

**CHILDREN WITH SPECIAL HEALTH CARE NEEDS SERVICES PROGRAM
DRUG REBATE AGREEMENT**

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STATE OF TEXAS
COUNTY OF TRAVIS

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
CHILDREN WITH SPECIAL HEALTH CARE NEEDS SERVICES PROGRAM
DRUG REBATE AGREEMENT

ARTICLE I. INTRODUCTION

THIS AGREEMENT (the “Agreement”) is between the DEPARTMENT OF STATE HEALTH SERVICES (“DSHS”), an administrative agency within the executive department of the State of Texas and having its principal office at 1100 W. 49th Street, Austin Texas 78756, and the Manufacturer/Labeler identified in the signature line of this Agreement.

The purpose of this Agreement is to establish Manufacturer/Labeler rebates for prescription outpatient drugs utilized by Children with Special Health Care Needs (CSHCN) Services Program 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 United States Food and Drug Administration (FDA).

“**ANDA**” means an Abbreviated New Drug Application” to the FDA.

“**AADA**” means an Abbreviated Antibiotic Drug Application to the FDA.

“**Agreement**” means this CSHCN Services Program 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 CSHCN, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

“**Children with Special Health Care Needs (CSHCN) Services Program**” means the DSHS program established to carry out the purposes and intent of the Texas Health and Safety Code, Chapter 35, Children with Special Health Care Needs Services Program.

“**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.

“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. The CSHCN Services Program 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.

“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; and other health-related services as provided by law.

“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 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.

“Innovator Multiple Source Drugs” 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.

“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.

“Medicare Part B” with reference to CSHCN means the CMS coverage of drugs payable under Part B.

“Medicare Part D” with reference to CSHCN means the CMS coverage of allowable out-patient drugs under Part D.

“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 DSHS and Manufacturer/Labeler, collectively.

“Party” means either DSHS 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 CSHCN Services Program. This information is based on claims paid by the CSHCN Services Program during a Quarter and not drugs that were dispensed during a Quarter. The Program Utilization Information to be supplied for the CSHCN Services Program 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 Contract Administrator” is the CSHCN Services Program contracted designee for the administration and collection of drug rebates.

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

“Recipient” shall mean any person enrolled in the CSHCN Services Program 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 DSHS.

“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 DSHS may apply the Program Utilization Information for the CSHCN Services Program 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 CSHCN Services 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, 2007, then the effective date of the Agreement will be April 1, 2007, and the Manufacturer/Labeler will be responsible for making the Rebate Payments for Covered Product utilization occurring on or after April 1, 2007.

This Agreement will supersede and replace all prior CSHCN Services Program drug rebate agreements between the Parties upon execution, on the first day of the quarter..

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 the CSHCN Services Program placement of the Covered Products on the CSHCN Services Program formulary.

(b) The CSHCN Services Program is authorized to enter into this Agreement under sections of Chapter 531, Texas Government Code, and Chapter 35, 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 DSHS 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 CSHCN Services Program will be sufficient if delivered to:

CSHCN Services Program
Texas Department of State Health Services
PO Box 149347, Mail Code 1938
Austin, Texas 78714-9347

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

General Counsel
Texas Department of State Health Services
1100 W. 49th Street, Mail Code 1919
Austin, Texas 78756

Notices concerning data transfer and information systems issues shall be sent to the CSHCN Services Program or its rebate contract administrator:

CSHCN Services Program
Texas Department of State Health Services
PO Box 149347, Mail Code 1938
Austin, Texas 78714-9347

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 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.

(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 performance by the department 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 DSHS 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 DSHS, 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 of 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(s), 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 DSHS’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) DSHS, including the VDP and the Office of Inspector General (OIG) personnel;
 - (2) any independent verification and validation contractor or quality assurance contractor, when acting on behalf of DSHS;
 - (3) Office of the State Auditor of Texas;
 - (4) a state or federal law enforcement agency;
 - (5) a special or general investigating committee of the Texas Legislature; and
 - (6) any other entity identified by DSHS.
- (e) Wherever manufacturer/labeler maintains such books, records, and supporting documentation Manufacturer/Labeler, agrees to:
 - (1) 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, including requiring any subcontractors to provide comparable access; or
 - (2) provide copies of books, records, and supporting documentation as requested by the State.

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, or the rebate contract administrator, 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, DSHS 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 DSHS 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 CSHCN Services Program 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 DSHS or the rebate contract administrator 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 DSHS'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) DSHS may terminate this Agreement for any reason with prior written notice to the Manufacturer/Labeler. Unless otherwise specified in DSHS's 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 DSHS 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 DSHS during a Quarter. The Manufacturer/Labeler will correctly calculate and provide DSHS or its contracted rebate administrator 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. DSHS or its contracted rebate administrator 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). In the event that the calculated Basic Rebate would establish a new Medicaid Best Price, the Unit Rebate Amount will be capped at the current Medicaid Best Price (the Unit Rebate Amount will be the AMP minus the 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 CSHCN Services Program drug rebate agreement with DSHS, then the Manufacturer/Labeler will be entitled to recalculate these rebates and deduct the overpayment from future Rebate Payments to DSHS.

(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 DSHS or its contracted rebate administrator 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 DSHS is in force; and

(3) Program Utilization Information for the CSHCN Services Program shows 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 DSHS or its contracted rebate administrator 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 DSHS or its contracted rebate administrator. 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 CSHCN rules.

The Manufacturer/Labeler agrees to comply with DSHS's rules and regulations governing the CSHCN Services Program, 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 DSHS or its contracted rebate administrator 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 the CSHCN Services Program.

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

ARTICLE V. DSHS'S OBLIGATIONS

Section 5.01 DSHS's rights and responsibilities.

(a) DSHS or its contracted rebate administrator will timely report Program Utilization Information for the CSHCN Services Program 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) DSHS or its contracted rebate administrator may at its own option compute and invoice the total rebate anticipated, based on information submitted by the Manufacturer/Labeler or from the Texas VDP or another HHSC division, but it will remain the responsibility of the Manufacturer/Labeler to correctly calculate the Unit Rebate Amount.

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

Upon request and subject to the provisions of Section 6.03, DSHS or its contracted rebate administrator 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) DSHS and its contracted rebate administrator, if applicable, 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), DSHS and its contracted rebate administrator, if applicable, 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 DSHS, the CSHCN Services Program or its contracted rebate administrator to carry out the VDP functions or as may be required by law.

(c) If DSHS or its contracted rebate administrator 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. DSHS 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, Texas Government Code, Chapter 552.

Section 6.02 Program Utilization Information for the CSHCN Services Program.

The Manufacturer/Labeler will hold Program Utilization Information for the CSHCN Services Program 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

DSHS, 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 DSHS or its contracted rebate administrator 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 DSHS 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 DSHS by the due date of the next quarterly payment specified in Section 4.02(b) *after* resolution of the dispute.

(c) DSHS and the Manufacturer/Labeler will use their best efforts to resolve the discrepancy within 180 days of receipt of such notification. If DSHS 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 DSHS 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 DSHS 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 DSHS nor any other conduct of any representative of DSHS relating to this Agreement shall be considered a waiver of the state's sovereign immunity to suit.

(4) *Manufacturer's/Labeler's Claims.* The submission, processing and resolution of the Manufacturer's/Labeler's claim are governed by Chapter 2260, Texas Government Code.

(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, DSHS and the Manufacturer/Labeler have each caused this Agreement to be signed and delivered by its duly authorized representative.

**DEPARTMENT OF STATE HEALTH
SERVICES**

MANUFACTURER/LABELER

By:

Name: Evelyn Delgado

Title: Assistant Commissioner
Family and Community Health
Services Division

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
ELECTRONIC SUBMISSION**

Electronic – 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 Record 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

**ATTACHMENT A
OPTION 2
LABELER QUARTERLY PRICING DATA
PAPER REPORTING FORMAT**

Paper

Paper submissions can be mailed to the data contact in the Agreement, or faxed to 804-217-7911 on the required form TX-CSHCN, included on the next page. This method is reserved for companies having 5 or fewer NDCs.

DATE: ___/___/_____
MM/DD/YYYY

PAGE ___ OF ___

PERIOD COVERED: QUARTERLY REPORT FOR ___/_____
Q YYYY

LABELER CODE _____ LABELER NAME _____

PRODUCT CODE: _____ PACKAGE SIZE CODE: _____

DRUG CATEGORY: ___
THERAPEUTIC EQUIV. CODE: ___
DESI INDICATOR: ___

AMP: _____

BEST PRICE: 00000.000000

DATE ENTERED MARKET: _____

BASELINE AMP: _____

DRUG TERMINATION DATE: _____

CORRECTION RECORD FLAG: ___ (Activate for Baseline Data and/or Pricing Data Corrections.)

UNIT TYPE: _____

UNITS PER PACKAGE SIZE CODE: _____

FDA APPROVAL DATE: _____

DRUG TYPE INDICATOR: ___

PRODUCT REGISTRATION NAME: _____

PRODUCT CODE: _____ PACKAGE SIZE CODE: _____

DRUG CATEGORY: ___
THERAPEUTIC EQUIV. CODE: ___
DESI INDICATOR: ___

AMP: _____

BEST PRICE: 00000.000000

DATE ENTERED MARKET: _____

BASELINE AMP: _____

DRUG TERMINATION DATE: _____

CORRECTION RECORD FLAG: ___ (Activate for Baseline Data and/or Pricing Data Corrections.)

UNIT TYPE: _____

UNITS PER PACKAGE SIZE CODE: _____

FDA APPROVAL DATE: _____

DRUG TYPE INDICATOR: ___

PRODUCT REGISTRATION NAME: _____

TX-CSHCN

ATTACHMENT A
TEXAS CSHCN SERVICES PROGRAM 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.

=====

Baseline AMP The AMP for the first quarter after the drug's Market Date. 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

=====

ATTACHMENT A
TEXAS CSHCN SERVICES PROGRAM DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS

=====
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

=====
Drug Termination Date Date drug was withdrawn from market or shelf life of last lot sold
if no longer distributed by labeler. Numeric values, 8-digit field.
(MMDDYYYY).

=====
Drug Type Indicator Indicator to show whether this drug product can be acquired only
by prescription or can be acquired OTC. Numeric value, 1 digit
field.
Valid values:
1 = Rx
2 = OTC

=====
FDA Approval Date Date of FDA approval of the NDA, without regard to whether the
drug has been sold or transferred to any entity, including a
subsidiary or division of the original Manufacturer/Labeler. For
OTC drugs, use Monograph date. Numeric values, 8-digit field,
(MMDDYYYY).

=====
Labeler Code First segment of National Drug Code that identifies the
manufacturer, labeler, relabeler, packager, repackager or
distributor of the drug. Numeric values only, 5-digit field, right
justified and 0-filled with 4 digit labeler codes.

=====
Labeler Name Company associated with labeler code. Alphanumeric values, 39
characters, left justified.

=====
Package Size Code Third segment of National Drug Code. Two-digit field, right
justified, 0-filled.

