a response is not provided within the period required by Subdivision (2).

Sec. 533.059. REDUCING ADMINISTRATIVE BURDENS ASSOCIATED WITH NATIONAL DRUG CODES. (a) A managed care organization shall 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) As soon as practicable after receiving notice from the Centers for Medicare and Medicaid Services 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 the Centers for Medicare and Medicaid Services or a prescription drug has been removed from that list, the commission and each managed care organization shall provide notice of the change, addition, or removal to providers by updating the

commission's or managed care organization's electronic database of national drug code numbers for rebate-eligible prescription drugs, as applicable.

Sec. 533.060. ANNUAL REPORT. Each managed care organization shall annually report to the commission:

(1) the total number of prescriptions dispensed to recipients enrolled in a managed care plan offered by the managed care organization;

(2) the percentage of prescription drugs described by Subdivision (1) for which prior authorization was required;

(3) the percentage of prescription drugs described by Subdivision (1) for which a step therapy protocol was required; and

(4) the number of exceptions and appeals sought and granted for prior authorizations, step therapy protocols, and other formulary requests.

SECTION 3. Not later than September 1, 2018, the Health and Human Services Commission shall conduct the initial study required by Section 533.057(c), Government Code, as added by this Act. The commission or a managed care organization may not change a prior authorization requirement or step therapy protocol for a prescription drug to which that section applies until the commission has completed the study.

SECTION 4. If before implementing any provision of this Act a state agency determines that a waiver or authorization from a federal agency is necessary for implementation of that provision, the agency affected by the provision shall request the waiver or authorization and may delay implementing that provision until the

waiver or authorization is granted.

SECTION 5. Except as otherwise provided by this Act, this Act takes effect September 1, 2017.