VERMONT SUPPLEMENTAL DRUG-REBATE AGREEMENT

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

Pharmaceutical Manufacturer ("Manufacturer") **Labeler Code**:	**Department of Vermont Health Access ("The State")**
Manufacturer Primary Billing Address:	**State Primary Billing Address:**
Manufacturer Primary Contact Person:	**State Primary Contact Person:**
Manufacturer Primary Contact Telephone:	**State Primary Contact Telephone:**
Manufacturer Primary Contact e-mail:	**State Primary Contact e-mail:**
Address for Notices required by Agreement ("Manufacturer Notice Address"):	**Address for Notices required by Agreement: ("State Notice Address"):**
	State of Vermont Department of Vermont Health Access Pharmacy Unit-Stacey Baker 280 State Drive, NOB1 South South Waterbury, VT 05671
Termination Date: ("Termination Date")	**Effective Date ("Effective Date")**

WE THE UNDERSIGNED PARTIES AGREE TO BE BOUND BY THIS CONTRACT

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

General Supplemental Rebate Terms

PURPOSE

1.1 The Manufacturer shall pay State Supplemental Rebates to the State whenever it receives Medicaid federal financial participation for the utilization of Manufacturer's Preferred Product(s) in the State's Medicaid Programs. This rebate will be paid in addition to rebates received under the Medicaid National Drug Rebate Agreement, pursuant to 42 U.S.C. § 1396r-8.

DEFINITIONS

2.1 "Agreement" shall mean this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.

2.2 "Average Manufacturer Price or AMP" shall have the meaning set forth in 42 U.S.C. §1396r-8 as implemented by 42 C.F.R. § 447.504.

2.3 "Best Price" shall have the meaning set forth in 42 U.S.C. §1396r-8 as implemented by 42 C.F.R. § 447.505.

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

2.5 "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.

2.6 "Days" shall mean calendar days unless otherwise specified.

2.7 "Medicaid PDL Utilization Information" shall mean the information on the total number of units of each dosage form and strength of the Manufacturer's Preferred Products reimbursed during a Quarter under the Medicaid State Plan supporting the State's invoice for State Supplemental Rebates.

2.8 "NDC" will have the meaning set forth in 42 C.F.R. § 447.502.

2.9 "National Medicaid Drug 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 (the "Secretary") and a manufacturer pursuant to 42 U.S.C. §1396r-8.

2.10 "National Unit Rebate Amount" or URA shall mean the computed amount to which the Medicaid PDL Utilization Information is applied by the State in invoicing Manufacturer for rebates in accordance with the National Medicaid Drug Rebate Agreement.

2.11 "Preferred Drug List or PDL" shall mean the list of Preferred Products developed by the State Drug Utilization Review (DUR) Board and adopted by the State.

2.12 "**Preferred Product"** shall mean any Contracted Product included on the Preferred Drug List. No Preferred Product shall be discouraged or disadvantaged in any way relative to any other drug product in its therapeutic class unless specifically stated otherwise in the Contracted Products Attachment of this Agreement.

2.13 "Quarter" shall mean calendar quarter unless otherwise specified.

2.14 "Rebate Payment Due Date" shall mean the date that is 30 days following Manufacturer's receipt of Medicaid PDL Utilization Information from the Department.

2.15 "State Supplemental Rebate" shall mean the quarterly amount invoiced by the State as calculated in accordance with the Contracted Product Attachment of this Agreement. Pursuant to 42 C.F.R. §447.504(c)(19), §447.504(e)(9), §447.505 (c)(7) State Supplemental Rebates shall mean rebates paid under a CMS-authorized supplemental rebate agreement that are excluded from AMP, AMP for 5i, and best price.

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

2.17 "Wholesale Acquisition Cost or WAC" shall mean 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.

MANUFACTURER'S RESPONSIBILITIES

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

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

3.3 Unless a dispute is raised pursuant to the Dispute Resolution section of this Agreement, Manufacturer shall make State Supplemental Rebate payments to the State for each Quarter no later than the Rebate Payment Due Date.

3.4 Interest on the State Supplemental Rebates payable under Section 3.2 of this Agreement begins accruing 38 calendar days from the postmark date of the State Supplemental Rebate Invoice sent to the Manufacturer and interest will continue to accrue until the postmark date of the Manufacturer's payment. For the rebate programs invoiced under this Agreement, if the date of mailing of a State Supplemental Rebate payable under Section 3.2 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 described in Section 3.1 but will be increased by ten percentage points or the maximum allowed by State law. Interest is calculated in the same manner as late rebate payment for the National Medicaid Drug Rebate Program.

3.5 Nothing in this Agreement shall be construed as prohibiting Manufacturer from discontinuing production, marketing or distribution of any Contracted Product or from transferring or licensing any Contracted Product to a third party. The Manufacturer shall notify the State of such action as soon as commercially reasonable.

3.6 Manufacturer agrees to pay State Supplemental Rebates on the Preferred Product(s) for as long as this Agreement or any of its Addenda are in force, and Medicaid PDL Utilization Information indicates utilization for that drug, regardless of whether there was a direct claim payment or an indirect payment including the All-Inclusive Population Based Payments (AIPBP) through Vermont Next Generation Model Accountable Care Organization agreement.

3.7 Unless notified otherwise, Manufacturer will send State Supplemental Rebate payments by certified mail, return receipt requested, to the State Primary Billing Address identified on the first page of this Agreement.

3.8 Manufacturer shall keep records (written or electronic) of the data and any other material from which the calculations of AMP and best price were derived in accordance with 42 CFR §447.510, and make such records available to the State or to the Secretary upon request. In the absence of specific guidance in 42 U.S.C. § 1396r-8, federal regulations and the terms of this agreement, the manufacturer may make reasonable assumptions in its calculations of AMP and best price, consistent with the purpose of 42 U.S.C. § 1396r-8, federal regulations and the terms of this agreement. A record (written or electronic) explaining these assumptions must also be maintained by the manufacturer in accordance with the recordkeeping requirements in 42 CFR 447.510, and such records must be made available to the State or to the Secretary upon request.

STATE'S RESPONSIBILITIES

4.1 The state shall maintain and publish a 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 the Contracted Products Attachment of this Agreement. The State 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.

4.2 The State will provide Medicaid PDL Utilization Information within ninety (90) days of the last day of each Quarter. This reporting shall be done in a manner consistent with the Medicaid National Drug Rebate Program. Medicaid PDL Utilization Information to be supplied includes, for each NDC number: 1) Product name; 2) Units; 3) Number of prescriptions; and 4) Total amount reimbursed. Medicaid PDL Utilization Information 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).

4.3 The State will maintain those data systems used to calculate the State Supplemental Rebates. In the event material discrepancies are discovered, the State will promptly justify its data or make an appropriate adjustment, which may include a credit as to the amount of the State Supplemental Rebates, or a refund to Manufacturer as the parties may agree. Any such adjustment shall be included on the next quarterly invoice.

4.4 The State shall maintain electronic claims records for the most recent four quarters that will permit Manufacturer to verify through an audit process the Medicaid PDL Utilization Information provided by the State.

4.5 The State warrants that CMS has authorized this Agreement.

DISPUTE RESOLUTION

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

5.2 In the event that in any Quarter a discrepancy in calculation of that quarter's State Supplemental Rebate is noted by Manufacturer, which Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State by the Rebate Payment Due Date.

5.3 If the Manufacturer in good faith believes the State's calculation of the State Supplemental Drug Rebate is erroneous, the Manufacturer shall pay the State that portion of the State Supplemental Rebate claimed that is not in dispute by the Rebate Payment Due Date. The balance in dispute, if any, plus interest will be paid by the Manufacturer to the State by the first Rebate Payment Due Date after resolution of the dispute.

5.4 The State and the Manufacturer will use their best efforts to resolve the discrepancy within sixty (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 State's calculation of the State Supplemental Rebate or Manufacturer's calculations and payment figures. Should additional information be required to resolve disputes, the State will cooperate with the Manufacturer in obtaining the additional information.

5.5 In the event that the State and the Manufacturer are not able to resolve a discrepancy regarding Medicaid PDL Utilization Information as provided for in Sections 5.1 through 5.4 , the Manufacturer may request a reconsideration of the State's determination within 30 days after the end of the 60-day period identified in Section 5.4. The Manufacturer shall submit with its written request its argument in writing, along with any other materials, supporting its position to the State. The State shall review the written argument and materials and issue a decision in the matter.

CONFIDENTIALITY PROVISIONS

6.1 The parties agree that confidential information will not be released publicly. Confidential information, including trade secrets, will not be disclosed or used except in connection with this Agreement or as may be required by law or judicial order.

6.2 The Manufacturer will hold the State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data from the State, that

information shall also be held confidential. The Manufacturer shall have the right to disclose the State's State Utilization Data to auditors who agree to keep such information confidential.

6.3 Pursuant to 42 USC 1396r-8(b)(3)(D), and other applicable state or federal laws, the parties agree that this Agreement and all information provided pursuant to this Agreement will not be disclosed and that the parties will not duplicate or use the information, except in connection with this Agreement or as may be required by judicial order. The parties further agree that any information provided by Manufacturer to the State pursuant to this Agreement and this Agreement itself constitute trade secrets and/or confidential or proprietary commercial and financial information not subject to public disclosure. Furthermore, the parties agree that any Manufacturer information received by the State shall constitute trade secrets and/or confidential or proprietary commercial and financial information of the Manufacturer not subject to public disclosure, except as otherwise provided for herein. If the services of a third party are used to administer any portion of this Agreement, Sections 6.1 through 6.4 of this Agreement shall apply to the third party. In the event that either party is required by law to disclose any provision of this Agreement or pricing information to any person, such party shall provide advance written notice to the other party sufficiently in advance of the proposed disclosure to allow the other party to seek a protective order or other relief.

6.4 Notwithstanding the non-renewal or termination of this Supplemental Rebate Agreement for any reason, these confidentiality provisions will remain in full force and effect.

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 The State may terminate its participation in this Agreement, 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 the 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. § 1320a7b(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 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 C.F.R. §447.504(c)(19), §447.504(e)(9), §447.505 (c)(7) removing or limiting the exclusion of the State Supplemental Rebate from AMP and/or 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.

GENERAL PROVISIONS

8.1 This Agreement will be governed and construed in accordance with 42 U.S.C. § 1396r-8 and all other applicable federal and state law and regulations.

8.2 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 will be mailed to the State at the address provided in this Agreement.

8.3 The Manufacturer agrees to be bound by the laws of the United States of America and the law of the State of Vermont. Any action or proceeding brought by the State or the Manufacturer in connection with this Agreement shall be brought to the Superior Court, Civil Division, Washington Unit.

8.4 Nothing herein shall be construed or interpreted as limiting or otherwise affecting the State'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.

8.5 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.

8.6 Manufacturer may not assign this Agreement, either in whole or in part, without the written consent of the State. However, in the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner subject to the conditions in this Agreement. If the Agreement is assigned pursuant to this Section, Manufacturer shall provide the State with an update of the information contained in Section 8.2, *supra*.

8.7 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.

8.8 The State and Manufacturer declare that this Agreement, including attachments, schedules and addenda, contains a total integration of all rights and obligations of the 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 the 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.

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

- Notice Provision
- 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.

8.10 The parties do not contemplate any circumstances under which indemnification of the other parties 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 the Manufacturer in the performance of this Agreement.

CONTRACTED PRODUCTS ATTACHMENT

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

Tier

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

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

Formula

- Formula 1: Percentage of WAC.
  Supplemental Rebate Amount per Unit = WAC multiplied by Contracted Rate
  [2] A value of 1.0 under "contracted rate"=100% of WAC

- Formula 2: Guaranteed Net Price.
  Supplemental Rebate Amount per Unit = WAC minus URA minus Contracted Rate