OHIO DEPARTMENT OF MEDICAID SUPPLEMENTAL REBATE AGREEMENT

This Agreement is entered into by the following parties on the date last signed below:

Pharmaceutical Manufacturer ("Manufacturer")	**Ohio Department of Medicaid ("Department")**
Manufacturer Primary Billing Address:	**Department Primary Billing Address:**
Manufacturer Primary Contact Person:	**Department Primary Contact Person:**
Manufacturer Primary Contact Telephone:	**Department Primary Contact Telephone:**
Manufacturer Primary Contact e-mail:	**Department Primary Contact e-mail:**
Address for Notices required by Agreement ("Manufacturer Notice Address"):	**Address for Notices required by Agreement: ("Department Notice Address"):**
Termination Date: ("Termination Date")	**Effective Date ("Effective Date")**

In consideration of the mutual covenants in this Agreement, including the General Supplemental Rebate Terms, the Contracted Products Attachment to this Agreement, and for other good and valuable consideration, the receipt, adequacy and legal sufficiency of which are hereby acknowledged, the parties have entered into this Agreement and have caused their duly authorized representatives to execute this Agreement below.

Manufacturer, by:	**Department, by:**
Signature:	Signature:
Printed Name:	Printed Name:
Title:	Title:
Date:	Date:

General Supplemental Rebate Terms

1. PURPOSE

The Department and Manufacturer have entered into this Agreement for the purpose of establishing a State Supplemental Rebate for utilization of the Manufacturer's Preferred Product(s) by Ohio Medicaid recipients, which will be in addition to rebates received under the Medicaid National Drug Rebate Agreement, pursuant to 42 U.S.C. §1396r-8. The parties intend for this Agreement to meet the requirements of 42 U.S.C. §1396r-8.

2. DEFINITIONS

2.1 **AMP** shall mean the Average Manufacturer Price as set forth in 42 U.S.C. §1396r-8 and final regulations promulgated by CMS, if any, as such statute or regulations may be amended from time to time.

2.2 **Best Price** shall mean Best Price as set forth in 42 U.S.C. §1396r-8 and final regulations promulgated by CMS, if any, as such statute or regulations may be amended from time to time.

2.3 **CMS** shall mean the Centers for Medicare & Medicaid Services of the United States Department of Health and Human Services or any successor or renamed agency having the authority to administer the Medicaid program.

2.4 **Contracted Product** shall mean any product listed on the Contracted Products Attachment of this Agreement.

2.5 **Medicaid Unified PDL (UPDL) Utilization Data** shall mean the information on the quarterly utilization of the Manufacturer's Preferred Products reimbursed through Fee-for-Service or dispensed through Managed Care Entities. Fee- for-Service Utilization Data is based on claims *paid* during the Quarter; Managed Care Entities Utilization Data is based on prescriptions *dispensed* during the quarter. Both may include Prior Quarter Adjustments. Medicaid UPDL Utilization Data to be supplied includes, for each NDC number: 1) Product name; 2) Number of units; 3) Number of prescriptions; and 4) Total amount reimbursed. Medicaid UPDL Utilization Data excludes data from covered entities identified in 42 U.S.C.

§256b(a)(4) and 42 U.S.C. §1396r-8(a)(5)(B) in accordance with 42 U.S.C. §256b(a)(5)(A) and 42 U.S.C.

§1396r-8(a)(5)(C).

2.6 **National Drug Code or NDC** shall have the meaning as set forth in 42 CFR 447.502.

2.7 **National Rebate Agreement** shall mean the rebate agreement developed and entered into by CMS on behalf of the Secretary of the United States Department of Health and Human Services or his or her designee and a manufacturer to pursuant to 42 U.S.C. §1396r-8.

2.8 **National Unit Rebate Amount or URA** shall mean the unit amount computed by CMS to which the Medicaid UPDL Utilization Data is applied by the State in invoicing Manufacturers for rebates in accordance with the National Rebate Agreement.

2.9 **Unified Preferred Drug List or UPDL** shall mean a list of Preferred Products adopted by the Department.

2.10 **Preferred Product** shall mean any Contracted Product included as preferred on the UPDL.

2.11 **Quarter** shall mean calendar quarter unless otherwise specified.

2.12 **Rebate Payment Due Date** shall mean the date that is 38 days following Manufacturer's receipt of Medicaid Utilization Information from the Department.

2.13 **State Supplemental Rebate** shall mean the quarterly amount invoiced by the Ohio Department of Medicaid as calculated in accordance with the Contracted Product Attachment of this Agreement. Pursuant to 42 CFR §447.504(c), State Supplemental Rebates are excluded from AMP. Pursuant to 42 CFR §447.505(c), State Supplemental Rebates are excluded from best price.

2.14 **Unit** shall mean drug unit in the lowest dispensable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams)

and shall be the same unit as specified by Manufacturer as part of the submission of data under 42 U.S.C. §1396r-8.

2.15 **Wholesale Acquisition Cost or WAC** shall mean the Manufacturer's list price for a drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the last day of the Quarter as published in MediSpan or its successor publication, if any.

2.16 **Managed Care Entities or MCE** shall mean a managed care organization, the single pharmacy benefit manager, a MyCare Ohio plan as defined in rule 5160-58-01 of the Administrative Code, and the OhioRISE plan as defined in rule 5160-59-01 of the Administrative Code.

3. MANUFACTURER'S RESPONSIBILITIES

3.1 Manufacturer will pay all rebates in accordance with Manufacturer's Medicaid National Drug Rebate Agreement.

3.2 Manufacturer will remit to the Department a State Supplemental Rebate for Medicaid Utilization of Contracted Product(s) that are designated as Preferred Products and are included on the UPDL during the Quarter. The Manufacturer shall pay to the Department the State Supplemental Rebate amount in accordance with the formula set forth in the Contracted Products Attachment of this Agreement.

3.3 Quarters shall be used in calculating the State Supplemental Rebate.

3.4 Absent a dispute raised pursuant to the Dispute Resolution section of this Agreement, Manufacturer shall make State Supplemental Rebate payments to the Department for each Quarter no later than the Rebate Payment Due Date. The Manufacturer is responsible for timely payment of the rebate by the Rebate Payment Due Date following receipt of, at a minimum, information on the number of units paid, by NDC number.

3.5 Manufacturer will pay the State Supplemental Rebate, including any applicable interest calculated in the same manner as the National Rebate Agreement. Interest on the State Supplemental Rebates payable under Section 3.2 of this Agreement

begins accruing 38 calendar days from postmark date of the State Supplemental Rebate invoice sent to Manufacturer, and interest will continue to accrue until the postmark date of Manufacturer's payment. Rebate payments mailed more than 68 days from the date of invoice shall include interest, calculated in accordance with federal guidelines.

3.6 Unless notified otherwise, Manufacturer will send State Supplemental Rebate payments to the Department Primary Billing Address identified on the first page of this Agreement.

4. DEPARTMENT RESPONSIBILITIES

4.1 Unified Preferred Drug List: The Department shall maintain and publish a Preferred Drug List that will be applicable to the fee-for-service program and Medicaid Managed Care Entities providing a pharmacy benefit to Medicaid recipients under the State Plan. Unless specifically stated otherwise in the Contracted Products Attachment to this Agreement, Preferred Products shall not be discouraged or disadvantaged in any way relative to any other drug product in its therapeutic class. Additionally, Preferred Products shall not be subject to clinical edits, prior authorization, step therapy or similar utilization management controls that are more restrictive than the FDA-approved Prescribing Information as of the Effective Date of this Agreement, except that the Department may also apply other clinical edits, prior authorization, step therapy or similar utilization management controls equally to all products in a therapeutic class.

4.2 The Department will maintain the data systems and audits as are necessary to ensure the accuracy of the data used to calculate the State Supplemental Rebate. In the event material discrepancies are discovered, the Department will make available supporting data that is then in existence concerning the claimed utilization, which may include an adjustment to the amount of the State Supplemental Rebates. Any such adjustment shall be included on the next quarterly invoice.

4.3 The Department shall maintain electronic claims records for the most recent four Quarters that will permit Manufacturer to verify through an audit process the

Medicaid UPDL Utilization Data provided by the Department. The Department and Manufacturer will develop mutually beneficial audit procedures, should such an audit be required to resolve disputes regarding Medicaid Utilization Data.

5. DISPUTE RESOLUTION

5.1 Utilization disputes will be handled in the same manner as the Medicaid National Drug Rebate dispute resolution process as described in the National Medicaid Drug Rebate Agreement.

6. CONFIDENTIALITY PROVISIONS

6.1 Pursuant to 42 USC § 1396r-8(b)(3)(D), Ohio Revised Code § 5164.756, and this Agreement, information disclosed by Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Department to anyone except those of its employees, consultants, contractors and agents who need to know the information provided that such persons and/or entities are notified of all confidentiality provisions as stated herein and expressly warrant and represent that they shall abide by such. In the event that the Department is required by law to disclose any provision of this Agreement or rebate information to any person other than as provided above, the Department shall provide written notice to Manufacturer sufficiently in advance of the proposed disclosure to allow Manufacturer to seek a protective order or other relief. This Section shall survive termination or expiration of this Agreement.

6.2 Manufacturer shall ensure that all information, records and data pertaining to applicants for and recipients of public assistance or to providers shall be protected from unauthorized disclosure by Manufacturer, its employees, consultants, contractors, agents and corporate affiliates and their employees pursuant to 42 CFR Part 431, Subpart F and any other applicable federal or state law.

7. NONRENEWAL OR TERMINATION

7.1 This Agreement shall be effective on the Effective Date and, absent early termination pursuant to the terms of this Agreement, shall continue in force until the Termination Date.

7.2 This Agreement may be terminated by the Department, in whole or as to any Contracted Product(s) or NDC(s) without cause as of the end of the calendar quarter upon sixty (60) days written notice to Manufacturer.

7.3 This Agreement may be immediately terminated by either party upon the occurrence of any one of the following events:

(a) A determination by any court of competent jurisdiction or any authorized governmental authority that the arrangements and transactions under this Agreement constitute a violation of any law or regulation including without limitation 42 U.S.C. § 1320a-7b(b) prohibiting illegal remuneration. (For the purposes of this Section, "authorized governmental authority" shall mean any officer or agency of the Federal Government (e.g., Office of Inspector General, Department of Justice, Department of Health and Human Services) or the State of Ohio having substantive jurisdiction over the subject matter of this Agreement; any state or federal program with which this Agreement is connected; any actions which must be taken by either party hereto in order to perform its obligations under this Agreement or any laws or regulations affecting the legality of this Agreement); or

(b) A modification to 42 CFR §447.504(c) removing or limiting the exclusion of the State Supplemental Rebate from AMP and/or to 42 CFR §447.505(c) removing or limiting the exclusion of the State Supplemental Rebate from best price.

7.4 Termination of this Agreement shall have no effect upon the rights and obligations of the parties arising out of any transaction occurring prior to the effective date of such termination including, without limitation, State Supplemental Rebates accrued but not yet paid and/or invoiced.

8. GENERAL PROVISIONS

This Agreement will be governed and construed in accordance with the laws of the State of Ohio and 42 U.S.C. §1396r-8, and all other applicable federal and state laws and regulations.

8.1 Any notice required to be given pursuant to the terms and provisions of this Agreement will be in writing and will be sent by parcel delivery service (UPS, FedEx or DHL). Notice to the Department will be sent to the Department Notice Address identified on the first page of this Agreement. Notice to Manufacturer will be sent to the Manufacturer Notice Address identified on the first page of this Agreement.

8.2 Manufacturer agrees to be bound by the laws of the State of Ohio and agrees that this Agreement shall be construed and interpreted in accordance with Ohio law without giving effect to the conflicts of law provisions thereof. This provision does not supersede federal law to the extent federal law is applicable and controlling.

8.3 Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's or Manufacturer's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

8.4 Manufacturer and the agents and employees of Manufacturer in the performance of this Agreement will act in an independent capacity and not as officers, employees or agents of the State of Ohio.

8.5 In the event of a transfer of ownership of a Contracted Product or of Manufacturer, the Agreement shall be automatically assigned to the new owner subject to the conditions of this Agreement. If a Contracted Product or this Agreement is assigned by Manufacturer, Manufacturer shall notify the Department of the new contact information and assignee shall be fully responsible for compliance with all terms and conditions of this Agreement applicable to Manufacturer.

8.6 Nothing in this Agreement will be construed so as to require the commission of any act contrary to law. If any provision of this Agreement is found to be invalid or illegal by a court of law, or inconsistent with federal requirements, this Agreement will be construed in all respects as if any invalid, unenforceable, or inconsistent provision were eliminated, and without any effect on any other provision. The parties agree to negotiate replacement provisions, to afford the parties as much of the benefit of their original bargain as is possible.

8.7 The Department and Manufacturer declare that this Agreement, including attachments, contains a total integration of all rights and obligations of both parties. There are no extrinsic conditions, collateral agreements or undertakings of any kind. In regarding this Agreement as the full and final expression of their contract, it is the express intention of both parties that any and all prior or contemporaneous agreements, promises, negotiations or representations, either oral or written, relating to the subject matter and period of time governed by this Agreement which are not expressly set forth herein are to have no force, effect, or legal consequences of any kind.

8.8 The following provisions of this Agreement may be altered by an amendment in writing signed by both parties and approved by the appropriate Department:

- Effective Date identified on the first page of this Agreement
- Contracted Products Attachment

The remainder of this Agreement will not be altered except by an amendment in writing signed by both parties and approved by CMS and the appropriate State control agencies.

8.9 Neither party contemplates any circumstances under which indemnification of the other party would arise. Nevertheless, should such circumstances arise, Manufacturer agrees to indemnify, defend and hold harmless the State, its officers, agents and employees from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by Manufacturer in the performance of this Agreement.

8.10 With the exception of a transfer of ownership of a Contracted Product or of Manufacturer as described in 8.5, this Agreement is not assignable by Manufacturer either in whole or in part without the written consent of the Department, which will not unreasonably be withheld. This Agreement is not assignable by the Department either in whole or in part without the written consent of Manufacturer, which will not unreasonably be withheld.

8.11 Performance under this Agreement shall be contingent on the authorization of the Agreement by CMS .

8.12 Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, terrorism, civil commotion, destruction of production facilities and materials, fire, earthquake, storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the parties, shall not constitute breach of this Agreement.

CONTRACTED PRODUCTS ATTACHMENT

Manufacturer	NDC	Product Description	Tier[1]	Formula[2]	Contracted Rate	Comments

[1] **Tier**

The Tier represents the number of brand drugs that may be preferred in the Contracted Product UPDL category. Manufacturers may submit offers for any or all Tiers.

- Tier 1 - The Contracted Product will be the only preferred brand product in the UPDL category.
- Tier 2 - The Contracted Product will be one of no more than two preferred brand products in the UPDL category.
- Tier 3 - The Contracted Product will be one of no more than three preferred brand products in the UPDL category.
- Tier 4 - The Contracted Product will be preferred (offer places no limitation on the number of preferred brand products in the UPDL category).

[2] **Formula**

- Formula 1: Percentage of WAC.
  Supplemental Rebate Amount per Unit = WAC multiplied by Contracted Rate
- Formula 2: Guaranteed Net Price.
  Supplemental Rebate Amount per Unit= WAC minus CMS URA minus Contracted Rate