GOVERNMENT CODE

TITLE 4. EXECUTIVE BRANCH

SUBTITLE I. HEALTH AND HUMAN SERVICES

CHAPTER 549. PROVISION OF DRUGS AND DRUG INFORMATION

SUBCHAPTER A. GENERAL PROVISIONS APPLICABLE TO PROVISION OF DRUGS UNDER VENDOR DRUG PROGRAM AND CERTAIN OTHER PROGRAMS

Text of section effective on April 01, 2025

Sec. 549.0001. BULK PURCHASING WITH ANOTHER STATE OF PRESCRIPTION DRUGS AND OTHER MEDICATIONS. (a) Subject to Subsection (b), the commission and each health and human services agency the executive commissioner authorizes may enter into an agreement with one or more other states for the joint bulk purchasing of prescription drugs and other medications to be used in Medicaid, the child health plan program, or another program under the commission's authority.

(b) A joint bulk purchasing agreement may not be entered into until:

(1) the commission determines that entering into the agreement would be feasible and cost-effective; and

(2) if appropriated money would be spent under the proposed agreement, the governor and the Legislative Budget Board grant prior approval to spend appropriated money under the proposed agreement.

(c) In determining the feasibility and cost-effectiveness of entering into a joint bulk purchasing agreement, the commission shall identify:

(1) the most cost-effective existing joint bulk purchasing agreement; and

(2) any potential groups of states with which this state could enter into a new cost-effective joint bulk purchasing agreement.

(d) If a joint bulk purchasing agreement is entered into, the commission shall adopt procedures applicable to an agreement and joint purchase described by this section. The procedures must ensure that this state receives:

(1) all prescription drugs and other medications purchased with money provided by this state; and

(2) an equitable share of any price benefits resulting from the joint bulk purchase.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0002. VALUE-BASED ARRANGEMENT IN MEDICAID VENDOR DRUG PROGRAM. (a) In this section, "manufacturer" has the meaning assigned by Section 549.0101.

(b) Subject to Subchapter D, the commission may enter into a value-based arrangement for the Medicaid vendor drug program by written agreement with a manufacturer based on outcome data or other metrics to which this state and the manufacturer agree in writing. The value-based arrangement may include a rebate, a discount, a price reduction, a contribution, risk sharing, a reimbursement, payment deferral or installment payments, a guarantee, patient care, shared savings payments, withholds, a bonus, or any other thing of value.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0003. PERIOD OF VALIDITY OF PRESCRIPTIONS UNDER MEDICAID. (a) This section does not apply to a prescription for a controlled substance, as defined by Chapter 481, Health and Safety Code.

(b) In the rules and standards governing the vendor drug program, the executive commissioner, to the extent allowed by federal law and laws regulating the writing of prescriptions and dispensing of prescription medications, shall ensure that a prescription written by an authorized health care provider under Medicaid is valid for the lesser of:

(1) the period for which the prescription is written; or

(2) one year.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0004. CERTAIN MEDICATIONS FOR SEX OFFENDERS PROHIBITED. (a) To the maximum extent allowed under federal law, the commission may not provide a sexual performance enhancing medication under the vendor drug program or any other health and human services program to an individual required to register as a sex offender under Chapter 62, Code of Criminal Procedure.

(b) The executive commissioner may adopt rules as necessary to implement this section.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0005. PRIOR APPROVAL OF AND PHARMACY PROVIDER ACCESS TO CERTAIN COMMUNICATIONS WITH CERTAIN RECIPIENTS AND ENROLLEES. (a) This section applies to:

(1) the vendor drug program for Medicaid and the child health plan program;

(2) the kidney health care program;

(3) the children with special health care needs program; and

(4) any other state program the commission administers that provides prescription drug benefits.

(b) A managed care organization, including a health maintenance organization, or a pharmacy benefit manager, that administers claims for prescription drug benefits under a program to which this section applies shall, at least 10 days before the date the organization or pharmacy benefit manager intends to deliver a communication to recipients or enrollees collectively under a program:

(1) submit a copy of the communication to the commission for approval; and

(2) if applicable, allow the pharmacy providers of the recipients or enrollees who are to receive the communication access to the communication.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

SUBCHAPTER B. REVIEW AND ANALYSIS OF CERTAIN PRESCRIPTION DRUG PURCHASES AND PATTERNS

Text of section effective on April 01, 2025

Sec. 549.0051. PERIODIC REVIEW OF VENDOR DRUG PROGRAM PURCHASES. (a) The commission shall periodically review all purchases made under the vendor drug program to determine the cost-effectiveness of including a component for prescription drug benefits in any capitation rate paid by this state under a Medicaid managed care program or the child health plan program.

(b) In making the determination required by Subsection (a), the commission shall consider the value of any prescription drug rebates this state receives.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0052. MEDICAID PRESCRIPTION DRUG USE AND EXPENDITURE PATTERNS. The commission shall:

(1) monitor and analyze Medicaid prescription drug use and expenditure patterns;

(2) identify the therapeutic prescription drug classes and individual prescription drugs that are most often prescribed to patients or that represent the greatest expenditures; and

(3) post the data the commission identifies under this section on the commission's Internet website and update the information on a quarterly basis.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

SUBCHAPTER C. SUPPLEMENTAL REBATES OR PROGRAM BENEFITS FOR PRESCRIPTION DRUGS

Text of section effective on April 01, 2025

Sec. 549.0101. DEFINITIONS. In this subchapter:

(1) "Labeler" means a person that:

(A) has a labeler code from the United States Food and Drug Administration under 21 C.F.R. Section 207.33; and

(B) receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

(2) "Manufacturer" means a manufacturer of prescription drugs as defined by 42 U.S.C. Section 1396r-8(k)(5), including a subsidiary or affiliate of a manufacturer.

(3) "Supplemental rebate" means a cash rebate a manufacturer pays to this state:

(A) on the basis of appropriate quarterly health and human services program utilization data relating to the manufacturer's products; and

(B) in accordance with a state supplemental rebate agreement negotiated with the manufacturer and, if necessary, approved by the federal government under 42 U.S.C. Section 1396r-8.

(4) "Wholesaler" means a person licensed under Subchapter I, Chapter 431, Health and Safety Code.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0102. REQUIREMENT TO NEGOTIATE FOR SUPPLEMENTAL REBATES FOR CERTAIN PROGRAMS. (a) Subject to Subsection (b), the commission shall negotiate with manufacturers and labelers, including generic manufacturers and labelers, to obtain supplemental rebates for prescription drugs provided under:

(1) the Medicaid vendor drug program in excess of the

Medicaid rebates required by 42 U.S.C. Section 1396r-8;

(2) the child health plan program; and

(3) any other state program the commission or a health and human services agency administers, including a community mental health center or state mental health hospital.

(b) The commission may by contract authorize a private entity to negotiate with manufacturers and labelers on the commission's behalf.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0103. VOLUNTARY NEGOTIATION FOR MANUFACTURER AND LABELER SUPPLEMENTAL REBATES. A manufacturer or labeler that sells prescription drugs in this state may voluntarily negotiate with the commission and enter into an agreement to provide supplemental rebates for prescription drugs provided under:

(1) the Medicaid vendor drug program in excess of the Medicaid rebates required by 42 U.S.C. Section 1396r-8;

(2) the child health plan program; and

(3) any other state program the commission or a health and human services agency administers, including a community mental health center or state mental health hospital.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0104. CONSIDERATIONS IN SUPPLEMENTAL REBATE NEGOTIATIONS. (a) In negotiating terms for a supplemental rebate amount, the commission shall consider:

(1) rebates calculated under the Medicaid rebate program in accordance with 42 U.S.C. Section 1396r-8;

(2) any other available information on prescription drug prices or rebates; and

(3) other program benefits as specified in Section 549.0106(b).

(b) In negotiating terms for a supplemental rebate, the commission shall use the average manufacturer price as defined in 42 U.S.C. Section 1396r-8(k)(1) as the cost basis for the product.
Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0105. REQUIRED DISCLOSURES IN NEGOTIATIONS FOR SUPPLEMENTAL REBATES. Before or during supplemental rebate agreement negotiations for a prescription drug being considered for the preferred drug list, the commission shall disclose to pharmaceutical manufacturers any clinical edits or clinical protocols that may be imposed on drugs within a particular drug category that are placed on the preferred drug list during the contract period. Clinical edits may not be imposed for a preferred drug during the contract period unless the disclosure is made.
Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0106. PROGRAM BENEFITS INSTEAD OF SUPPLEMENTAL REBATES; MONETARY CONTRIBUTION OR DONATION. (a) For purposes of this section, a program benefit may mean a disease management program authorized under this title, a drug product donation program, a drug utilization control program, prescriber and beneficiary counseling and education, a fraud or abuse initiative, and another service or administrative investment with guaranteed savings to a program a health and human services agency operates.

(b) The commission may enter into a written agreement with a manufacturer to accept a program benefit instead of a supplemental rebate only if:

(1) the program benefit yields savings that are at least equal to the amount the manufacturer would have provided under a state supplemental rebate agreement during the current biennium as determined by the written agreement;

(2) the manufacturer:

(A) posts a performance bond guaranteeing savings to this state; and

(B) agrees that if the savings are not achieved in accordance with the written agreement, the manufacturer will forfeit the bond to this state, less any savings that were achieved; and

(3) the program benefit is in addition to other program benefits the manufacturer currently offers to recipients of Medicaid or related programs.

(c) For purposes of this subchapter, the commission may consider a monetary contribution or donation to the arrangements described in Subsection (b) for the purpose of offsetting expenditures to other state health care programs, but that funding may not be used to offset expenditures for covered outpatient drugs as defined by 42 U.S.C. Section 1396r-8(k)(2) under the vendor drug program. An arrangement under this subsection may not yield less than the amount this state would have benefited under a supplemental rebate. The commission may consider an arrangement under this subchapter as satisfying the requirements of Section 549.0204(a).

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0107. LIMITATIONS ON AGREEMENT TO ACCEPT PROGRAM BENEFITS INSTEAD OF SUPPLEMENTAL REBATES. (a) A commission agreement to accept a program benefit described by Section 549.0106:

(1) may not prohibit the commission from entering into a similar agreement with another entity that relates to a different drug class;

(2) must be limited to a period the commission expressly determines; and

(3) subject to Subsection (b), may cover only a product that has received United States Food and Drug Administration approval as of the date the commission enters into the agreement.

(b) A new product the United States Food and Drug Administration approves after the commission enters into the agreement may be incorporated into the agreement only under an amendment to the agreement.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0108. TREATMENT OF PROGRAM BENEFITS FOR CERTAIN PURPOSES. Other than as required to satisfy the provisions of this subchapter, a program benefit described by Section 549.0106 is considered an alternative to, and not the equivalent of, a supplemental rebate. A program benefit must be treated in this state's submissions to the federal government, including, as appropriate, waiver requests and quarterly Medicaid claims, so as to maximize the availability of federal matching payments.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

SUBCHAPTER D. CONFIDENTIALITY OF INFORMATION RELATING TO PRESCRIPTION DRUG REBATE NEGOTIATIONS AND AGREEMENTS

Text of section effective on April 01, 2025

Sec. 549.0151. CERTAIN PRESCRIPTION DRUG INFORMATION CONFIDENTIAL. (a) Notwithstanding any other state law other than Sections 549.0152 and 549.0153, information the commission obtains or maintains regarding prescription drug rebate negotiations or a supplemental Medicaid or other rebate agreement, including trade secrets, rebate amount, rebate percentage, and manufacturer or labeler pricing, is confidential and not subject to disclosure under Chapter 552.

(b) Information that is confidential under Subsection (a) includes information described by that subsection that the commission obtains or maintains in connection with:

(1) the vendor drug program;

(2) the child health plan program;

(3) the kidney health care program;

(4) the children with special health care needs program; or

(5) another state program the commission or a health and human services agency administers.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0152. GENERAL PRESCRIPTION DRUG INFORMATION NOT CONFIDENTIAL; EXCEPTION. General information about the aggregate costs of different classes of prescription drugs is not confidential under Section 549.0151(a), except that a drug name or information that could reveal a drug name is confidential.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0153. EXISTENCE OR NONEXISTENCE OF SUPPLEMENTAL REBATE AGREEMENT NOT CONFIDENTIAL. Information about whether the commission and a manufacturer or labeler reached or did not reach a supplemental rebate agreement under Subchapter C for a particular prescription drug is not confidential under Section 549.0151(a).

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

SUBCHAPTER E. PREFERRED DRUG LISTS

Text of section effective on April 01, 2025

Sec. 549.0201. DEFINITION. In this subchapter, "board" means the Drug Utilization Review Board.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0202. PREFERRED DRUG LISTS REQUIRED FOR MEDICAID VENDOR DRUG AND CHILD HEALTH PLAN PROGRAMS. In a manner that complies with state and federal law, the commission shall adopt preferred drug lists for:

(1) the Medicaid vendor drug program; and

(2) prescription drugs purchased through the child health plan program.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0203. PREFERRED DRUG LISTS AUTHORIZED FOR CERTAIN PROGRAMS. The commission may adopt preferred drug lists for:

(1) community mental health centers;

(2) state mental health hospitals; and

(3) any state program the commission or a state health and human services agency administers other than a program for which Section 549.0202 requires the adoption of preferred drug lists.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0204. LIMITATION ON DRUGS INCLUDED ON PREFERRED DRUG LISTS; EXCEPTIONS. (a) The preferred drug lists adopted under this subchapter may contain only drugs provided by a manufacturer or labeler that reaches an agreement with the commission on supplemental rebates under Subchapter C.

(b) Notwithstanding Subsection (a), the preferred drug lists may contain:

(1) a drug provided by a manufacturer or labeler that has not reached a supplemental rebate agreement with the commission if the commission determines that including the drug on the preferred drug lists will not have a negative cost impact to this state; or

(2) a drug provided by a manufacturer or labeler that

has reached an agreement with the commission to provide program benefits instead of supplemental rebates as described by Subchapter C.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0205. CONSIDERATIONS FOR INCLUDING DRUG ON PREFERRED DRUG LISTS. (a) In making a decision regarding the placement of a drug on each of the preferred drug lists adopted under this subchapter, the commission shall consider:

(1) the board's recommendations under Section 549.0309;

(2) the drug's clinical efficacy;

(3) the price of competing drugs after deducting any federal and state rebate amounts; and

(4) program benefit offerings solely or in conjunction with rebates and other pricing information.

(b) The commission shall consider including on a preferred drug list:

(1) multiple methods of delivery within each drug class, including liquid, capsule, and tablet, including an orally disintegrating tablet; and

(2) all strengths and dosage forms of a drug.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0206. SUBMISSION OF EVIDENCE TO SUPPORT INCLUDING DRUG ON PREFERRED DRUG LISTS. (a) In this section, "labeler" and "manufacturer" have the meanings assigned by Section 549.0101.

(b) The commission shall ensure that a manufacturer or labeler may submit written evidence that supports including a drug on the preferred drug lists before a supplemental rebate agreement is reached with the commission.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01,

eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0207. PUBLICATION OF INFORMATION RELATING TO AND DISTRIBUTION OF PREFERRED DRUG LISTS. (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 reviewed drug;

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

(3) the rationale for any departure from a board recommendation under Section 549.0309.

(b) The commission shall:

(1) provide for the distribution of current copies of the preferred drug lists adopted under this subchapter by posting the lists on the Internet; and

(2) mail copies of the lists to a health care provider on the provider's request.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

SUBCHAPTER F. PRIOR AUTHORIZATION FOR CERTAIN DRUGS

Text of section effective on April 01, 2025

Sec. 549.0251. DRUGS SUBJECT TO PRIOR AUTHORIZATION REQUIREMENTS. (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 Subchapter E unless:

(1) the drug is exempt from prior authorization requirements by federal law; or

(2) the executive commissioner is prohibited under

Sections 549.0252 and 549.0253(a) from requiring prior authorization for the drug.

(b) The executive commissioner may require prior authorization for the reimbursement of a drug provided through any state program, other than a program described by Subsection (a), that the commission or a state health and human services agency administers, including a community mental health center and a state mental health hospital if the commission adopts a preferred drug list under Subchapter E that applies to that facility and the drug is not included in the appropriate list.

(c) The executive commissioner shall require that the prior authorization be obtained by the prescribing physician or prescribing practitioner.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0252. PRIOR AUTHORIZATION AND CERTAIN PROTOCOL REQUIREMENTS PROHIBITED FOR CERTAIN ANTIRETROVIRAL DRUGS. (a) In this section, "antiretroviral drug" means a drug that treats human immunodeficiency virus infection or prevents acquired immune deficiency syndrome. The term includes:

(1) protease inhibitors;

(2) non-nucleoside reverse transcriptase inhibitors;

(3) nucleoside reverse transcriptase inhibitors;

(4) integrase inhibitors;

(5) fusion inhibitors;

(6) attachment inhibitors;

(7) CD4 post-attachment inhibitors;

(8) CCR5 receptor antagonists; and

(9) other antiretroviral drugs used to treat human immunodeficiency virus infection or prevent acquired immune deficiency syndrome.

(b) The executive commissioner, in the rules and standards governing the Medicaid vendor drug program, may not require a clinical, nonpreferred, or other prior authorization for an antiretroviral drug, or a step therapy or other protocol, that

could restrict or delay the dispensing of the drug except to minimize fraud, waste, or abuse.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0253. PRIOR AUTHORIZATION PROHIBITED FOR CERTAIN NONPREFERRED ANTIPSYCHOTIC DRUGS. (a) The executive commissioner, in the rules and standards governing the vendor drug program, may not require prior authorization for a nonpreferred antipsychotic drug that is included on the vendor drug formulary and prescribed to an adult patient if:

(1) during the preceding year, the patient was prescribed and unsuccessfully treated with a 14-day treatment trial of an antipsychotic drug that is included on the appropriate preferred drug list adopted under Subchapter E and for which a single claim was paid;

(2) the patient has previously been prescribed and obtained prior authorization for the nonpreferred antipsychotic drug and the prescription is for the purpose of drug dosage titration; or

(3) subject to federal law on maximum dosage limits and commission rules on drug quantity limits, the patient has previously been prescribed and obtained prior authorization for the nonpreferred antipsychotic drug and the prescription modifies the dosage, dosage frequency, or both, of the drug as part of the same treatment for which the drug was previously prescribed.

(b) Subsection (a) does not affect:

(1) a pharmacist's authority to dispense the generic equivalent or interchangeable biological product of a prescription drug in accordance with Subchapter A, Chapter 562, Occupations Code;

(2) any drug utilization review requirements prescribed by state or federal law; or

(3) clinical prior authorization edits to preferred and nonpreferred antipsychotic drug prescriptions.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01,

eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0254. ADMINISTRATION OF PRIOR AUTHORIZATION REQUIREMENTS. (a) The commission may by contract authorize a private entity to administer the prior authorization requirements imposed by Sections 549.0251 and 549.0255 through 549.0259 on the commission's behalf.

(b) The commission shall ensure that the prior authorization requirements are implemented in a manner that minimizes the cost to this state and any administrative burden placed on providers.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0255. PREREQUISITE TO IMPLEMENTING PRIOR AUTHORIZATION REQUIREMENT FOR CERTAIN DRUGS. Until the commission completes a study evaluating the impact of a prior authorization requirement on recipients of certain drugs, the executive commissioner shall delay requiring prior authorization for drugs that are used to treat patients with illnesses that:

(1) are life-threatening;

(2) are chronic; and

(3) require complex medical management strategies.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0256. NOTICE OF PRIOR AUTHORIZATION REQUIREMENT IMPLEMENTATION AND PROCEDURES. Not later than the 30th day before the date a prior authorization requirement is implemented, the commission shall post on the Internet for consumers and providers:

(1) notice of the implementation date; and

(2) a detailed description of the procedures to be used in obtaining prior authorization.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0257. PRIOR AUTHORIZATION PROCEDURES. (a) The commission shall establish procedures for the prior authorization requirement under the Medicaid vendor drug program to ensure that the requirements of 42 U.S.C. Section 1396r-8(d)(5) are met. The procedures must ensure that:

(1) a prior authorization requirement is not imposed for a drug before the drug has been considered at a meeting of the Drug Utilization Review Board under Subchapter G;

(2) a response to a request for prior authorization is provided by telephone or other telecommunications device within 24 hours after receipt of the request; and

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

(b) The commission shall implement procedures to ensure that a recipient or enrollee under Medicaid, the child health plan program, or another state program the commission administers, or an individual who becomes eligible under Medicaid, the child health plan program, or another state program the commission or a health and human services agency administers, receives continuity of care in relation to certain prescriptions the commission identifies.

(c) The commission shall ensure that requests for prior authorization may be submitted by telephone, facsimile, or electronic communications through the Internet.

(d) The commission shall provide an automated process that may be used to assess a Medicaid recipient's medical and drug claim history to determine whether the recipient's medical condition satisfies the applicable criteria for dispensing a drug without an additional prior authorization request.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0258. PRIOR AUTHORIZATION AUTOMATION AND POINT-OF-SALE REQUIREMENTS. The executive commissioner, in the rules and standards governing the vendor drug program and as part of the requirements under a contract between the commission and a Medicaid managed care organization, shall:

(1) require, to the maximum extent possible based on a pharmacy benefit manager's claim system, automation of clinical prior authorization for each drug in the antipsychotic drug class; and

(2) ensure that, at the time a nonpreferred or clinical prior authorization edit is denied, a pharmacist is immediately provided a point-of-sale return message that:

(A) clearly specifies the contact and other information necessary for the pharmacist to submit a prior authorization request for the prescription; and

(B) instructs the pharmacist to dispense, only if clinically appropriate under federal or state law, a 72-hour supply of the prescription.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0259. APPLICABILITY OF PRIOR AUTHORIZATION REQUIREMENTS TO PRIOR PRESCRIPTIONS. The commission shall ensure that a prescription drug prescribed before implementation of a prior authorization requirement for that drug for a recipient or enrollee under Medicaid, the child health plan program, or another state program the commission or a health and human services agency administers, or for an individual who becomes eligible under Medicaid, the child health plan program, or another state program the commission or a health and human services agency administers, is not subject to any prior authorization requirement under this subchapter until the earlier of:

(1) the date the recipient or enrollee exhausts all the prescription, including any authorized refills; or

(2) the expiration of a period the commission

prescribes.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0260. APPEAL OF PRIOR AUTHORIZATION DENIAL UNDER MEDICAID VENDOR DRUG PROGRAM. A recipient of drug benefits under the Medicaid vendor drug program may appeal through the Medicaid fair hearing process a denial of prior authorization under this subchapter for a covered drug or covered dosage.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

SUBCHAPTER G. DRUG UTILIZATION REVIEW BOARD

Text of section effective on April 01, 2025

Sec. 549.0301. DEFINITION. In this subchapter, "board" means the Drug Utilization Review Board.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0302. BOARD COMPOSITION; APPLICATION PROCESS. (a) The composition of the board must comply with federal law, including 42 C.F.R. Section 456.716. The executive commissioner shall determine the board's composition, which must include:

(1) two representatives of managed care organizations, one of whom must be a physician and one of whom must be a pharmacist, as nonvoting members;

(2) at least 17 physicians and pharmacists who:

(A) provide services across the entire population of Medicaid recipients and represent different specialties, including at least one of each of the following types of physicians:

(i) a pediatrician;

(ii) a primary care physician;

(iii) an obstetrician and gynecologist;

(iv) a child and adolescent psychiatrist; and

(v) an adult psychiatrist; and

(B) have experience in either developing or practicing under a preferred drug list; and

(3) a consumer advocate who represents Medicaid recipients.

(b) The executive commissioner by rule shall develop and implement a process by which an individual may apply to become a board member and shall post the application and information regarding the application process on the commission's Internet website.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0303. CONFLICTS OF INTEREST. (a) A voting board member may not have a contractual relationship with, ownership interest in, or other conflict of interest with:

(1) a pharmaceutical manufacturer or labeler; or

(2) an entity the commission engages to assist in developing preferred drug lists or administering the Medicaid Drug Utilization Review Program.

(b) The executive commissioner may implement this section by:

(1) adopting rules that identify prohibited relationships and conflicts; or

(2) requiring the board to develop a conflict-of-interest policy that applies to the board.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0304. BOARD MEMBER TERMS. Board members serve staggered four-year terms.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0305. PRESIDING OFFICER. The voting board members shall elect from among the voting members a presiding officer. The presiding officer must be a physician.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0306. INAPPLICABILITY OF OTHER LAW TO BOARD. Chapter 2110 does not apply to the board.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0307. ADMINISTRATIVE SUPPORT FOR BOARD. The commission shall provide administrative support and resources as necessary for the board to perform the board's duties.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0308. RULES FOR BOARD OPERATION. (a) The executive commissioner shall adopt rules governing the board's operation, including:

(1) rules governing the procedures the board uses to provide notice of a meeting; and

(2) rules prohibiting the board from discussing confidential information described by Subchapter D in a public meeting.

(b) The board shall comply with the rules adopted under this section and Section 549.0311.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01,

eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0309. GENERAL POWERS AND DUTIES OF BOARD. (a) In addition to performing any other duties required by federal law, the board shall:

(1) develop and submit to the commission recommendations for the preferred drug lists the commission adopts under Subchapter E;

(2) suggest to the commission restrictions or clinical edits on prescription drugs;

(3) recommend to the commission educational interventions for Medicaid providers;

(4) review drug utilization across Medicaid; and

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

(b) In developing recommendations for the preferred drug lists, the board shall consider the clinical efficacy, safety, and cost-effectiveness of, and any program benefit associated with, a product.

(c) To the extent feasible, the board:

(1) shall review all drug classes included in the preferred drug lists at least once every 12 months; and

(2) may recommend inclusions in and exclusions from the lists to ensure that the lists provide for a range of clinically effective, safe, cost-effective, and medically appropriate drug therapies for the diverse segments of the Medicaid population, children receiving health benefits coverage under the child health plan program, and any other affected individuals.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0310. BOARD MEETINGS; REVIEW OF CERTAIN PRODUCTS. (a) The board shall hold a public meeting quarterly at the call of the presiding officer and shall permit public comment before voting

on any changes in the preferred drug lists the commission adopts under Subchapter E, the adoption of or changes to drug use criteria, or the adoption of prior authorization or drug utilization review proposals. The location of the quarterly public meeting may rotate among different geographic areas across this state, or allow for public input through teleconferencing centers in various geographic areas across this state.

(b) The board shall hold public meetings at other times at the call of the presiding officer.

(c) Minutes of each meeting shall be made available to the public not later than the 10th business day after the date the minutes are approved.

(d) The board may meet in executive session to discuss confidential information as described by Section 549.0308.

(e) Board members appointed under Section 549.0302(a)(1) may attend quarterly and other regularly scheduled meetings, but may not:

(1) attend executive sessions; or

(2) access confidential drug pricing information.

(f) In this subsection, "labeler" and "manufacturer" have the meanings assigned by Section 549.0101. The commission shall ensure that a drug that has been approved or had any of the drug's particular uses approved by the United States Food and Drug Administration under a priority review classification is reviewed by the board at the next regularly scheduled board meeting. On receiving notice from a manufacturer or labeler of the availability of a new product, the commission, to the extent possible, shall schedule a review for the product at the next regularly scheduled board meeting.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0311. BOARD SUMMARY OF CERTAIN INFORMATION REQUIRED. (a) The executive commissioner by rule shall require the board or the board's designee to present a summary of any clinical efficacy and safety information or analyses regarding a

drug under consideration for a preferred drug list the commission adopts under Subchapter E that is provided to the board by a private entity that contracted with the commission to provide the information. Confidential information described by Subchapter D must be omitted from the summary.

(b) The board or the board's designee shall provide the summary in electronic form before the public meeting at which consideration of the drug occurs.

(c) The summary must be posted on the commission's Internet website.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0312. PUBLIC DISCLOSURE OF CERTAIN BOARD RECOMMENDATIONS REQUIRED. (a) The commission or the commission's agent shall publicly disclose, immediately after the board's deliberations conclude, each specific drug recommended for or against preferred drug list status for each drug class included in the preferred drug list for the Medicaid vendor drug program. The disclosure must include:

(1) the general basis for the recommendation for each drug class; and

(2) for each recommendation, whether a supplemental rebate agreement or program benefit agreement was reached under Subchapter C.

(b) The disclosure must be posted on the commission's Internet website not later than the 10th business day after the date of conclusion of board deliberations that result in recommendations made to the executive commissioner regarding the placement of drugs on the preferred drug list.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

SUBCHAPTER H. MEDICAID DRUG UTILIZATION REVIEW PROGRAM

Text of section effective on April 01, 2025

Sec. 549.0351. DEFINITIONS. In this subchapter:

(1) "Medicaid Drug Utilization Review Program" means the program the vendor drug program operates to improve the quality of pharmaceutical care under Medicaid.

(2) "Prospective drug use review" means the review of a patient's drug therapy and prescription drug order or medication order before dispensing or distributing a drug to the patient.

(3) "Retrospective drug use review" means the review of prescription drug claims data to identify patterns of prescribing.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0352. DRUG USE REVIEWS. (a) The commission shall provide for an increase in the number and types of retrospective drug use reviews performed each year under the Medicaid Drug Utilization Review Program in comparison to the number and types of reviews performed in the state fiscal year ending August 31, 2009.

(b) In determining the number and types of drug use reviews to be performed, the commission shall:

(1) allow for the repeat of retrospective drug use reviews that address ongoing drug therapy problems and that, in previous years, improved client outcomes and reduced Medicaid spending;

(2) consider implementing disease-specific retrospective drug use reviews that:

(A) address ongoing drug therapy problems in this state; and

(B) reduced Medicaid prescription drug use expenditures in another state; and

(3) regularly examine Medicaid prescription drug claims data to identify occurrences of potential drug therapy problems that may be addressed by repeating successful retrospective drug use reviews performed in this state or another state.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0353. ANNUAL REPORT. (a) In addition to any other information required by federal law, the commission shall include the following information in the annual report regarding the Medicaid Drug Utilization Review Program:

(1) a detailed description of the program's activities; and

(2) estimates of cost savings anticipated to result from the program's performance of prospective and retrospective drug use reviews.

(b) The cost-saving estimates for prospective drug use reviews under Subsection (a) must include savings attributed to drug use reviews performed through the vendor drug program's electronic claims processing system and clinical edits screened through the prior authorization system implemented under Subchapter F.

(c) The commission shall post the annual report regarding the Medicaid Drug Utilization Review Program on the commission's Internet website.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

SUBCHAPTER I. PHARMACEUTICAL PATIENT ASSISTANCE PROGRAM INFORMATION

Text of section effective on April 01, 2025

Sec. 549.0401. DEFINITION. In this subchapter, "patient assistance program" means a program a pharmaceutical company offers under which the company provides a drug to individuals in need of assistance at no charge or at a substantially reduced cost. The term does not include the provision of a drug as part of a clinical trial.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01,

eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0402. PROVISION OF PROGRAM INFORMATION BY PHARMACEUTICAL COMPANY. Each pharmaceutical company that does business in this state and that offers a patient assistance program shall inform the commission of:

(1) the existence of the program;

(2) the eligibility requirements for the program;

(3) the drugs covered by the program; and

(4) information used for applying for the program, such as a telephone number.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0403. PUBLIC ACCESS TO PROGRAM INFORMATION. (a) The commission shall establish a system under which members of the public can call a toll-free telephone number to obtain information about available patient assistance programs. The commission shall ensure that the system is staffed at least during normal business hours with individuals who can:

(1) determine whether a patient assistance program is offered for a particular drug;

(2) determine whether an individual may be eligible to participate in a program; and

(3) assist an individual who wishes to apply for a program.

(b) The commission shall publicize the telephone number to pharmacies and drug prescribers.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

SUBCHAPTER J. STATE PRESCRIPTION DRUG PROGRAM

Text of section effective on April 01, 2025

Sec. 549.0451. DEVELOPMENT AND IMPLEMENTATION OF STATE PRESCRIPTION DRUG PROGRAM. The commission shall develop and implement a state prescription drug program that operates in the same manner as the vendor drug program operates in providing prescription drug benefits to Medicaid recipients.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0452. PROGRAM ELIGIBILITY. An individual is eligible for prescription drug benefits under the state prescription drug program if the individual is:

(1) a qualified Medicare beneficiary, as defined by 42 U.S.C. Section 1396d(p)(1);

(2) a specified low-income Medicare beneficiary who is eligible for assistance under Medicaid for Medicare cost-sharing payments under 42 U.S.C. Section 1396a(a)(10)(E)(iii);

(3) a qualified disabled and working individual, as defined by 42 U.S.C. Section 1396d(s); or

(4) a qualifying individual who is eligible for assistance under Medicaid under 42 U.S.C. Section 1396a(a)(10)(E)(iv).

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0453. RULES. (a) The executive commissioner shall adopt rules necessary for implementing the state prescription drug program.

(b) In adopting rules for the state prescription drug program, the executive commissioner:

(1) shall consult with an advisory panel composed of an equal number of physicians, pharmacists, and pharmacologists the executive commissioner appoints; and

(2) may:

(A) require an individual who is eligible for

prescription drug benefits to pay a cost-sharing payment;

(B) authorize the use of a prescription drug formulary to specify which prescription drugs the state prescription drug program will cover;

(C) to the extent possible, require clinically appropriate prior authorization for prescription drug benefits in the same manner as prior authorization is required under the vendor drug program; and

(D) establish a drug utilization review program to ensure the appropriate use of prescription drugs under the state prescription drug program.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0454. GENERIC EQUIVALENT AUTHORIZED. In rules adopted for the state prescription drug program, the executive commissioner may require that, unless the practitioner's signature on a prescription clearly indicates that the prescription must be dispensed as written, a pharmacist may select a generic equivalent of the prescribed drug.

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.

Text of section effective on April 01, 2025

Sec. 549.0455. PROGRAM FUNDING AND FUNDING PRIORITIES. (a) Prescription drugs under the state prescription drug program may be funded only with state money unless funds are available under federal law to fund all or part of the program.

(b) If money available for the state prescription drug program is insufficient to provide prescription drug benefits to all individuals who are eligible under Section 549.0452, the commission shall:

(1) limit the number of enrollees based on available funding; and

(2) provide the prescription drug benefits to eligible

individuals in the following order of priority:

(A) individuals eligible under Section 549.0452(1);

(B) individuals eligible under Section 549.0452(2); and

(C) individuals eligible under Sections 549.0452(3) and (4).

Added by Acts 2023, 88th Leg., R.S., Ch. 769 (H.B. 4611), Sec. 1.01, eff. April 1, 2025.