

**CHILDREN'S HEALTH INSURANCE PROGRAM
DRUG REBATE AGREEMENT**

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STATE OF TEXAS
COUNTY OF TRAVIS

TEXAS HEALTH AND HUMAN SERVICES COMMISSION
CHILDREN'S HEALTH INSURANCE PROGRAM
DRUG REBATE AGREEMENT

ARTICLE I. INTRODUCTION

THIS AGREEMENT (the "Agreement") is between the HEALTH AND HUMAN SERVICES COMMISSION ("HHSC"), an administrative agency within the executive department of the State of Texas and having its principal office at 4900 North Lamar Boulevard, Austin Texas 78751, and the Manufacturer/Labeler identified in the signature line of this Agreement.

HHSC operates the Children's Health Insurance Program ("CHIP") in accordance with Chapter 62 of the Texas Health and Safety Code and as authorized under by XXI of the federal Social Security Act. The purpose of this Agreement is to establish Manufacturer/Labeler rebates for prescription outpatient drugs utilized by CHIP Recipients.

ARTICLE II. DEFINITIONS

As used in this Agreement, the following terms and conditions shall have the meanings assigned below:

"ADA" means Antibiotic Drug Approval issued by the FDA.

"ANDA" means an Abbreviated New Drug Application" to the FDA.

"AADA" means an Abbreviated Antibiotic Drug Application to the FDA.

"Agreement" means this CHIP Drug Rebate agreement, including all documents attached or incorporated by reference.

"Average Manufacturer Price" ("AMP") shall mean the average price paid to a Manufacturer/Labeler by wholesalers for drugs distributed to retail pharmacies. This definition shall be consistent with the definition set forth in Section [1927\(k\)\(1\)](#) of the Social Security Act (42 U.S.C. §1396r-8(k)(1)).

"Basic Rebate" means the rate for Single Source Drugs and Innovator Multiple Source Drugs, calculated using the same methodology set forth in Social Security Act, 42 U.S.C. §1396r-8 *et seq.*

"Best Price" is defined by 42 U.S.C. §1396r-8 *et seq.*

"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 administer Medicare and oversee state administration of Medicaid and CHIP, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

"Children's Health Insurance Program (CHIP)" means the Texas health insurance program that is the subject of this Agreement, authorized and funded pursuant to Title XXI, Social Security Act (42 U.S.C. §§ 1397aa-1397jj) and administered by HHSC.

"Commissioner" means the Executive Commissioner of HHSC.

“Consumer Price Index-Urban Factor (CPI-U Factor)” means the additional rebate for Single Source Drugs and Innovator Multiple Source Drugs, as described in §1927(c)(2) of the Social Security Act. The CPI-U Factor will not be applied to the calculation of the Unit Rebate Amount paid pursuant to this Agreement.

“Covered Outpatient Drug” has the same meaning as set forth in 42 U.S.C. §1396r-8 (k)(2)-(4), *et seq.*, and with respect to the Manufacturer/Labeler 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’s labeler code segment of the NDC number. HHSC may restrict or exclude from payment certain Covered Outpatient Drugs.

“Covered Product(s)” includes the Manufacturer’s/Labeler’s Covered Outpatient Drugs identified in the signature line of this Agreement as the subject matter of this Agreement.

“ELA” means Establishment License Approval issued by the FDA.

“FDA” means the United States Food and Drug Administration.

“Health and Human Services Commission (HHSC)” means the administrative agency within the executive department of Texas state government established under Chapter 531, Texas Government Code, and authorized to administer CHIP under Chapter 62, Texas Health and Safety Code, or its designee.

“Innovator Multiple Source Drugs” means all Covered Outpatient Drugs approved under a NDA, PLA, ELA, or 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 product meets this definition.

“Labeler” means an entity that has a labeler code from the FDA under [21 C.F.R. §207.20](#) and receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

“Manufacturer” means a manufacturer of prescription drugs as defined by [Section 1927\(k\)\(5\)](#) of the Social Security Act (42 U.S.C. §1396r-8(k)(5)), including a subsidiary or affiliate of a manufacturer.

“Marketed” means that a drug was first sold by a manufacturer/labeler in the United States after FDA approval.

“National Drug Code (NDC)” is the identifying drug number maintained by the FDA. For the purposes of this Agreement, the complete eleven (11) digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code.

“NDA” means a New Drug Application to the FDA.

“Noninnovator Multiple Source Drug” includes Covered Outpatient Drugs approved under an ANDA or an AADA.

“OMB” means the United States Office of Management and Budget.

“Parties” means HHSC and Manufacturer/Labeler, collectively.

“Party” means either HHSC or Manufacturer/Labeler, individually.

“Program Utilization Information” means the information on the total number of units of each dosage form and strength of the Manufacturer’s/Labeler’s Covered Products reimbursed during a Quarter under CHIP. This information is based on claims paid by CHIP during a Quarter and not drugs that were dispensed during a Quarter. The CHIP Program Utilization Information to be supplied includes:

- (a) NDC number;

- (b) product name;
- (c) units paid for during the Quarter by NDC number;
- (d) total number of prescriptions paid for during the Quarter by NDC number; and
- (e) the total amount paid during the Quarter by NDC number.

Program Utilization Information does not include claims submitted by entities receiving Public Health Service Prices.

“Public Health Service Price” means the Covered Outpatient Drug purchase price used by covered entities as certified under 42 U.S.C. §256b.

“Quarter” means calendar quarter unless otherwise specified.

“Rebate Payment” means, with respect to the Manufacturer’s/Labeler’s Covered Products, the Quarterly payment by the Manufacturer/Labeler to HHSC.

“Recipient” shall mean any person enrolled in CHIP and eligible to receive outpatient prescription drug benefits.

“Reconciliation of State Invoice (ROSI)” means the form generated by the OMB and completed by the Manufacturer/Labeler for purposes of invoice reconciliation.

“Single Source Drug” means a Covered Outpatient Drug approved under a PLA, ELA or ADA.

“Subcontract” means any written agreement between Manufacturer/Labeler and other party to fulfill the requirements of this Agreement. All subcontracts are required to be in writing, and are subject to review and approval by HHSC.

“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).

“Unit Rebate Amount” for Covered Products means the unit amount computed by the Manufacturer/Labeler to which HHSC may apply the CHIP Program Utilization Information in invoicing the Manufacturer/Labeler for the Rebate Payment due. The Unit Rebate Amount for Covered Products will be determined in accordance with Section 4.02 of this Agreement.

“U.S.C.” means the United States Code.

“Vendor Drug Program (VDP)” means the HHSC program established to provide coverage of outpatient drugs under the CHIP Program.

“Wholesaler” means an entity licensed under [Chapter 431, Subchapter I](#), of the Texas Health and Safety Code.

ARTICLE III. GENERAL TERMS & CONDITIONS

Section 3.01 Elements of the Agreement.

The agreement between the Parties will consist of this final executed Agreement and any amendments thereto executed.

Section 3.02 Effective date.

This Agreement is effective on the first day of the Quarter in which the Manufacturer/Labeler executes the Agreement. By way of example only, if the Manufacturer/Labeler executes the Agreement on May 1, 2006, then the effective date of the Agreement will be April 1, 2006, and the Manufacturer/Labeler will be responsible for making the Rebate Payments for Covered Product utilization occurring on or after April 1, 2006.

This Agreement will supercede and replace all prior CHIP drug rebate agreements between the Parties.

Section 3.03 Consideration and legal authority.

(a) The Manufacturer/Labeler will make Rebate Payments in accordance with the terms and conditions of this Agreement in consideration for HHSC's placement of the Covered Products on the CHIP formulary.

(b) HHSC is authorized to enter into this Agreement under sections of Chapter 531, Texas Government Code, and Chapter 62, Texas Health & Safety Code. Manufacturer/Labeler is authorized to enter into this Agreement pursuant to the authorization of its governing board or controlling owner or officer.

(c) The person or persons signing and executing this Agreement warrant and guarantee that he, she, or they have been duly authorized to execute this Agreement and to validly and legally bind HHSC or the Manufacturer/Labeler to all of its terms, performances, and provisions.

Section 3.04 Governing law.

This Agreement will be governed by and construed in accordance with Texas laws, rules and regulations and, when applicable, federal laws, rules and regulations. Any ambiguities will be interpreted in the manner that best effectuates statutory intent. Provided the dispute resolution requirements of Article XII are met, proper venue for litigation arising from this Agreement is the State District Courts of Travis County, Texas.

Section 3.05 Notices.

(a) Any notice under this Agreement must be written and sent either by facsimile with the original copy subsequently mailed; by registered or certified mail, return receipt requested; or by hand delivery with a receipt provided.

(b) Any notice under this Agreement to HHSC will be sufficient if delivered to:

Director of Program Operations
Vendor Drug Program, Medicaid and CHIP Division
Health & Human Services Commission
PO Box 85200, Mail Code H-630
Austin, Texas 78708-5200

With a copy of notice of breach of agreement under Section 7.02(c)(2)(A) to:

General Counsel
Health and Human Services Commission
4900 North Lamar Blvd., 4th Floor
Austin, Texas 78751

Notices concerning data transfer and information systems issues shall be sent to:

Pharmacy Claims and Rebate Administration
Health and Human Services Commission
PO Box 85200, Mail Code H-630

Austin, TX 78708-5200

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

(c) Any notice under this Agreement to Manufacturer/Labeler will be sufficient if delivered to the address provided in Manufacturer's/Labeler's signature line.

(d) Either Party may change its designee or address upon five (5) days' prior written notice to the other Party.

Section 3.06 No waiver of legal rights or sovereign immunity.

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

(b) Nothing in this Agreement will be construed as a waiver or relinquishment of any legal rights of the Manufacturer/Labeler or the Commissioner under the U.S. Constitution; the Social Security Act; other federal laws, rules or regulations; or state laws, rules or regulations.

Section 3.07 Amendment of the Agreement.

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 the Manufacturer/Labeler and the Commissioner, or his or her designee.

Section 3.08 Construction of the Agreement.

(a) Severability.

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 construed to be illegal or invalid, such interpretation will not affect the legality or validity of any of its other provisions. The illegal or invalid provision will be deemed stricken and deleted to the same extent and effect as if never incorporated in this Agreement, but all other provisions will remain in full force and effect.

(b) Headings.

The article and section headings in this Agreement are for reference and convenience only and may not be considered in the interpretation of this Agreement.

(c) Global drafting conventions.

(1) The terms "include," "includes," and "including" are terms of inclusion, and where used in this Agreement, are deemed to be followed by the words "without limitation."

(2) Any references to "sections," "appendices," or "attachments" are deemed to be references to sections, appendices, or attachments to this Agreement.

(3) Any references to agreements, contracts, statutes, or administrative rules or regulations in this Agreement are deemed references to these documents as amended, modified, or supplemented from time to time during the term of this Agreement.

(d) Due dates.

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 or state or federal holiday.

Section 3.09 Force majeure.

Neither Manufacturer/Labeler nor HHSC will be liable to the other for any delay in, or failure of performance, of any requirement contained in the Agreement caused by a force majeure event. The existence of such causes of delay or failure will extend the period of performance in the exercise of reasonable diligence until after the causes of delay or failure have been removed. Each Party must inform the other in writing with proof of receipt within ten (10) business days of the existence of a force majeure event or otherwise waive this right as a defense.

Section 3.10 Assignment.

The Manufacturer/Labeler will not have the right to assign this Agreement to a third party without the prior written consent of HHSC, which consent shall not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve the Manufacturer/Labeler of responsibility for the performance of any obligations that have accrued prior to such assignment.

Section 3.11 Record keeping and audit.

(a) The Manufacturer/Labeler agrees to maintain, and require its subcontractors to maintain, supporting financial information and documents that are adequate to ensure the accuracy and validity the Rebate Payments made pursuant to this Agreement. Such documents will be maintained and retained by the Manufacturer/Labeler or its subcontractors for a period of five (5) years after the date of a Rebate Payment or until the resolution of all litigation, claim, financial management review or audit pertaining to such Rebate Payment, whichever is longer.

(b) Upon reasonable notice, Manufacturer/Labeler must provide, and cause its subcontractors to provide, the officials and entities identified in this section with prompt, reasonable, and adequate access to any records, books, documents, and papers that are directly pertinent to the scope of this Agreement.

(c) Manufacturer/Labeler and its subcontractors must provide the access described in this section upon HHSC's request. This request may be for, but is not limited to, the following purposes:

- (1) examination;
- (2) audit;
- (3) investigation;
- (4) contract administration; or
- (5) the making of copies, excerpts, or transcripts.

(d) The access required must be provided to the following officials and/or entities:

- (1) United States Department of Health and Human Services;
- (2) Centers for Medicare and Medicaid Services;
- (3) Comptroller General of the United States;
- (4) HHSC, including the VDP and the Office of Investigations and Enforcement personnel;

(5) any independent verification and validation contractor or quality assurance contractor, when acting on behalf of HHSC;

(6) Office of the State Auditor of Texas;

(7) a state or federal law enforcement agency;

(8) a special or general investigating committee of the Texas Legislature; and

(9) any other entity identified by HHSC.

(e) Manufacturer/Labeler agrees to provide the access described wherever it maintains such books, records, and supporting documentation. Manufacturer/Labeler further agrees to provide such access in reasonable comfort and to provide any furnishings, equipment, or other conveniences deemed reasonably necessary to fulfill the purposes described in this Section. Manufacturer/Labeler will require its subcontractor to provide comparable access and accommodations.

Section 3.12 No waiver of contractual rights.

The failure of either Party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waive any such right or remedy in the future. Every right and remedy given by this Agreement to the Parties may be exercised from time to time as often as appropriate.

Section 3.13 Over/Underpayment.

(a) If either Party discovers an error in the Rebate Payment, it shall notify the other of such error. The Parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the Parties will resolve their dispute in accordance with the terms of Article VII of this Agreement.

(b) Any undisputed overpayment shall be deducted from one or more subsequent Rebate Payment(s) payable under this Agreement. In the event that no subsequent Rebate Payments are payable, HHSC will refund any such overpayment to Manufacturer/Labeler within thirty (30) days of the Parties' acknowledgement of the overpayment.

(c) Manufacturer/Labeler will remit any undisputed underpayment to HHSC within thirty (30) days of the Parties' acknowledgement of such underpayment.

Section 3.14 Discretion to market.

Nothing in this Agreement shall be construed to prohibit Manufacturer/Labeler from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that Manufacturer/Labeler is liable for the Rebate Payment only for Covered Products (as identified by the 11-digit NDC code) distributed (directly or through the wholesale channel) to retail pharmacies and dispensed to CHIP Recipients. If Manufacturer/Labeler elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, Manufacturer/Labeler shall make every reasonable effort to notify HHSC prior to such actions.

Section 3.15 Certification by Manufacturer/Labeler.

By signing this Contract, the person signing on behalf of the Manufacturer/Labeler certifies that this Agreement has not been altered, amended, or changed from HHSC's format.

Section 3.16 Renewal 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 effective date of this Agreement and will be automatically renewed for additional successive terms of one year unless the Manufacturer/Labeler gives written notice of intent not to renew the Agreement at least ninety (90) days before the end of the current period.

(b) The Manufacturer/Labeler may terminate the Agreement for any reason, and such termination will become effective the later of:

(1) the first day of the first calendar quarter beginning sixty (60) days after the Manufacturer/Labeler gives written notice requesting termination, or

(2) the ending date of the term of the Agreement if a non-renewal notice has been given in accordance with Section 3.16(a).

(c) HHSC may terminate this Agreement for any reason with prior written notice to the Manufacturer/Labeler. Unless otherwise specified in HHSC's the notice of termination, the Agreement will terminate at the end of the Quarter then in effect.

(d) Any non-renewal or termination will not affect rebates due before the effective date of termination.

ARTICLE IV. MANUFACTURER'S/LABELER'S OBLIGATIONS

Section 4.01 Accuracy of Manufacturer's/Labeler's information and payments.

The Manufacturer/Labeler certifies that it will accurately calculate and report information and pay rebates in accordance with the terms of this Agreement. The information reported to HHSC pursuant to this Agreement shall not conflict with information submitted to the CMS pursuant to 42 U.S.C. §1396r-8 *et seq.*

Section 4.02 Rebate payments.

The Manufacturer/Labeler agrees to the following:

(a) To calculate and make a Rebate Payment on all undisputed units of the Manufacturer's/Labeler's Covered Products paid for by HHSC during a Quarter. The Manufacturer/Labeler will correctly calculate and provide HHSC with the Unit Rebate Amount not later than thirty (30) days after the last day of each Quarter. The Manufacturer/Labeler must submit this information in one of the formats specified in Attachment A. HHSC may, at its option, compute the total rebate anticipated, based on information submitted by the Manufacturer/Labeler, but it shall remain the Manufacturer's/Labeler's responsibility to correctly calculate the Unit Rebate Amount.

(1) The Manufacturer/Labeler will calculate the Unit Rebate Amount for Non-innovator Multiple Source Drugs using the same methodology set forth in Social Security Act, 42 U.S.C. §1396r-8 *et seq.* (AMP multiplied by 11 percent).

(2) Except as provided in Section 4.02(a)(3), below, the Manufacturer/Labeler will calculate the Unit Rebate Amount for Single Source Drugs and Innovator Multiple Source Drugs using the same methodology set forth in Social Security Act, 42 U.S.C. §1396r-8 *et seq.* for the Basic Rebate (the greater of the AMP multiplied by 15.1 percent, or the AMP minus Best Price).

Manufacturer/Labeler will not include the CPI-U Factor in its calculation of the Unit Rebate Amount. In the event that the Manufacturer/Labeler has paid rebates for Single Source Drugs or Innovator Multiple Source Drugs using the CPI-U Factor pursuant to a prior CHIP drug rebate

agreement with HHSC, then the Manufacturer/Labeler will be entitled to recalculate these rebates and deduct the overpayment from future Rebate Payments to HHSC.

(3) For a Single Source Drug or an Innovator Multiple Source Drug that is new to the marketplace and has no prior sales history, the Manufacturer will not be required to pay a rebate until it has established a Medicaid Best Price for the product. Once the Manufacturer establishes a Medicaid Best Price, it will calculate the Unit Rebate Amount for the product in accordance with Section 4.02(a)(2), above. The Manufacturer will make Rebate Payments for the product beginning the Quarter it establishes the Medicaid Best Price.

(b) To submit a ROSI and make Rebate Payments each quarter within thirty-eight (38) days after HHSC postmarks the Program Utilization Information. If the Manufacturer's/Labeler's most current Unit Rebate Amount information is not correctly reflected in the Program Utilization Information, then the Manufacturer/Labeler shall calculate and make payment for all undisputed units using the most current Unit Rebate Amount within the thirty-eight (38) day timeframe set forth herein. If the Manufacturer/Labeler fails to submit accurate or timely payments, it will be responsible for payment of interest on the amount due at the prime rate established by the federal government as of the date the Rebate Payment was due, but in no event will this amount exceed the highest lawful rate of interest.

(c) To continue to make a Rebate Payment on all of the Covered Products for as long as:

(1) The Manufacturer/Labeler has legal ownership of the NDC number;

(2) This Agreement or an equivalent agreement with HHSC is in force; and

(3) CHIP Program Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer/Labeler continues to market that drug. If there are no sales by the Manufacturer/Labeler during a Quarter, the Unit Rebate Amount last reported will be used in calculating rebates.

Section 4.03 Pricing data.

In accordance with the requirements of Texas Government Code §531.070, the Manufacturer/Labeler will provide HHSC with the AMP data necessary to determine the cost basis for the Covered Product(s) and calculate or verify the calculation of rebates pursuant to this Agreement.

Section 4.04 Prior period adjustments.

A prior period adjustment is a change in the Rebate Payment based on a Manufacturer's/Labeler's revised AMP or Best Price data for a prior rebate period after that rebate period's pricing data have been submitted to HHSC. The Manufacturer/Labeler must submit changes to the AMP or Best Price within three (3) years (twelve (12) Quarters) from the date that the prior rebate period's data are due.

Section 4.05 Compliance with CHIP rules.

The Manufacturer/Labeler agrees to comply with HHSC's rules and regulations governing CHIP and the VDP, as amended or modified.

Section 4.06 Conflicts of interest.

The Manufacturer/Labeler shall establish safeguards that 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.

Section 4.07 Licensing and certification.

The Manufacturer/Labeler will comply with all applicable federal and state licensing and certification requirements.

Section 4.08 Changes in ownership status.

Manufacturer/Labeler will promptly notify the HHSC of any changes in ownership status. In the event of a change of ownership, the rebate obligation remains with the legal owner of the NDC number.

Section 4.09 Exclusion from CHIP.

If the Manufacturer/Labeler fails to comply with the terms of this Agreement, HHSC may exclude the Manufacturer's/Labeler's Covered Products from coverage in the CHIP program for a minimum of one Quarter.

ARTICLE V. HHSC'S OBLIGATIONS

Section 5.01 HHSC's rights and responsibilities.

(a) HHSC will timely report CHIP Program Utilization Information to the Manufacturer/Labeler on a Quarterly basis using the same format as that used by the Texas Medicaid VDP for Medicaid drug rebate invoices.

(b) HHSC may at its own option compute and invoice the total rebate anticipated, based on information submitted by the Manufacturer/Labeler, but it will remain the responsibility of the Manufacturer/Labeler to correctly calculate the Unit Rebate Amount. HHSC may, at its own option, delegate responsibility for determining Program Utilization Information to the Texas VDP or another HHSC division.

Section 5.02 Manufacturer's/Labeler's right to review HHSC's claims records.

Upon request and subject to the provisions of Section 6.03, HHSC will provide the Manufacturer/Labeler with claims records relating to the generation of the Manufacturer's/Labeler's Quarterly invoice under this Agreement.

ARTICLE VI. CONFIDENTIALITY

Section 6.01 Manufacturer's/Labeler's Information.

(a) HHSC will comply with the requirements of Texas Government Code §531.071, regarding the confidentiality of drug rebates, drug pricing and rebate negotiations.

(b) To the extent authorized under the Texas Public Information Act (Texas Government Code Chapter 552), HHSC will treat commercial information disclosed by the Manufacturer/Labeler in connection with this Agreement as confidential, and will not disclose such information in a form that reveals the Manufacturer's/Labeler's identity or prices charged by the Manufacturer/Labeler, except as necessary by HHSC to carry out the VDP functions or as may be required by law.

(c) If HHSC receives a request for information relating to commercial information disclosed by the Manufacturer/Labeler pursuant to this Agreement, it will timely request an opinion from the Texas Attorney General in accordance with Texas Government Code Chapter 552. HHSC will invoke the exception of Texas Government Code §552.101, relating to information made confidential by law, and §552.110, relating to the nondisclosure of trade secret, commercial or financial information. The Manufacturer/Labeler expressly understands and agrees that it will bear the burden of demonstrating the confidentiality of the information under the Texas Public Information Act, 42 U.S.C. §1396-r(8), or other federal law.

Section 6.02 CHIP Program Utilization Information.

The Manufacturer/Labeler will hold CHIP Program Utilization Information confidential, especially with respect to any client identification information. If the Manufacturer/Labeler receives further information on such data, that information will also be held confidential. The Manufacturer/Labeler will observe state confidentiality statutes, regulations, and other promulgated rules or policy.

Section 6.03 Patient Information

HHSC, its agents, employees and contractors shall not provide to the Manufacturer/Labeler any patient identifiable information or protected health information or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

Section 6.04 Survival of Confidentiality Provisions.

Notwithstanding the non-renewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

ARTICLE VII. DISPUTE RESOLUTION

Section 7.01 Program Utilization Information.

(a) If in any Quarter a discrepancy in Program Utilization Information is discovered by the Manufacturer/Labeler, the Manufacturer/Labeler will provide HHSC written notice of the discrepancy by submitting a ROSI prior to the due date set forth in Section 4.02(b) of this Agreement.

(b) If the Manufacturer/Labeler in good faith believes the Program Utilization Information is incorrect, the Manufacturer/Labeler will pay HHSC that portion of the rebate amount claimed that is not disputed within the required due date in Section 4.02(b). The balance due, if any, plus interest at the prime rate established by the federal government as of the date the Rebate Payment was due, will be paid or credited by the Manufacturer/Labeler to HHSC by the due date of the next quarterly payment specified in Section 4.02(b) *after* resolution of the dispute.

(c) HHSC and the Manufacturer/Labeler will use their best efforts to resolve the discrepancy within 180 days of receipt of such notification. If HHSC and the Manufacturer/Labeler are unable to resolve the discrepancy within 180 days, the dispute resolution procedure set forth in Section 7.02 will apply.

(d) Adjustments to Rebate Payments will be made if information indicates that either Program Utilization Information or Unit Rebate Amounts were greater or lesser than the amount previously specified.

Section 7.02 Dispute Resolution Procedures.

(a) General agreement of the Parties.

The Parties mutually agree that the interests of fairness, efficiency, and good business practices are best served when the Parties employ all reasonable and informal means to resolve any dispute under this Agreement. The Parties express their mutual commitment to using all reasonable and informal means of resolving disputes prior to invoking a remedy provided elsewhere in this Section 7.02.

(b) Duty to negotiate in good faith.

Any dispute that in the judgment of any Party to this Agreement may materially or substantially affect the performance of any Party will be reduced to writing and delivered to the other Party. The Parties must then negotiate in good faith and use every reasonable effort to resolve such dispute and the Parties shall not resort to any formal proceedings unless they have reasonably determined that a negotiated resolution is not possible. The resolution of any dispute disposed of by agreement between the Parties shall be reduced to writing and delivered to all Parties within ten (10) business days.

(c) Claims for breach of Agreement.

(1) *General requirement.* As required by Chapter 2260, Texas Government Code, a claim for breach of this Agreement by Manufacturer/Labeler must be resolved in accordance with the dispute resolution process established by HHSC in accordance with Chapter 2260, Texas Government Code.

(2) *Negotiation of claims.* A claim for breach of this Agreement by Manufacturer/Labeler that the Parties cannot resolve in the ordinary course of business or through the use of all reasonable and informal means must be submitted to the negotiation process provided in Chapter 2260, Subchapter B, Texas Government Code.

(A) To initiate the process, Manufacturer/Labeler must submit written notice in accordance with Section 3.05 of this Agreement that specifically states that Manufacturer/Labeler invokes the provisions of Chapter 2260, Subchapter B, Texas Government Code.

(B) Compliance by the Manufacturer/Labeler with Chapter 2260, Subchapter B, Texas Government Code, is a condition precedent to the filing of a contested case proceeding under Chapter 2260, Subchapter C, of the Texas Government Code.

(3) *Contested case proceedings.* The Parties expressly agree that the contested case process provided in Chapter 2260, Subchapter C, Texas Government Code, will be Manufacturer/Labeler's sole and exclusive process for seeking a remedy for any and all alleged breaches of contract by HHSC if the Parties are unable to resolve their disputes under Section 7.02(c).

(A) The Parties also agree that compliance with the contested case process provided in Chapter 2260, Subchapter C, Texas Government Code, will be a condition precedent to seeking consent to sue from the Texas Legislature under Chapter 107, Civil Practices & Remedies Code. Neither the execution of this Agreement by HHSC nor any other conduct of any representative of HHSC relating to this Agreement shall be considered a waiver of the state's sovereign immunity to suit.

(4) *HHSC rules.* The submission, processing and resolution of the Manufacturer's/Labeler's claim are governed by the rules to be adopted by HHSC pursuant to Chapter 2260, Texas Government Code.

(A) Manufacturer/Labeler expressly acknowledges that, as of the Effective Date of this Agreement, HHSC has not adopted rules to implement the requirements of Chapter 2260, Texas Government Code. Manufacturer/Labeler expressly waives any claim regarding the absence of any such rules at the Effective Date.

(5) *Manufacturer's/Labeler's duty to perform.* Neither the occurrence of an event constituting an alleged breach of contract nor the pending status of any claim for breach of contract is grounds for the suspension of performance, in whole or in part, by Manufacturer/Labeler of any duty or obligation under this Agreement.

IN WITNESS HEREOF, HHSC and the Manufacturer/Labeler have each caused this Agreement to be signed and delivered by its duly authorized representative.

**TEXAS HEALTH & HUMAN SERVICES
COMMISSION**

MANUFACTURER/LABELER

By:

Name: Charles E. Bell, M.D.

Title: Deputy Executive Commissioner

Date:

Manufacturer's/Labeler's Name:

By:

Name:

Title:

Address:

EIN# or TIN#

Phone No.

Manufacturer's/Labeler's Covered Products
and Labeler Code(s)

Date:

**ATTACHMENT A
OPTION 1
LABELER QUARTERLY PRICING DATA**

**3 1/2" DISKETTE – CMS' MDRI format
In ASCII .txt format**

Source: Drug Manufacturer/Labelers
Target: Texas

Drug Price File

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "4"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7-10	NDC #2
Package Size Code	2	11 -12	NDC #3
Period Covered	5	13 -17	QYYYY (Qtr/Yr)
AMP *	11	18 – 28	99999V999999
Best Price * / **	11	29 – 39	99999V999999
Filler	24	40 – 63	
Correction Flag	1	64 – 64	See Quarterly Pricing Data Definitions
Drug Category	1	65 – 65	See Quarterly Pricing Data Definitions
Filler	1	66 - 66	

* Zero filled and not used for initial submission

** Only for Single Source and Innovator Multiple Source Drugs, otherwise zero filled

TEXAS CHIP DRUG REBATE PROGRAM QUARTERLY PRICING DATA DEFINITIONS

AMP (Average Manufacturer's Price) The AMP per unit per product code only for the period covered, based on sales. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes. Numeric values, 11-digit field: 5 whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places.

Best Price Numeric values, 11-digit field; 5 whole numbers and 6 decimal places. Only for Single Source and Innovator Multiple Source Drugs, otherwise zero fill.

Correction Record Flag Indicator that this record corrects and replaces a record already submitted for the initial submission. Numeric value, 1 digit field. Only send 0 records.
Valid values:
 0 = Original record
 1 = Correction record

Date Entered Market If marketed prior to 10-01-90, first day of the first month that the drug was marketed for the entire month; otherwise, actual date the product is marketed. Numeric values, 8-digit field (MMDDYYYY).

DESI Drug Indicator A DESI drug is any drug that lacks substantial evidence of effectiveness (less than effective (LTE)) and is subject by the FDA to a Notice of Opportunity for Hearing (NOOH). This includes drugs which are identical, related or similar (IRS) to DESI drugs. Numeric value,
1 digit.
Valid values:
 2 = Safe and effective or non-DESI drug
 3 = Drug under review (no NOOH issued)
 4 = LTE/IRS drug for SOME indications
 5 = LTE/IRS drug for ALL indications
 6 = LTE/IRS drug withdrawn from market

Drug Category Classification of drug for purposes of rebate calculations. Alphanumeric values,
1 character.
Valid values:
 N = Non-innovator multiple source
 S = Single source
 I = Innovator multiple source

TEXAS CHIP DRUG REBATE PROGRAM QUARTERLY PRICING DATA DEFINITIONS

Product Code Second segment of National Drug code. Numeric values only, 4-digit field, right justified, 0-filled.

Product Registration Name Product name as it appears on FDA registration form. Alphanumeric values, 63 characters, left justified.

Therapeutic Equivalence Code The classification as contained in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the FDA Orange Book) for the last day of the calendar quarter for which the rebate payment is being made. Alphanumeric values, 2 character field.

Valid Values:

AA	BC	BS
AB	BD	BT
AN	BE	BX
AO	BN	NR - Not rated
AP	BP	A1 thru A9 = AB value
AT	BR	

Unit Type Basic measurement that represents the smallest unit by which the drug is normally measured. The rebate amount will be calculated per unit. Alphanumeric values, 3-character field, left justified.

Valid values:

AHF = refers only to injectable Anti-Hemophilic Factor (AHF) units
CAP = Capsule
SUP = Suppository
GM = Gram
ML = Milliliter
TAB = Tablet
TDP = Transdermal Patch
EA = EACH (Refers to drugs not identifiable by any other drug type as given in program instructions.)

Units Per Package Size Code Total number of units, as defined in the Unit Type field, in the smallest dispensable container or entity for the product defined by the full NDC. Numeric values, 10-digit field: 7 whole numbers and 3 decimal places.