REBATE AGREEMENT
Between
Department of State Health Services– Kidney Health Care State Pharmaceutical Assistance Program
and

_____

(hereinafter referred to as the Manufacturer)

The Commissioner, on behalf of the Department of State Health Services (DSHS), or any successor thereto, and the Manufacturer, on its own behalf, hereby agree to the following:

I. DEFINITIONS

(a) "Centers for Medicare and Medicaid Services (CMS)" means the agency of the U.S. Department of Health and Human Services having the delegated authority to operate the Medicaid program.

(b) "Commissioner" means the Commissioner of DSHS, or any successor thereto, or any officer or employee of DSHS or successor agency to whom the authority to implement this agreement has been delegated.

(c) "Covered Outpatient Drug" will have the same meaning as set forth in 42 U.S.C.§1396r-8 (k)(2)-(4), *et seq*., and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this Agreement, all of those covered outpatient drugs are identified by the Manufacturer's labeler code segment of the National Drug Code (NDC) number. Certain covered outpatient drugs may be restricted or excluded from program payment at DSHS option but will be included by the Manufacturer for purposes of this Agreement.

(d) "Health and Human Services Commission (HHSC)" means the agency designated by the State of Texas with primary responsibility for providing oversight of designated Health and Human Services agencies, including DSHS, and administering certain Health and Human Services programs.

(e) "Innovator Multiple Source Drug" will have the same meaning as set forth in 42 U.S.C. §1396r-8(k)(7)(A)(ii), *et seq*., and will include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA), or Antibiotic Drug Approval (ADA). A covered outpatient drug marketed by a cross-licensed producer or distributor under the approved NDA will be included as an innovator multiple source drug when the drug product meets this definition.

(f) "Kidney Health Care Program (KHC)" means the DSHS program established to provide adequate kidney care and treatment for the citizens of the State of Texas and to carry out the purposes and intent of the Texas Kidney Health Care Act, Texas Health and Safety Code, Chapter 42, Kidney Health Care.

(g) "Manufacturer" will have the meaning as set forth in 42 U.S.C. §1396r-8(k)(5), *et seq*., except, for purposes of this agreement, it will also mean the entity holding legal title to or possession of the NDC number of the covered outpatient drug.

(h) "Marketed" means that a drug was first sold by a manufacturer in the United States after Food and Drug Administration (FDA) approval.

(i) "National Drug Code (NDC)" is the identifying drug number maintained by the U. S. Food and Drug Administration. For the purposes of this agreement the complete eleven (11) digit NDC number will be used including labeler code (which is assigned by the Food and Drug Administration and identifies the establishment), product code (which identifies the specific product or formulation), and package size code.

(j) "Noninnovator Multiple Source Drug" will have the meaning as set forth in 42 U.S.C. §1396r-8(k)(7)(A)(iii), *et seq*. It also includes covered outpatient drugs approved under an Abbreviated New Drug Application or an Abbreviated Antibiotic Drug Application.

(k) "Program Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's covered outpatient drugs reimbursed during a quarter under KHC. This information is based on claims paid by KHC during a calendar quarter and not drugs that were dispensed during a calendar quarter. The KHC Program Utilization Information to be supplied includes: 1) NDC number; 2) product name; 3) units paid for during the quarter by NDC number; 4) total number of prescriptions paid for during the quarter by NDC number, and 5) the total amount paid during the quarter by NDC number. KHC may, at its own option, compute the total rebate anticipated, based on their own records, but it will remain the responsibility of the manufacturer to correctly calculate the rebate amount based on its correct determination under 42 U.S.C. §1396r-8, *et seq*. KHC may, at its own option, delegate responsibility for determining Program Utilization Information to the Texas Medicaid Vendor Drug Program, or any successor thereto.

(l) "Public Health Service price" means the covered outpatient drug purchase price used by covered entities as certified under 42 U.S.C. §256b.

(m) "Quarter" means calendar quarter unless otherwise specified.

(n) "Rebate Payment" means, with respect to the Manufacturer's covered outpatient drugs, the quarterly payment by the Manufacturer to the KHC Program, calculated in accordance with the provisions of this agreement.

(o) Single Source Drug" will have the meaning set forth in 42 U.S.C. §1396r-8(k)(7)(A)(iv), *et seq*. It also includes a covered outpatient drug approved under a Product License Approval, Establishment License Approval or Antibiotic Drug Approval.

(p) "Department of State Health Services (DSHS)" means the agency designated by the State of Texas with the primary responsibility for providing health services, including: disease prevention; health promotion; indigent care; certain acute care services; health care facility regulation, excluding long-term care facilities; licensing of certain health professions; mental and substance abuse services; and other health-related services as provided by law.

(q) "Unit" means a drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, grams for ointments or creams).

(r) "Unit Rebate Amount" for Covered Outpatient Drugs means the unit amount computed by the CMS to which the KHC Program Utilization Information may be applied by DSHS in invoicing the Manufacturer for the rebate payment due.

(s) "Vendor Drug Program (VDP)" means the HHSC program, or any successor thereto, established to provide coverage of outpatient drugs under the Medicaid Program.

(t) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the manufacturer sells the Covered Outpatient Drug but which does not relabel or repackage the Covered Outpatient Drug.

II. MANUFACTURER'S RIGHTS AND RESPONSIBILITIES

To become or remain reimbursable by KHC for Covered Outpatient Drugs, the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section IV(b) of this agreement, to make a rebate payment to KHC for the Manufacturer's Covered Outpatient Drugs paid for by KHC during a quarter.

(b) These payments shall be made using the same unit type and rebate amount per unit as those applied under 42 U.S.C. §1396r-8, *et seq*.

(c) Except as provided under section IV(b), to make such rebate payments for each calendar quarter within 38 days after receiving from KHC the Program Utilization Information defined in this agreement. Although a specific amount of information has been defined in section I (l) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 38 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(d) To comply with all applicable state and federal law.

(e) To continue to make a rebate payment on all of the covered outpatient drugs for as long as the manufacturer has legal ownership of the NDC number, for any quarter covered by the term of this Rebate Agreement even when the payment is made after the term has expired, and for as long as KHC Program Utilization Information reports that payment was made

for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the unit rebate amount last reported will be used in calculating rebates.

(f) To have the option to audit the Program Utilization Information provided by KHC.

(g) Manufacturer may not report or recalculate pricing changes or dispute utilization or pricing data farther back than the execution date of this agreement or 12 quarters from the quarter in which the data were due to CMS, whichever is the shorter time period, unless CMS, the Office of the Inspector General (OIG) or its designee reviews pricing data and determines that adjustments or revisions are necessary.

III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

(a) The Commissioner will use his best efforts to ensure that KHC reports Program Utilization Information to the Manufacturer within 60 days of the last day of each quarter using the same format as that used by the Texas Medicaid Vendor Drug Program.

(b) If the Manufacturer fails to comply with the terms of section II, the Commissioner may exclude a Covered Outpatient Drug or Drugs from coverage in the KHC program.

IV. DISPUTE RESOLUTION -- PROGRAM UTILIZATION INFORMATION

(a) If in any quarter a discrepancy in Program Utilization Information is discovered by the Manufacturer which the Manufacturer and KHC in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy by NDC number to KHC prior to the due date set forth in section II (c) of this agreement.

(b) If the Manufacturer in good faith believes the Program Utilization Information is incorrect, the Manufacturer will pay KHC that portion of the rebate amount claimed which is not disputed within the required due date in section II(c). The balance due, if any, plus interest at the rate calculated in accordance with applicable Texas law for interest owed on rebates in the Medicaid Vendor Drug Rebate Program, will be paid or credited by the Manufacturer to KHC by the due date of the next quarterly payment specified in section II after resolution of the dispute.

(c) Nothing in this Section will preclude the right of the Manufacturer to audit the KHC Program Utilization Information reported or required to be reported by KHC. The Commissioner will encourage the Manufacturer and KHC to develop mutually beneficial audit procedures consistent with those in use with the Texas Medicaid Vendor Drug Program.

(d) Adjustments to rebate payments will be made if information indicates that either KHC Program Utilization Information or unit rebate amounts were greater or lesser than the amount previously specified.

V. CONFIDENTIALITY PROVISIONS

(a) The KHC Program shall not disclose information provided by the Manufacturer in connection with this agreement in a form that identifies the Manufacturer or discloses prices charged for drugs by the Manufacturer, except as authorized by 42 U.S.C. §1396r-8(b)(3)(d).

(b) The Manufacturer will hold KHC Program Utilization Information confidential, especially with respect to any client identification information. If the Manufacturer audits this information or receives further information on such data, that information will also be held confidential. The Manufacturer will observe state confidentiality statutes, regulations, and other properly adopted rules or policy.

(c) Notwithstanding the nonrenewal or termination of this agreement for any reason, these confidentiality provisions will remain in full force and effect, in accordance with applicable law.

VI. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this agreement, this Agreement will be effective for an initial period of one year beginning on the date specified in section IX of this agreement and will be automatically renewed for additional successive terms of one year unless the Manufacturer gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) Either party to the agreement may terminate the agreement for any reason, and such termination will become effective the later of the first day of the first calendar quarter beginning 90 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with section VI(a).

(c) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provision of this agreement shall be sent in writing.

Notice to the Commissioner shall be sent to:	Commissioner of Health Dept. of State Health Services - MC 1911 P.O. Box 149347 Austin, TX 78714-9347
Notice to KHC shall be sent to:	Purchased Health Services Unit Manager Dept. of State Health Services – MC 1938 P.O. Box 149347 Austin, TX 78714-9347
Notices concerning data transfer and information systems issues shall be sent to:	ATTN: Heather Murphy Medicaid/CHIP Pharmacy Contracts and Rebates Health and Human Services Commission H-630 PO Box 85200 Austin, TX 78708-5200

These addresses may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer's notification to KHC at the address in this agreement, or through the customary notification to CMS.

(a) In the event of a change of ownership of the Manufacturer, the rebate obligation remains with the legal owner of the NDC number.

(b) Nothing in this agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this agreement is found to be invalid by a court of law, this agreement will be construed in all respects as if the invalid or unenforceable provision has been stricken from the agreement and without any effect on any other provision.

(c) Nothing in this agreement will be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the U. S. Constitution, the Social Security Act, other federal laws or regulations, the Texas Constitution, state law, or state rules.

(d) The rebate agreement will be construed in accordance with federal and state law.

(e) The Manufacturer and DSHS are responsible for the performance of their respective contractors or subcontractors, if any, which fulfill responsibilities pursuant to this agreement.

(f) Except for the conditions specified in section VII (a), this agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to

alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Commissioner and the Manufacturer. Amendments or modifications to this agreement will become effective on a date agreed upon by both parties.

(g) In the event that a due date falls on a weekend or state or federal holiday, the report or other item will be due on the first business day following that weekend, state or federal holiday.

(h) Drug products purchased using Public Health Service acquisition prices are exempt from this agreement.

VIII. ASSURANCES

(a) The Manufacturer shall establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

(b) The parties expressly agree that no provision of this agreement is in any way intended to constitute a waiver by DSHS or the State of Texas of any immunities from suit or from liability that DSHS or the State of Texas may have by operation of law.

(c) The Manufacturer shall maintain documentation for all payments made to DSHS under this agreement. The books, records and documents of the Manufacturer, insofar as they relate to work performed or money remitted under this agreement, shall be maintained for a period of three full years from the date of the final payment and all other pending matters are closed. The records shall be subject to audit, at any reasonable time and upon reasonable notice, by DSHS, the Comptroller of Public Accounts, or their duly appointed representatives.

(d) The Manufacturer may audit the books, records and documents of DSHS that relate to the generation of a quarterly invoice under this contract. DSHS shall retain all records for a minimum of three years.

(e) The Manufacturer agrees to indemnify and hold harmless DSHS as well as officers, agents, and employees of DSHS, from all claims, losses, or suits accruing or resulting from personal injury allegedly caused by a defect in the Manufacturer's covered outpatient drugs furnished pursuant to this contract, except claims, losses, or suits arising from any negligence by DSHS, its officers, agents, employees, contractors or subcontractors or any negligence of a third party, its (their) officers, agents, employees, contractors, subcontractors. DSHS shall give the Manufacturer written notice of each such claim or suit and full right and opportunity to conduct the Manufacturer's down defense thereof, together with full information and all reasonable cooperation.

Notwithstanding any indemnification clause, DSHS shall have full authority to conduct its own defense, negotiations, and settlements, but the Manufacturer's indemnification nevertheless remains in full force and effect. Any settlement shall only be reimbursable by the Manufacturer if the Manufacturer approves such settlement in advance, and any liability upon unsuccessful defense shall only be reimbursable by the Manufacturer if the Manufacturer has full opportunity to participate equally in the defense of the action.

(f) The parties acknowledge and agree that entering into this agreement terminates any preceding rebate agreement, but shall not reduce or terminate the company's accrued liability for rebates under any preceding rebate agreement.

IX. EFFECTIVE DATE

This rebate agreement will be effective the first day of the calendar quarter that begins after the date the agreement is fully executed.

X. SIGNATURES

FOR THE COMMISSIONER OF THE DEPARTMENT OF STATE HEALTH SERVICES

By: _____

Title: _____

Date: _____

ACCEPTED FOR THE MANUFACTURER

By: _____

Title: _____

Name of Manufacturer: _____

Manufacturer Address: _____

_____

Manufacturer Labeler Code(s): _____

Date: _____