By: Raymond H.B. No. 3732

A BILL TO BE ENTITLED

AN ACT

relating to prescription drug benefits under the Medicaid program.

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

SECTION 1. Section 531.073(a), Government Code, is amended to read as follows:

(a) The executive commissioner, in the rules and standards governing the Medicaid vendor drug program and the child health plan program, shall require prior authorization for the reimbursement of a drug that is not included in the appropriate preferred drug list adopted under Section 531.072, except as provided by Section 531.0731 and for any drug exempted from prior authorization requirements by federal law. Except as provided by Section 531.0731, the [~~The~~] executive commissioner may require prior authorization for the reimbursement of a drug provided through any other state program administered by the commission or a state health and human services agency, including a community mental health center and a state mental health hospital if the commission adopts preferred drug lists under Section 531.072 that apply to those facilities and the drug is not included in the appropriate list. The executive commissioner shall require that the prior authorization be obtained by the prescribing physician or prescribing practitioner.

SECTION 2. Subchapter B, Chapter 531, Government Code, is amended by adding Section 531.0731 to read as follows:

Sec. 531.0731. CONTINUITY OF CARE IN RELATION TO PRESCRIPTION DRUGS. The commission shall ensure that a prescription drug prescribed to a person who is newly enrolled in the child health plan program, Medicaid, or another state program administered by the commission or a health and human services agency, or who is newly enrolled in a Medicaid managed care health plan, is not subject to a prior authorization requirement for up to one year after the date of the person's enrollment, if:

(1) the patient had previously been prescribed the drug to treat a medical condition; and

(2) the person's physician prescribes the drug to treat the person's medical condition based on the physician's determination that the prescription is the most appropriate course of treatment for the medical condition.

SECTION 3. Section 531.0736, Government Code, is amended by amending Subsection (b) to read as follows:

(b) In addition to performing any other duties required by federal law, the board shall:

(1) develop and submit to the commission recommendations for preferred drug lists adopted by the commission under Section 531.072;

(2) suggest to the commission restrictions or clinical edits on prescription drugs in accordance with Section 531.0738;

(3) review existing restrictions or clinical edits on prescription drugs for appropriateness in accordance with Section 531.0738;

(4) recommend to the commission educational

interventions for Medicaid providers;

(5) [~~(4)~~] review drug utilization across Medicaid; and

(6) [~~(5)~~] perform other duties that may be specified by law and otherwise make recommendations to the commission.

SECTION 4. Subchapter B, Chapter 531, is amended by adding Sections 531.0738, 531.07381, 531.07382, and 531.07383 to read as follows:

Sec. 531.0738. DRUG UTILIZATION REVIEW BOARD: SUGGESTION AND REVIEW OF RESTRICTIONS AND CLINICAL EDITS. (a) In performing the requirements under Sections 531.0736(b)(2) and (3), the board shall evaluate the appropriateness of and make a recommendation regarding a restriction or clinical edit or protocol on a prescription drug. The committee's evaluation and recommendation must:

(1) be based on only a determination of the safety and efficacy of the restriction or clinical edit or protocol;

(2) ensure the restriction or clinical edit is written for the needs of all applicable populations, including pediatric and obstetric populations; and

(3) include an explanation of the basis for the committee's recommendation that is written in such a way that would allow a person without medical training to understand.

(b) To perform the requirements under Section 531.0736(b)(3), the board shall establish a periodic review schedule for existing restrictions or clinical edits or protocols. The schedule must require review of a restriction or clinical edit

on a prescription drug no less frequently than once every two years. A restriction or clinical edit on a prescription drug has no effect and may not be enforced beginning on the date of the second anniversary of the most recent review of the restriction or edit by the board unless the restriction or clinical edit has been evaluated and renewed by the board.

(c) In determining the safety and efficacy of a restriction or clinical edit, the board:

(1) may consider public comment or clinical information including scientific evidence, standards of practice, peer-reviewed medical literature, randomized clinical trials, pharmacoeconomic studies, and outcomes research data; and

(2) may not rely solely on manufacturer package inserts.

Sec. 531.07381. SUSPENSION OF RESTRICTION OR CLINICAL EDIT ON PRESCRIPTION DRUG. The executive commissioner by rule shall adopt a process by which the commission amends or suspends a restriction or clinical edit on a prescription drug. The process must:

(1) allow providers or Medicaid managed care organization medical or pharmacy directors to submit to the commission evidence that the restriction or clinical edit:

(A) jeopardizes patient safety or care by imposing undue administrative burdens to patients or providers; or

(B) is clinically inaccurate or otherwise inappropriate;

(2) require the commission's Medicaid medical director

to:

(A) review submitted clinical information to determine whether the restriction or clinical edit should be amended or suspended in the interest of patient safety or care; and

(B) submit a recommendation based on the medical director's determination regarding the restriction or clinical edit to the executive commissioner; and

(3) no later than 10 business days after the date the executive commissioner receives the medical director's recommendation), require the executive commissioner to amend or suspend the restriction or clinical edit in accordance with the medical director's determination, as applicable.

Sec. 531.07382. STEP THERAPY PROTOCOLS. (a) In this section and in Section 531.07383:

(1) "Clinical practice guideline" means a statement systematically developed by physicians and other health care providers to assist a patient or health care provider in making a decision about appropriate health care for a specific clinical circumstance or condition.

(2) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by a health benefit plan issuer, utilization review organization, or independent review organization to determine the medical necessity and appropriateness of a health care service or prescription drug.

(3) "Step therapy protocol" means a protocol that requires an enrollee to use a prescription drug or sequence of

prescription drugs other than the drug that the enrollee's physician recommends for the enrollee's treatment before the health benefit plan provides coverage for the recommended drug.

(b) The commission may require a step therapy protocol before providing coverage for a prescription drug only if the commission establishes, implements, and administers the step therapy protocol in accordance with clinical review criteria readily available to the health care industry. The clinical review criteria must be based on:

(1) generally accepted clinical practice guidelines that are:

(A) developed and endorsed by a multidisciplinary panel of experts described by Subsection (b); and

(B) based on high quality studies, research, and medical practice that are:

(i) created by an explicit and transparent process that:

(a) minimizes bias and conflicts of interest;

(b) explains the relationship between treatment options and outcomes;

(c) rates the quality of the evidence supporting the recommendations; and

(d) considers relevant patient subgroups and preferences; and

(ii) updated at appropriate intervals after a review of new evidence, research, and treatments; or

(2) if clinical practice guidelines described by Subdivision (1) are not reasonably available, peer-reviewed publications developed by independent experts, which must include physicians, with expertise applicable to the relevant health condition.

(c) A multidisciplinary panel of experts consisting of physicians and other health care providers that develops and endorses clinical practice guidelines under Subsection (a)(1) must manage conflicts of interest by:

(1) requiring each member of the panel's writing or review group to:

(A) disclose any potential conflict of interest, including a conflict of interest involving an insurer, managed care organization, or pharmaceutical manufacturer; and

(B) recuse himself or herself in any situation in which the member has a conflict of interest;

(2) using a methodologist to work with writing groups to provide objectivity in data analysis and the ranking of evidence by preparing evidence tables and facilitating consensus; and

(3) offering an opportunity for public review and comment.

(d) This section may not be construed to prohibit:

(1) the commission from requiring a patient to try an AB-rated generic equivalent drug before providing coverage for the equivalent branded prescription drug, unless the drug:

(A) has been demonstrated to be ineffective on the patient;

(B) has caused an adverse reaction in or physical or mental harm to the patient; or

(C) is likely to cause an adverse reaction in or physical or mental harm to the patient; or

(2) a prescribing provider from prescribing a prescription drug that is determined to be medically appropriate.

Sec. 531.07383. OVERRIDE OF RESTRICTIONS ON MEDICATION SEQUENCE IN STEP THERAPY PROTOCOL. (a) The commission shall establish a clear and convenient process for a prescribing health professional to request electronically, in writing, or by phone an override of a step therapy protocol.

(b) The commission shall grant a request for an override of a step therapy protocol to a prescribing health professional within, subject to Subsections (c) and (d), a reasonable time after the health professional completes the process for the request of the override, if:

(1) the prescribing health professional can demonstrate that the patient has previously failed the preferred treatment required under the step therapy protocol, or that the preferred treatment or another drug in the same pharmacologic class or with the same mechanism of action as the preferred treatment, has been ineffective or had a diminished effect for the treatment of a recipient's medical condition after two attempts of following the protocol; or

(2) based on sound clinical evidence or medical and scientific evidence, the prescribing health professional can demonstrate that the preferred treatment required under the step

therapy protocol:

(A) is expected or likely to be ineffective based on the known relevant physical or mental characteristics of the recipient and known characteristics of the drug regimen; or

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

(c) Except as provided by Subsection (e), if the commission does not deny an exception request described by Subsection (a) before 48 hours after the commission receives the request, the request is considered granted.

(d) If an exception request 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 patient probable, the request is considered granted if commission does not deny the request before 24 hours after the organization receives the request.

(e) The process established under this section must allow a prescribing health professional to appeal a denial of a request for an override of a step therapy protocol to the commission's medical director.

SECTION 5. Section 531.0741, Government Code, is amended to read as follows:

Sec. 531.0741. PUBLICATION OF INFORMATION REGARDING COMMISSION AND DRUG UTILIZATION REVIEW BOARD DECISIONS [~~ON PREFERRED DRUG LIST PLACEMENT~~]. (a) The commission shall publish on the commission's Internet website any decisions on preferred drug list placement, including:

(1) a list of drugs reviewed and the commission's decision for or against placement on a preferred drug list of each drug reviewed;

(2) for each recommendation, whether a supplemental rebate agreement or a program benefit agreement was reached under Section 531.070; and

(3) the rationale for any departure from a recommendation of the Drug Utilization Review Board under Section 531.0736.

(b) The commission shall publish on the commission's Internet website in a section of the website dedicated to prescription drug information:

(1) information on restrictions or clinical edits for a prescription drug, including a preferred drug, including the evaluation and recommendation required under Section 531.0738 that relates to the restriction or clinical edit; and

(2) the periodic review schedule established under Section 531.0738(b).

(c) The commission must publish the information required under this section in a manner that would allow a provider to search a preferred drug list to easily determine whether a prescription drug or drug class is subject to any restrictions or clinical edits.

SECTION 6. Subchapter B, Chapter 531, Government Code is amended by adding Section 531.0761 to read as follows:

Sec. 531.0761. PRESCRIPTION OF GENERIC EQUIVALENTS. (a) Notwithstanding any other section of law and in a manner that complies with applicable federal law, the commission shall ensure

that a preferred drug list adopted by the commission for the Medicaid vendor drug program and for prescription drugs purchased through the child health plan program establishes a generic equivalent of a prescribed drug as a preferred drug.

(b) If a physician or other health care practitioner acting within the practitioner's scope of delegated authority writes a prescription for a generic equivalent of a prescribed drug, the commission may not require the physician or practitioner to specify the national drug code on the prescription.

Sec. 531.0762. UPDATING NATIONAL DRUG CODES. (a) No later than the 15th business day after the day the commission receives notice from the Centers for Medicaid and Medicare Services that a National Drug Code has been eliminated or changed, the commission shall update its electronic database and notify Medicaid managed care organizations.

SECTION 7. Subchapter A, Chapter 533, Government Code, is amended by adding Section 533.022 to read as follows:

Sec. 533.022. PHARMACY BENEFIT PLAN REQUIREMENTS. (a) The commission shall require that the pharmacy benefit plan of a managed care organization that contracts with the commission to provide health care services to recipients must:

(1) adopt the restrictions or clinical edits as recommended by the Drug Utilization Review Board under Section 531.0738 and impose no other restrictions or clinical edits than those recommended by the board;

(2) adopt the process adopted under Section 531.07381 for amending or suspending a restriction or clinical edit on a

prescription drug;

(3) adhere to the step therapy guidelines and override procedures under Sections 531.07382 and 531.07383, including a procedure for an appeal under Section 531.07383(e) to the managed care organization's medical director.

SECTION 8. Section 533.005(a-1), Government Code, is amended to read as follows:

(a-1) The requirements imposed by Subsections (a)(23)(A), (B), and (C) do not apply, and may not be enforced, on and after August 31, 2030 [~~2018~~].

SECTION 9. 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 10. (a) The Drug Utilization Review Board shall establish a schedule for reviewing restrictions and clinical edits on prescription drugs provided as benefits under the Medicaid program as required by Section 531.0738, Government Code, as added by this Act, no later than March 1, 2018.

(b) The Drug Utilization Review Board shall complete a review of all restrictions and clinical edits on prescription drugs that are provided as benefits under the Medicaid program that are in effect on the effective date of this Act, as required by Section 531.0738, Government Code, as added by this Act, no later than September 1, 2018.

(c) The Health and Human Services Commission may not allow a restriction or clinical edit on a prescription drug provided as a benefit under the Medicaid program to be enforced or to have any effect before the Drug Utilization Review Board reviews the restriction or clinical edit in accordance with Subsection (b) of this SECTION, unless the Health and Human Services Commission requires the enforcement or imposition of the restriction or clinical edit by administrative rule or by contract with a managed care organization that contracts with the commission to provide health care benefits to enrollees in the Medicaid program.

SECTION 11. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2017.