NORTH DAKOTA MEDICAID SUPPLEMENTAL DRUG REBATE AGREEMENT

1. PARTIES

This Agreement is entered between the state of North Dakota, acting through its North Dakota Department of Health & Human Services, Medical Services Division (Department), and _____ (Manufacturer). The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, agree as follows:

2. PURPOSE

It is the intent of this Agreement that Department will receive a State Supplemental Rebate for the Medicaid population, in addition to rebates received under the CMS Rebate Agreement, pursuant to 42 USC 1396r-8, for Manufacturer's Covered Product(s) quarterly utilization in the North Dakota Medicaid Program. The parties also intend for this Agreement to meet the requirements of 42 USC 1396r-8.

3. DEFINITIONS

3.1 Agreement means this North Dakota Medicaid Supplemental Drug Rebate Agreement, including all documents attached or incorporated by reference.

3.2 AMP means the Average Manufacturer Price as defined in 42 USC 1396r-8(k)(1) and final regulations promulgated by the CMS, as such statute or regulations may be amended from time to time.

3.3 Best Price means Best Price as defined in 42 USC 1396r-8(c)(1)(C) and final regulations promulgated by CMS, as such statute or regulations may be amended from time to time.

3.4 CMS means the Centers for Medicare & Medicaid Services (formerly known as the Health Care Financing Administration) of the U.S. Department of Health & Human Services, or any successor or renamed agency carrying out the functions and duties previously carried out by that office.

3.5 CMS Rebate means any rebate provided by a Manufacturer pursuant to 42 USC 1396r-8.

3.6 CMS Rebate Agreement means Manufacturer's drug rebate contract with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration), entered into pursuant to 42 USC 1396r-8.

3.7 Contract Quarter means the quarters ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of the Agreement.

3.8 Covered Product means any drug product listed in Attachment A.

3.9 Medicaid Member means any person enrolled in the State Medicaid Program or Children's Health Insurance Program and eligible to receive Medicaid benefits under a fee-for-service or managed care arrangement.

3.10 NDC means National Drug Code as defined in 21 CFR 207.33, as such statute or regulations may be amended from time to time.

3.11 PDL means the preferred drug list developed by Department with input from the ND Medicaid Drug Use Review (DUR) Board applicable to fee-for-service and may be applicable to managed care programs providing a covered outpatient drug benefit to Medicaid Members.

3.12 State Supplemental Rebate means, with respect to the Covered Product, the quarterly payment by Manufacturer pursuant to Section 4.2 of this Agreement.

3.13 Rebate Summary means the report set forth in 42 USC 1396r-8(b)(2)(A)

3.14 State Utilization Data means the claim level detail showing reimbursement to providers under the State Medicaid Program. State Utilization Data excludes claims which are subject to an agreement under 42 USC 256b(a)(4) in accordance with 42 USC 256b(a)(5)(A) and 1396r-8(a)(5)(C).

3.15 Unit means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments and creams) and is the same unit as specified by Manufacturer as part of its submission of data under the CMS Rebate Agreement.

3.16 WAC means the Wholesale Acquisition Cost, as defined in 42 USC 1395w-3a(c)(6) and final regulations promulgated by the CMS as such statute or regulations may be amended from time to time. The WAC used for State Supplemental Rebate invoicing must be the published WAC price of a Covered Product by NDC as published by First Databank for the last day of the Contract Quarter for which the State Utilization Data for the Covered Product is reported to the Manufacturer.

4. MANUFACTURER'S RESPONSIBILITIES

4.1 This Agreement does not relieve Manufacturer from its obligation to pay

any other rebates, including any CMS Rebate or a separate supplemental rebate.

4.2 Manufacturer shall remit to Department a State Supplemental Rebate for Covered Product). The State Supplemental Rebate must be paid based on the State Utilization Data for both fee-for-service and managed care Medicaid Members if managed care. Medicaid Members are required to follow the PDL adopted by Department during the Contract Quarter, including prior quarter adjustments ("PQAs"). Manufacturer shall pay to Department the State Supplemental Rebate amount in accordance with the formula set forth in Attachment A.

4.3 The Contract Quarters to be used for calculating the State Supplemental Rebates in Section 4.2 of this Agreement will be those ending on March 31, June 30, September 30, and December 31, of each calendar year during the term of this Agreement.

4.4 Notwithstanding external factors such as disputes or data inaccuracies, Manufacturer shall submit the State Supplemental Rebate payment within 38 days of the postmark date of the invoice and Rebate Summary from Department.

4.5 Manufacturer shall pay the State Supplemental Rebate, including any applicable interest in accordance with 42 USC 1396r-8(b)(1)(A) and the terms of the National Medicaid Drug Rebate Agreement. Interest on the State Supplemental Rebates payable under Section 4.2 of this Agreement begins accruing 38 calendar days from the postmark date of the Department's invoice and supporting Rebate Summary and interest will continue to accrue until the postmark date of Manufacturer's payment. For State Supplemental Rebates invoiced for first Contract Quarter and thereafter, if Department has not received the undisputed State Supplemental Rebates payable under Section 4.2 of this Agreement, including interest, within 180 days of the postmark date of Department's invoice and supporting Rebate Summary sent to Manufacturer, this Agreement may be terminated.

4.6 This Agreement does not prohibit Manufacturer from discontinuing production, marketing, or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. If Manufacturer elects to discontinue production, marketing, or distribution of any Covered Product or to transfer or license any Covered Product to a third party, Manufacturer shall make every reasonable effort to notify Department prior to such action so Department can negotiate with such third party for State Supplemental Rebates on the Covered Product or remove such Covered Product from the PDL.

4.7 Unless notified otherwise, Manufacturer will send State Supplemental

Rebate payments by Electronic Fund Transfer (EFT)/Automated Clearing House (ACH) or certified mail, return receipt requested, to the following address.

Check payable to:
North Dakota Department of Health & Human Services
Attn: Finance Division
600 East Boulevard Avenue, Department 325
Bismarck, ND 58505-0250

5. DEPARTMENT RESPONSIBILITIES

5.1 Covered Product must be listed on the PDL and may not be discouraged or disadvantaged in any way relative to any other drug product in its market basket unless specifically stated in Attachment A of this Agreement. Covered Product may be eligible for the State Supplemental Rebate only in the quarter in which Covered Product are listed on the PDL.

5.2 Department shall provide State Utilization Data to Manufacturer on a quarterly basis for claims paid for Covered Product, including Prior Quarter Adjustments (PQAs), for fee-for-service and managed care Medicaid Members if managed care Medicaid Members are required to follow the PDL adopted by Department during the Contract Quarter. Fee-for-service State Utilization Data will be based on paid claims' date of payment during a Contract Quarter. Managed Care State Utilization Data will be based on paid claims' date of service during a Contract Quarter.

5.3 Department shall maintain the data systems necessary to ensure the accuracy of the Rebate Summaries used to calculate the State Supplemental Rebates For the most recent twelve quarters, Department shall cooperate with Manufacturer to develop mutually beneficial audit procedures, if an audit is required.

5.4 Department warrants that it received CMS approval to receive State Supplemental Rebates for fee-for-service and managed care Medicaid Members as provided under this Agreement.

5.5 Department shall submit the State Supplemental Rebate invoice to Manufacturer within 90 days after the Contract Quarter. State Supplemental Rebate invoices may be amended after submission to reflect newly adjudicated claims for Covered Product provided in the Contract Quarter covered by the quarterly State Supplemental Rebate invoice.

5.6 Department, its agents, employees, and contractors may not provide Manufacturer any patient personally identifiable information (PII) or protected health information (PHI) or any other information prohibited or

regulated by laws or regulations governing confidentiality of medical or other information.

6. DISPUTE RESOLUTION

6.1 Manufacturer may deduct any overpayment incurred during previous Contract Quarters from subsequent State Supplemental Rebates payable under this Agreement. If no subsequent State Supplemental Rebates are payable, Department shall refund the overpayment to Manufacturer within 90 days after an acknowledgement or final determination that the overpayment has been made. Manufacturer will remit any underpayment to Department within 90 days after an acknowledgement or final determination that an underpayment has been made.

6.2 Utilization disputes will be handled in the same manner as a CMS Rebate dispute including that manufacturers may initiate disputes, hearing requests, and audits of invoiced utilization Units within 12 quarters from the last day of the quarter from postmark date of the invoice to the manufacturer. If in any Contract Quarter a discrepancy in calculation of the State Rebate is noted by Manufacturer, Manufacturer will provide written notice of the discrepancy to Department.

6.3 If Manufacturer, in good faith, believes Department's calculation of the State Supplemental Rebate is erroneous, Manufacturer shall pay Department that portion of the State Supplemental Rebate claimed which is not disputed by the required date in Section 4.4. The balance in dispute, if any, will be paid or credited by Manufacturer or Department by the due date of the next quarterly payment after resolution of the dispute.

6.4 Department and Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of written notification. Either party, at any time, and at its own expense, may hire a mutually selected independent auditor to verify the accuracy of Department's calculation of the State Supplemental Rebate.

6.5 If Department and Manufacturer are not able to resolve a discrepancy within 60 days, Manufacturer may appeal in writing to:

North Dakota Department of Health & Human Services
Medical Services Division
600 East Boulevard Avenue, Department 325
Bismarck, ND 58505-0250

6.6 If all attempts to resolve a dispute fail, the parties will resolve their

dispute in accordance with the North Dakota Administrative Agencies Practice Act.

7. CONFIDENTIALITY PROVISIONS

7.1 Pursuant to 42 USC 1396r-8(b)(3)(D), information disclosed by Manufacturer under this Agreement in a form which identifies a specific Manufacturer or the prices charged for drugs by Manufacturer is confidential and may not be disclosed except as necessary to carry out the Agreement or as required by judicial order. Department agrees that information provided to Department under this Agreement, which Department determines, in its sole discretion, is protected from mandatory public disclosure under a specific exception to the North Dakota open records law found in North Dakota Century Code chapter 44-04, is confidential. If Department utilizes the services of a third-party to develop and maintain the PDL, or to administer any part of this Agreement, all provisions of this section apply to the third-party. If Department is required by law to disclose any provision of this Agreement or pricing information to any person other than as provided above, Department shall provide advance written notice to Manufacturer of the proposed disclosure, when possible, to allow Manufacturer to seek a protective order or other relief.

7.2 Except for disclosures prohibited in this Agreement, Department must disclose to the public upon request any records it receives from Manufacturer. Any records obtained or generated by Manufacturer under this Agreement, except for records that are confidential under this Agreement, may be open to the public upon request under certain circumstances under the North Dakota open records law found in North Dakota Century Code chapter 44-04. Manufacturer agrees to contact Department immediately upon receiving a request for information under the open records law and to comply with Department's instructions on how to respond to the request.

7.3 Information revealing the identity of Medicaid Members is confidential and may not be disclosed by either party except as necessary to carry out this Agreement or as required by judicial order.

7.4 Manufacturer shall hold the State Utilization Data confidential. If Manufacturer audits this data or receives further information on the data, that information is also confidential. Manufacturer may disclose State Utilization Data to auditors who agree to keep the data confidential.

8. TERM, TERMINATION, OR NONRENEWAL

8.1 This Agreement is effective on January 1, 20XX, and shall continue in force until December 31, 20XX.

8.2 This Agreement may be terminated, without cause, by either party upon

30 days' written notice. Termination is effective the 30th day after the date of delivery of the electronic transmission or shown on the certified mail return receipt in which a party gives written notice requesting termination.

8.3 If either of the following occurs, each party may enter into good faith negotiations with the other to seek to agree on reasonable terms for maintaining the intent of the Agreement. If the parties do not agree within 30 days of the date of delivery of the electronic transmission or shown on the certified mail return receipt in which a party requests negotiations, either party may terminate this Agreement upon expiration of the 30-day period, with immediate effect.

a) A statutory enactment, rule promulgation, or any final legal or administrative determination made by any court or authorized governmental authority that materially impairs either party's ability to carry out its obligations under this Agreement or that finds the arrangements and transactions under this Agreement violate any law or regulation. For the purposes of this Section, 8.3, "authorized governmental authority" means any officer or agency of the Federal Government (e.g., Office of Inspector General, Department of Justice, Department of Health & Human Services) or the State of North Dakota (e.g., North Dakota Attorney General) having substantive jurisdiction over the subject matter of this Agreement; or any state or federal program with which this Agreement is connected.

b) A determination by CMS that the State Supplemental Rebates paid or payable by Manufacturer under this Agreement will affect or be included in Best Price or AMP calculations for determining CMS Rebates.

8.4 A termination will not affect State Supplemental Rebates due or owing on or before the effective date of termination.

8.5 If either party commits a material breach of this Agreement, the non-breaching party shall deliver written notice of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach within 30-days of receipt of written notification. If the breaching party fails to cure the breach, the non-breaching party may terminate this Agreement at the end of the 30-day cure period. The non-breaching party shall give the breaching party final written notice of the termination of this Agreement.

9. GENERAL PROVISIONS

9.1 The state of North Dakota and Department do not waive sovereign immunity by entering this Agreement and specifically retain immunity and all defenses available to them as sovereigns pursuant to North Dakota

state law.

9.2 This Agreement will be governed and construed in accordance with 42 USC 1396r-8; and all other applicable federal, state, and local laws, rules, and regulations.

9.3 Any notice required to be given under this Agreement will be in writing and will be sent electronically or by certified mail, return receipt requested.

Notice to Department will be sent to:

Brendan Joyce, PharmD
Administrator, Pharmacy & Clinical Services
Medical Services Division
North Dakota Department of Health & Human Services
600 East Boulevard Avenue, Department 325
Bismarck, ND 58505-0250
Email: bjoyce@nd.gov

Notice to Manufacturer will be sent to:

«Notice_Contact»
«Manufacturer»
«Address_1»
«Address_2» «Address_3»
«City», «State» «Zip»
Email

9.4 This Agreement will be construed and interpreted in accordance with North Dakota law. Any action to enforce this Agreement must be adjudicated exclusively in the state District Court of Burleigh County, North Dakota. Each Party consents to the exclusive jurisdiction of such court and waives any claim of lack of jurisdiction or *forum non conveniens*.

9.5 This Agreement may not be construed or interpreted as limiting or otherwise affecting Department's or Manufacturer's ability to pursue its rights arising out of the terms and conditions of the Agreement if a dispute between the parties is not otherwise resolved.

9.6 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 North Dakota.

9.7 If there is a transfer in ownership of Manufacturer, this Agreement is not assignable to the new owner without the written consent of Department, which will not unreasonably be withheld. Additionally, Manufacturer may

assign or transfer this Agreement to an affiliate upon written notice to Department, provided that the assignee agrees to abide by all terms of this Agreement. The Agreement is not assignable by Department either in whole or in part without the written consent of Manufacturer, which will not unreasonably be withheld. An assignment does not relieve any party of responsibility for the performance of any obligations under this Agreement that have accrued prior to the assignment.

9.8 This Agreement may not be construed 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 shall negotiate replacement provisions, to afford the parties as much of the benefit of this Agreement as is possible.

9.9 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 does not impair or waive that 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.

9.10 The provisions of this Agreement that by their nature are intended to continue in their effect following expiration or termination of this Agreement shall survive any such expiration or termination, are Sections 4.2, 5.3, 6, 7, 9.4, 9.13.

9.11 This Agreement, including Attachment A, contains a total integration of all rights and obligations of both parties. There are no extrinsic conditions, collateral agreements or undertakings of any kind. 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 in this Agreement have no force, effect, or legal consequences of any kind.

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

a) 8.1 Effective Date
b) 9.3 Notice Provision
c) Attachment A (Covered Products and Rebate Formula)

9.13 Manufacturer agrees to indemnify, defend and hold harmless Department, 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.

9.14 Performance under this Agreement is contingent on the non-occurrence of the event described in Section 8.3(b) of this Agreement and on CMS's valid authorization of the North Dakota Supplemental Rebate Program

9.15 The business arrangement contemplated by this Agreement is not subject to the provisions of 42 USC 1320a-7b(b) prohibiting illegal remuneration. If 42 USC 1320a-7b(b) is determined to apply, the business arrangement contemplated by this Agreement meets the discount exception found in 42 USC 1320a-7b(b)(3)(A), which excludes from prohibited activities the practice of discounting or other reductions in price obtained by a provider of services or other entity under a Federal health care program, if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program. Department currently provides CMS full and unfettered access to all information held by Department regarding the State Medicaid Program and shall continue to do so.

9.16 Noncompliance with any obligations of this Agreement 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, does not constitute breach of contract.

9.17 If a lawsuit is filed by Department to obtain performance due under this Agreement, and Department is the prevailing party, Manufacturer shall pay Department's reasonable attorney fees and costs in connection with the lawsuit, except when prohibited by North Dakota Century Code § 28-26-04.

9.18 All records, regardless of physical form, and the accounting practices and procedures of Manufacturer relevant to this Agreement are subject to examination by the North Dakota State Auditor, the Auditor's designee, or Federal auditors, if required. Manufacturer shall maintain all of these records for at least three (3) years following completion of this Agreement and be able to provide them at any reasonable time. Department, the North Dakota State Auditor, or Auditor's designee shall provide reasonable notice to Manufacturer prior to conducting examination.

9.19 In connection with its respective obligations under this Agreement, each party shall comply with all applicable federal, state and local laws and regulations.

9.20 Department and Manufacturer each represent and warrant to the other that the person signing below has all requisite legal power and authority to execute this Agreement on behalf of each party and each party is bound by that signature.

As evidence of their Agreement to the foregoing terms and conditions, the parties have signed below.

_____	_____
Brendan Joyce, PharmD Administrator, Pharmacy & Clinical Services ND Medicaid North Dakota Department of Health & Human Services	Date
_____	_____
«Primary_Signatory» «Primary_Sig_Title» «Name»	Date

ATTACHMENT A

Covered Products and Rebate Formula

The products to which the Supplemental Rebate Agreement shall apply are the following:

9 Digit NDC	Product Description	Tier[1]	Formula[2]	Contracted Rate	Comments	Excluded NDCs

[1] Tier (Preferred Brand Levels)

Preferred Brand Levels, referred to as Tiers in the offer entry system, represent how Department will use an offer in a given tier. Manufacturers may submit an offer in any combination of or all of the four possible tiers. An offer must be made for all state grouping categories in any selected tier.

Levels 1-3

- The preferred brand level or tier number represents the number of preferred drugs in that PDL category

Level 4

- Manufacturer's drug will be one of four or more drugs in that PDL category

[2] Formula

- Formula 101: Percentage of WAC. Formula for State Supplemental Rebate calculation: WAC*% of WAC = State Supplemental Rebate Amount per Unit
- Formula 102: Guaranteed Net Price. Formula for State Supplemental Rebate

calculation: WAC-CMS Rebate-Guaranteed Net Price = State Supplemental Rebate Amount per Unit