

SSDC

NORTH DAKOTA MEDICAID SUPPLEMENTAL DRUG REBATE AGREEMENT

1. PARTIES

This Agreement is made and entered into by and between the state of North Dakota, acting through its North Dakota Department of Human Services, Medical Services Division (Department), and «Name» (Manufacturer), Labeler Code [REDACTED]. The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

2. PURPOSE

It is the intent of this Agreement that the Department will receive a Supplemental Rebate for the Medicaid population, in addition to rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8), for the 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 federal law at Section 1927 of the Social Security Act (42 USC 1396r-8).

3. DEFINITIONS

- 3.1 AMP shall mean the Average Manufacturer Price as set forth in 42 USC 1396r-8; as such statute may be amended from time to time excluding State Supplemental Rebate amounts.
- 3.2 Best Price shall mean Best Price as set forth in 42 USC 1396r-8; as such statute may be amended from time to time, excluding State Supplemental Rebate amounts.
- 3.3 CMS Agreement means the Manufacturer's drug rebate contract with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration), entered pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8).
- 3.4 CMS Basic Rebate means, with respect to the Covered Product(s), the quarterly payment by the Manufacturer pursuant to the Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act [42 USC 1396r-8(c)(1) and 42 USC 1396r-8(c)(3)].

- 3.5 CMS CPI Rebate means, with respect to the Covered Product(s), the quarterly payment by the Manufacturer pursuant to the Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act [42 USC 1396r-8(c)(2)].
- 3.6 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.
- 3.7 Covered Product(s) means any prescription drug product listed in Attachment A.
- 3.8 Guaranteed Net Price shall mean the final fixed price of the drug assured by the Manufacturer to the State. It shall be calculated as the WAC minus the CMS rebate and minus the State Supplemental Rebate necessary to equal the guaranteed net price to the State by «Name» for the Covered Product for the calendar quarter.
- 3.9 National Rebate shall mean any discount provided by a Manufacturer pursuant to 42 USC 1396r-8.
- 3.10 Preferred Drug List (PDL) shall mean the list developed by the North Dakota Drug Utilization Review Board (DUR Board) and adopted by the Department applicable to fee-for-service and may be applicable to managed care programs providing a covered outpatient drug benefit to Medicaid recipients under the Medicaid State Plan.
- 3.11 Rebate Summary means the report itemizing the State Utilization Data supporting the Department's invoice for Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement.
- 3.12 State Supplemental Rebate means, with respect to the Covered Product(s), the quarterly payment by the Manufacturer pursuant to Section 4.2 of this Agreement.
- 3.13 State Utilization Data means the claim level detail showing reimbursement to providers under the North Dakota Medicaid Program. State Utilization Data excludes data from covered entities identified in Title 42 USC 256b(a)(4) in accordance with Title 42 USC 256b(a)(5)(A) and 1396r-8(a)(5)(C).
- 3.14 Step Utilization shall mean a potentially defined order of therapeutic choices within either the preferred or non-preferred drug list categories.
- 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 or creams).

3.16 "Wholesale Acquisition Cost" ("WAC") shall mean with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price. The WAC used for supplemental invoicing shall be the lowest published WAC price of a Covered Product by National Drug Code ("NDC") as published by First DataBank on the last day of the calendar quarter that corresponds to the calendar quarter for which the Medicaid Utilization Information for the Covered Product is reported to the Manufacturer.

4. MANUFACTURER'S RESPONSIBILITIES

4.1 Nothing in this agreement shall be construed to relieve the Manufacturer from its obligation to provide the Department a CMS Rebate for the Covered Product(s), including, but not limited to, the CMS Basic Rebate and, as appropriate, the CMS CPI Rebate (hereinafter referred to collectively as "CMS Rebates").

4.2 In addition to the CMS Rebates described in Section 4.1 of this Agreement, the Manufacturer will remit to the Department a State Supplemental Rebate for Covered Product(s) included on the Preferred Drug List. The supplemental rebates shall be paid based on the utilization data for both fee-for-service and managed care Medicaid members if managed care Medicaid members are subject to follow the Preferred Drug List adopted by the Department during the contract quarter. The Manufacturer shall pay to the Department the State Supplemental Rebate amount in accordance with the formula set forth in Attachment A. This State Supplemental Rebate is in addition to the CMS Rebates.

4.3 The quarters to be used for calculating the Rebates in Sections 4.1 and 4.2 of this Agreement will be those ending on March 31st, June 30th, September 30th and December 31st of each calendar year during the term of this Agreement.

4.4 Each participating Manufacturer will be required to submit the supplemental rebate payment within 30 days of the Manufacturer's receipt of the Rebate Summary from the Department. The Department shall submit the State Supplemental Rebate invoice to the Manufacturer within 90 days after the fiscal quarter in which the Product was paid by the Department. The Manufacturer shall have no obligation for claims that are not submitted as part of the Rebate Summary from the Department.

4.5 The Manufacturer will pay the State Supplemental Rebate, including any applicable interest in accordance with Section 1903(d)(5) of the Act. Interest on the Rebates payable under Section 4.1 and 4.2 of this Agreement begins accruing 38 calendar days from receipt of the Department's invoice and supporting Rebate Summary sent to the Manufacturer and interest will continue to accrue until the

postmark date of the Manufacturer's payment. For Rebates invoiced for first Contract Quarter (2017) or thereafter, if the date of mailing of the Rebate payable under Section 4.2 of this Agreement is 69 days or more from the date of mailing of the invoice, the interest rate will be calculated as required under federal guidelines. For Rebates invoiced for first Contract Quarter (2017) and thereafter, if the Department has not received the Rebates payable under Section 4.1 or 4.2 of this Agreement, including interest, within 180 days of the postmark date of the Department's invoice and supporting Rebate Summary sent to the Manufacturer, this Agreement will be deemed to be in default and will be terminated in accordance with Section 8.2 of this Agreement. Interest will not accrue on any amount withheld pursuant to Section 6.2.

- 4.6 The Manufacturer may deduct any overpayment from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, the Department will refund any such overpayment to the Manufacturer within 30 days after an acknowledgement or final determination that the overpayment has been made. The Manufacturer will remit any underpayment to the Department within 30 days after an acknowledgement or final determination that an underpayment has been made.
- 4.7 Nothing in this Agreement shall be construed to prohibit the Manufacturer from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. If the Manufacturer elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, the Manufacturer shall make every reasonable effort to notify the Department prior to such action so that the Department can negotiate with such third party for State Supplemental Rebates on such Covered Product or remove such Covered Product from the Preferred Drug List and/or Recommended Drug List. Upon notification of the Manufacturer's election to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, the Covered Product shall be removed from the definition of "Covered Products."
- 4.8 Unless notified otherwise, the Manufacturer will send Rebate payments by certified mail, return receipt requested, to the following address.

Check payable to:
North Dakota Department of Human Services
Fiscal Administration
600 East Boulevard Avenue, Department 325

5. DEPARTMENT RESPONSIBILITIES

- 5.1 Preferred Drug List: Preferred Products shall not be discouraged or disadvantaged in any way relative to any other drug product in its therapeutic class unless specifically stated otherwise in Attachment A of this Agreement. The Department may apply clinical edits, prior authorization, step therapy or similar utilization management controls to a Preferred Product that are consistent with, but not more restrictive than, the FDA-approved Prescribing Information as of the effective date of this Agreement. 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. The Department shall place Covered Products in an advantaged position relative to non-preferred Products regarding Preferred Drug List status, and depending on the designated preferred tier, the Department may place Covered products in an advantaged position relative to other preferred products (Step Utilization). Certain- Preferred drugs, including Step Utilization drugs may be subject to prior authorization, i.e., preferred but with prior authorization. The Department will comply with all provisions of Section 1927(d).
- 5.2 The Department will provide State Utilization Data for claims paid for fee-for-service and managed care Medicaid members if managed care Medicaid members are subject to follow the Preferred Drug List adopted by the Department during the contract quarter to the Manufacturer on a quarterly basis. Fee-for-service utilization data will be based on claims paid during a quarter. Managed Care utilization data will be based on claims paid with a date of service during a quarter.
- 5.3 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 Rebates. In the event material discrepancies are discovered, the Department will promptly justify its data or make an appropriate adjustment, which may include a credit as to the amount of the Rebates, or a refund to the Manufacturer as the parties may agree.
- 5.4 The Department shall maintain electronic claims records for the most recent four Contract Quarters that will permit the Manufacturers to verify through an audit process the Rebate Summaries provided by the Department. The Department will also cooperate with the Manufacturer to develop mutually beneficial audit procedures, should such audit(s) be required to resolve disputes regarding

Utilization Information.

- 5.5 Upon implementation of this Agreement, and from time to time thereafter, the Department and the Manufacturer will meet to discuss any data or data system improvements which are necessary or desirable to ensure that the data and any information provided by the Department to the Manufacturer are adequate for the purposes of this Agreement.
- 5.6 The 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 and that the Manufacturer's participation in the North Dakota Supplemental Drug Rebate Program will not affect the Manufacturer's Best Price and the AMP.

6. DISPUTE RESOLUTION

- 6.1 Utilization disputes will be handled in the same manner as the Federal Drug Rebate program.
- 6.2 In the event that in any quarter a discrepancy in calculation of the State Supplemental Rebate is noted by the Manufacturer, that the Manufacturer and the Department in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy to the Department.
- 6.3 If the Manufacturer in good faith believes the Department's calculation of the State Supplemental Rebate is erroneous, the Manufacturer shall pay the Department that portion of the 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 the Manufacturer or the Department by the due date of the next quarterly payment after resolution of the dispute.
- 6.4 The Department and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of written notification. Either party may, at any time, and at its own expense, hire a mutually agreed upon independent auditor to verify the accuracy of the Department's calculation of the State Supplemental Rebate or the Manufacturer's calculations and payment figures. Should an audit of pharmacy records be required to resolve disputes, the Department will cooperate with the Manufacturer and provide information by zip code of pharmacy provider upon the Manufacturer's request.
- 6.5 In the event that the Department and the Manufacturer are not able to resolve a discrepancy within 60 days, the Manufacturer may appeal in writing to:

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

- 6.6 If all attempts to resolve any 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), the parties agree that information disclosed by the Manufacturer under this Agreement in a form which discloses the identity of a specific Manufacturer or the prices charged for drugs by the Manufacturer is confidential and shall not be disclosed except as necessary to carry out the Agreement or as may be required by judicial order. Therefore, the Department agrees that confidential information provided to the Department under this Agreement, including the Agreement itself is exempted from disclosure by statute. To the extent that the 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 shall apply to the third-party, and the Department shall have the third-party sign a written agreement ensuring the third-party will comply with all aspects of this section. In the event that the Department is required by law to disclose any provision of this Agreement or pricing information to any person other than as provided above, the Department shall provide advance written notice to the Manufacturer sufficiently in advance of the proposed disclosure to allow the Manufacturer to seek a protective order or other relief.
- 7.2 The parties agree that information revealing the identity of Medicaid recipients is confidential and shall not be disclosed except as necessary to carry out this Agreement or as may be required by judicial order. The foregoing shall not prevent the disclosure by the Manufacturer to the Department of information regarding the National Rebates for Covered Products.
- 7.3 The Manufacturer will hold the Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Information to auditors who agree to keep such information confidential.
- 7.4 The provisions of this section and any confidentiality agreement executed pursuant to this section shall survive termination or expiration of this Agreement.

8. TERM, TERMINATION OR NONRENEWAL

- 8.1 This Agreement shall be effective on January 1, 2019, and shall continue in force until December 31, 2019.
- 8.2 This Agreement may be terminated by either party by giving written notice to the other party at least 30 days' prior to the effective date of the termination. Up until the effective date of termination, the Manufacturer's Covered Product(s) will not be discouraged or disadvantaged in any way relative to any other brand name pharmaceutical product on North Dakota's Medicaid Preferred Drug List. After the effective date of the termination, the Manufacturer's Covered Product(s) will be available to the North Dakota Medicaid Program beneficiaries only through prior authorization, and the Manufacturer's obligation to pay State Supplemental Rebates will terminate. Termination shall become effective the 30th day after a party gives written notice requesting termination.
- 8.3 This Agreement may be immediately terminated upon the occurrence of any one of the following events:
- (a) A determination by any court or any authorized governmental authority that the arrangements and transactions under this Agreement or any similar agreement constitute a violation of any law or regulation, including, without limitation, 42 USC 1320a-7b(b) prohibiting illegal remunerations. (For the purposes of this Section, 8.3, "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 North Dakota (e.g., North Dakota Attorney General) 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 determination by CMS that the State Supplemental Rebates paid or payable by the Manufacturer under this Agreement will affect or be included in Best Price or AMP calculations for determining rebates paid pursuant to 42 USC 1396r-8.
- 8.4 Any renewal or termination will not affect rebates due or owing on or before the effective date of termination.

9. GENERAL PROVISIONS

- 9.1 Sovereign Immunity. The State of North Dakota and the Department do not waive sovereign immunity by entering into this Agreement and specifically retain immunity and all defenses available to them as sovereigns pursuant to North Dakota state law.
- 9.2 This Agreement may be terminated, without cause, by either party upon 30 days' written notice. This Agreement may be terminated immediately for cause if the Manufacturer fails to perform in accordance with the terms and conditions of this Agreement. Should the Manufacturer fail to perform in a manner consistent with the terms and conditions set forth in this Agreement, payment under this Agreement may be withheld until such time as the Manufacturer performs its duties and responsibilities.
- 9.3 This Agreement will be governed and construed in accordance with Title 42 USC Section 1396r-8; Title 42 of the Code of Federal Regulations; and all other applicable federal law and regulations.
- 9.4 Any notice required to be given pursuant to the terms and provisions of this Agreement will be in writing and will be sent by certified mail, return receipt requested. Notice to the Department will be sent to:

Brendan Joyce, PharmD
Pharmacy Program Manager
Medical Services Division
North Dakota Department of Human Services
600 East Boulevard Avenue, Department 325
Bismarck, ND 58505-0250

Notice to the Manufacturer will be sent to:

«Notice_Contact»
«Notice_Contact_Title»
«Name»
«Address_1»
«Address_2» «Address_3»
«City», «State» «Zip»

- 9.5 The Manufacturer agrees to be bound by the laws of the State of North Dakota and agrees that this Agreement shall be construed and interpreted in accordance with North Dakota law.

- 9.6 Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's or the 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.
- 9.7 The Manufacturer and the agents and employees of the 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.
- 9.8 In the event of a transfer in ownership of the Manufacturer, the Agreement is not assignable to the new owner without the written consent of the Department.
- 9.9 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.
- 9.10 The Department and the Manufacturer declare that 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. 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.
- 9.11 The following provisions of this Agreement may be altered by an amendment in writing signed by both parties and approved by the appropriate State control:
- 8.1 Effective Date
 - 9.4 Notice Provision
 - Attachment A (Covered Products and Rebate Formula)

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. Any modification of the formula to include non-Medicaid population groups must be authorized by CMS.

- 9.12 Neither party contemplates any circumstances under which indemnification of the other party would arise. Nevertheless, should such circumstances arise, the 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 the Manufacturer in the performance of this Agreement.
- 9.13 This Agreement is not assignable by «Name» (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 «Name» (MANUFACTURER), which will not unreasonably be withheld.
- 9.14 In as much as the State Supplemental Rebate required by this Agreement is for North Dakota Medicaid Program beneficiaries, it is agreed that the State Supplemental Rebate does not establish a new Best Price or AMP for purposes of the participating Manufacturer's CMS Agreement. Performance under this Agreement shall be 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 of which this Agreement forms a part.
- 9.15 In the event that the Department determines, as a result of a therapeutic category review that a Covered Product(s) of the Manufacturer included on the North Dakota Medicaid Preferred Drug List should require prior authorization unless for appropriateness of therapy review using best practice standards, the parties agree that the terms of Section 8.2 shall apply.
- 9.16 If during the duration of this Agreement a generic equivalent of any Covered Product should become available, and no Federal Upper Limit is established, the Department will allow Covered Product to remain on the Preferred Drug List so long as the net cost to the State, as defined in Attachment A, is not more than the lowest reimbursement cost for a generic equivalent.
- 9.17 It is the Department's belief that the business arrangement contemplated by this Agreement is not subject to the provisions of 42 USC 1320a-7b(b) prohibiting illegal remuneration. Should the above provisions apply, it is the Department's belief that 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. The Department currently provides CMS full and unfettered access to all information held by the Department regarding the implementation of the North Dakota Medicaid Program, and shall continue to do so throughout the implementation of the State Supplemental Rebate and North Dakota Medicaid Preferred Drug List.

- 9.18 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 contract.

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

Brendan Joyce, PharmD
Administrator, Pharmacy Services
ND Medicaid
North Dakota Department of 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 the Member States 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

- Step-care will not be used to influence the preferred prescribing choices of physicians in these levels
- The preferred brand level or tier number represents the number of preferred drugs in that PDL category

Level 4

- Step-care will not be used to influence the preferred prescribing choices of physicians in this level
- Manufacturer’s drug will be one of four or more drugs in that PDL category

² Formula

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