CHILDREN WITH SPECIAL HEALTH CARE NEEDS SERVICES PROGRAM

DRUG REBATE AGREEMENT

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TEXAS HEALTH AND HUMAN SERVICES COMMISSION
CHILDREN WITH SPECIAL HEALTH CARE NEEDS SERVICES 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 with Special Health Care Needs Services Program ("CSHCN") in accordance with Chapter 35 of the Texas Health and Safety Code.

The purpose of this Agreement is to establish Manufacturer/Labeler rebates for prescription outpatient drugs utilized by CSHCN clients.

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 CSHCN 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.*

"Children with Special Health Care Needs (CSHCN) Services Program" means the Texas health insurance program established to carry out the purposes and intent of the Texas Health and Safety Code, Chapter 35 that is the subject of this Agreement.

"Client" shall mean any person enrolled in CSHCN and eligible to receive outpatient prescription drug benefits.

"**Commissioner**" means the Executive Commissioner of HHSC, or any successor thereto, or any officer or employee of HHSC 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.

"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 CSHCN under Chapter 35, Texas Health and Safety Code, or its designee.

"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.

"Medicaid Services" means the Health and Human Services Commission 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.

"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 CSHCN. This information is based on claims paid by CSHCN during a Quarter and not drugs that were dispensed during a Quarter. The CSHCN 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 Contract Administrator" is the CSHCN 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 HHSC.

"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 CSHCN Services 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 CSHCN Services Program.

"Wholesaler" means an entity licensed under Chapter 431, Subchapter I, of the Texas Health and Safety Code.

ARTICLE III. 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:

CSHCN Services Program
Health & Human Services Commission
Attn: Michael Blood, Director of Contract Administration & Provider Monitoring
701 W. 51st
Austin, Texas 78751

Copy to: Contract Administration Provider Monitoring (CAPM)
Attn: Theresa Ihekwoaba
Email Address: mcdcontractmanagement@hhsc.state.tx.us
Fax Number: (512) 438-5204

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 the CSHCN Services Program:

CSHCN Services Program
Health & Human Services Commission
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) business days prior written notice to the other Party.

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 or its Rebate Contract Administration Provider Monitoring – Services Team 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. It is the Manufacturer's/Labeler's responsibility to ensure that it makes the following calculations in accordance with the most current laws and regulations for Unit Rebate Amounts.

(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.*

(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. 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).

(3) 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 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.

(4) 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 Reconciliation of State Invoice (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) CSHCN 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 the 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 12 Quarters) from the date that the prior rebate period's data are due.

Section 4.05 Compliance with CSHCN rules.

The Manufacturer/Labeler will comply with HHSC's rules and regulations governing the CSHCN Services Program and the VDP, as amended or modified.

Section 4.06 Conflicts of interest.

The Manufacturer/Labeler shall establish safeguards that prohibit its 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 pertaining to the rebates rules and rebate programs related to this Agreement.

Section 4.08 Changes in ownership status.

Manufacturer/Labeler will promptly notify HHSC within 10 business days 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, HHSC may exclude the Manufacturer's/Labeler's Covered Products from coverage in the CSHCN program for a minimum of one Quarter.

Section 4.10 Compliance with Law

In connection with its respective obligations under this Agreement, each Party shall comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements. By signing this Agreement, the Manufacture/Labeler provides written verification in accordance with Texas Government Code Chapter 2270 that it:

1) represents and warrants that it does not boycott Israel and will not boycott Israel during the term of this Agreement.

2) represents and warrants that it is not engaged in business with Iran, Sudan, or a foreign terrorist organization, as prohibited by Section 2252.152 of the Texas Government Code.

Section 4.11– Labeler Quarterly Data Pricing Report

The Manufacturer/Labeler must complete and submit the Labeler Quarterly Data Pricing Report Quarterly which is attached as Attachment A and is incorporated into this Agreement.

Section 4.12 Compliance with Data Use Agreement (DUA).

The Manufacturer/Labeler must comply with the Data Use Agreement which is attached as Attachment B and is incorporated into this Agreement.

Section 4.13 Compliance with Uniform Terms and Conditions (UTC).

The Manufacturer/Labeler must comply with the Uniform Terms and Conditions which is attached as Attachment C and is incorporated into this Agreement.

ARTICLE V. HHSC'S OBLIGATIONS

Section 5.01 HHSC's Rights and Responsibilities.

(a) HHSC or the Rebate Contract Administrator will report the CSHCN Program Utilization Information on a Quarterly basis and any changes within 10 business days to the Manufacturer/Labeler 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 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 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, the CSHCN Services Program to carry out the VDP functions or as may be required by law.

(c) If HHSC or the Rebate Contract Administrator receives a request for information relating to commercial information disclosed by the Manufacturer/Labeler pursuant to this Agreement, it will timely submit the request to the Texas Attorney General in accordance with Texas Government Code Chapter 552. HHSC will notify the Manufacture/Labeler of the request and the exceptions of the 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 CSHCN Program Utilization Information.

The Manufacturer/Labeler will hold CSHCN 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, including compliance with the attached DUA.

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 including compliance with the attached DUA.

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 or the Rebate Contract 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 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 of the date of the resolution of the dispute.

(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 resolved in accordance with the dispute resolution process established by HHSC in accordance with Chapter 2260, 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.

(2) *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.

(3) *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
By:

_____
Signature

_____
Printed Name

_____
Title

_____
Date

_____

MANUFACTURER/LABELER
By:

_____
Manufacturer's/Labeler's Name

_____
Printed Name

_____
Signature

_____
Title

_____
Address

_____
EIN# or TIN#

_____
Phone Number

_____
Manufacturer's/Labeler's Labeler Code(s)

_____
Date:

_____

The Attachments below are incorporated in this Agreement:

1) Attachment A - Labeler Quarterly Pricing Data
2) Attachment B – Data Use Agreement (DUA)
3) Attachment C – Uniform Terms and Conditions (UTC)

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ATTACHMENT A
LABELER QUARTERLY PRICING DATA

_____
Labeler Code (as assigned by FDA)

_____
Labeler Name (Corporate name associated with Labeler Code)

Please indicate the media preference you intend to use for transmitting data identified in Appendix A of the Agreement. The instructions, technical specifications and materials appropriate to the option specified will be mailed to you upon receipt of your signed agreement.
Using CMS's MDRI system. Record formats are attached.

_____
Please print name

_____
Title

ATTACHMENT A
OPTION 1
LABELER QUARTERLY PRICING DATA

Electronic file in ASCII .txt format
Source: Drug Manufacturer/Labelers
Target: Texas
Drug Price File
Field Size Position Remarks
Record ID 1 1 - 1 Constant of "Q
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

OPTION 2
LABELER QUARTERLY PRICING DATA

Electronic file in ASCII .txt format
Source: Drug Manufacturer/Labelers
Target: Texas
Drug Price File
Field Size Position Remarks
Record ID 1 1 - 1 Constant of "C
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.)

URA * 11 18 – 28 99999V999999
Filler 24 29 – 52
Correction Flag 1 53 – 53 See Quarterly Pricing Data Definitions
Drug Category 1 54 – 54 See Quarterly Pricing Data Definitions
Filler 1 55 - 55
* Zero filled and not used for initial submission
** Only for Single Source and Innovator Multiple Source Drugs, otherwise zero filled

TEXAS CSHCN SERVICES PRORAM DRUG REBATE PROGRAM QUARTERLY PRICING DATA DEFINITIONS

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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.

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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.

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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).

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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

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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

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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).

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Drug Type 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

TEXAS CSHCN SERVICES PROGRAM DRUG REBATE PROGRAM QUARTERLY PRICING DATA DEFINITIONS

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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).

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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.

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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.

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Period Covered Calendar quarter and year covered by data submission. Numeric 5-digit field, QYYYY.
Valid values for Q:
1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4. = October 1 - December 31
Valid values for YYYY: Four-digit calendar year covered.

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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.

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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

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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.)

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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.

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