



VERMONT SUPPLEMENTAL DRUG REBATE AGREEMENT

1.1 This Supplemental Drug-Rebate Agreement ("Agreement") is made and entered into this _____ day of _____, _____ by and between the State of Vermont, Department of Vermont Health Access or its successor (the "State") and _____ (the "Manufacturer"), Labeler Code _____. The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

PURPOSE

2.1 It is the intent of this Agreement that the State will receive State Supplemental Rebates, in addition to the CMS Rebates received under the Medicaid Drug Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8), for the Manufacturer's Supplemental Covered Product(s) quarterly utilization in the State's Medicaid Programs in which there is Medicaid federal financial participation. The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).

DEFINITIONS

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

3.2 "**Average Manufacturer Price or AMP**" shall mean the average price paid to Manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from

the Manufacturer. This definition shall be consistent with the definition set forth in section 1927(k)(1) of the Social Security Act (42 U.S.C. § 1396r-8(k)(1)).

3.3 “Best Price” shall mean, the Best Price as defined in Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).

3.4 “Chemical Type” shall mean the number and its meaning assigned by the Food and Drug Administration (FDA), one through eight, which represents the newness of a drug formulation or a new indication for an existing drug formulation.

3.5 “Competitive Product” shall mean any FDA-approved prescription brand name drug (or drug approved during the term of this Agreement) in the same therapeutic category that competes with Covered Product.

3.6 “Covered Product ” shall mean the pharmaceutical product(s) of the Manufacturer pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8).

3.7 “CMS Rebate” shall mean, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer's Medicaid Drug Rebate Agreement, made in accordance with Section 1927(c)(1), 1927(c)(2) or 1927(c)(3) of the Social Security Act [42 U.S.C. §1396r-8(c)(1), 42 U.S.C. §1396r-8(c)(2) and 42 U.S.C. § 1396r-8(c)(3)].

3.8 “CMS” shall mean the Centers for Medicare & Medicaid Services (formerly known as the Health Care Financing Administration) within the Federal Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such an office.

3.9 “CMS Unit Rebate Amount” shall mean, the unit amount computed by CMS to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the CMS Rebate payment due.

3.10 “Drug Reimbursement Amount” shall mean the total amount per unit allowable as calculated by the State, specific to each drug, that the State reimburses to State of Vermont Medicaid providers per unit of drug under the State Medicaid program, in accordance with applicable state and federal laws and regulations.

3.11 “Guaranteed Net Price or GNP and Guaranteed Net Unit Price or GNUP” shall mean the final fixed price of the drug assured by the Manufacturer to the State. It shall be calculated as WAC minus the CMS Unit Rebate Amount minus the State Supplemental Rebate necessary to equal the guaranteed net price to the State by Manufacturer for the Covered Product for the calendar quarter.

3.12 “Line Extension Drug” shall mean any drug meeting the definition of a Line Extension Drug as defined in any final rule published by the Centers for Medicare and Medicaid Services (CMS) clarifying Section 1927(c)(2)(C) of the Social Security Act. Line Extension Drugs must be new formulations of existing, rebatable, oral, solid dosage medications as defined by federal law. Until the final rule is published the term Line Extension Drug shall mean a drug that is designated as Chemical Type 2, 3, 4, or 6 on the Food and Drug Administration’s (FDA) list of Chemical Types. *See* 77 Fed. Reg. 5339 (Feb. 2, 2012).

3.13 “Manufacturer” shall mean, for purposes of this Agreement, the party identified as such in Section 1.1 of this Agreement, which may be a pharmaceutical manufacturer, labeler or other entity not prohibited by law from entering into this Agreement.

3.14 “Maximum Allowable Cost or MAC” shall mean the lowest reimbursement rate established by the State for a Covered Product.

3.15 “Medicaid Drug Rebate Agreement” shall mean the agreement in place between Manufacturer and the Secretary of HHS, pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508). CMS is the agency within HHS having the delegated authority to operate the Medicaid Program.

3.16 “Medicaid Member” shall mean any person enrolled in the State’s Medicaid Program or other public assistance programs under Vermont’s Section 1115 Global Commitment Waiver and eligible to receive prescription drug benefits funded under Title XIX.

3.17 “Net Price per Unit” or “Net Price” shall mean with respect to Supplemental Covered Product the Drug Reimbursement Amount minus all applicable rebates, including the CMS Rebate and any State Supplemental Rebate, per Unit. Net Price may also take into account any Unit Rebate Offset Amount.

3.18 “Participation Commencement Date” shall mean the date a Manufacturer's Supplemental Covered Product is effectively placed in the State’s Preferred Drug List Program by distribution of it (via website or otherwise) to State of Vermont Medicaid providers and prescribers. It is the date when the State’s entitlement to a State Supplemental Rebate from the Manufacturer accrues.

3.19 “Preferred Drug List or PDL” shall mean a document listing various pharmaceutical products covered by the State Medicaid Program for the purpose of guiding the prescribing, dispensing and acquisition of pharmaceutical products. All drugs of manufacturers with Medicaid Drug Rebate Agreements with HHS will remain covered, although some drugs that are non-preferred will require Prior Authorization consistent with Section 1927 of the Social Security Act (42 U.S.C §1396r-8). The State Drug Utilization Review (DUR) Board will

review drugs on a monthly or bi-monthly basis to make recommendations to the State for drugs to be listed as preferred or non-preferred on the PDL.

3.20 “Preferred Drug List Program” shall mean a process by which the State DUR Board designates and maintains the list of drug products that are preferred over other drugs in the same Product Category (on the PDL), for the purpose of guiding the prescribing, dispensing and acquisition of those drugs.

3.21 “State Supplemental Rebate Summary” shall mean the State’s report itemizing the State Utilization Data supporting the State's invoice for State Supplemental Rebates. The State Supplemental Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the Medicaid Drug Rebate Agreement.

3.22 “State” shall mean the State of Vermont, the Department of Vermont Health Access or its successor, or any agent or agents that the State designates to perform the State of Vermont’s responsibilities as set forth in the terms and conditions of this Agreement.

3.23 “State Medicaid Program” shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Members.

3.24 “State Supplemental Rebate” shall mean, with respect to the Supplemental Covered Product(s), the quarterly payment by Manufacturer pursuant to Section 4.2 of this Agreement.

3.25 “State Utilization Data” shall mean the data used by the State to reimburse State of Vermont Medicaid providers under the State’s Medicaid Program. State Utilization Data excludes data from covered entities identified in Title 42 U.S.C. §256b(a)(4) in accordance with Title 42 V.S.C. §256b(a)(5)(A) and 1396r-8(a)(5)(C).

3.26 “Step Care” or “Step Therapy Program” shall mean a potentially defined order of therapeutic choices within either the preferred or non-preferred drug list categories.

3.27 “Supplemental Covered Product” shall mean the pharmaceutical product(s) of the Manufacturer, as detailed in the Attachment A or a comparative attachment, upon which a State Supplemental Rebate will be paid pursuant to this Agreement.

3.28 “Supplemental Covered Product Category” or “Product Category” shall mean a defined group of pharmaceutical products considered to compete with one another in the market and that are also thought to be therapeutic alternatives in many situations. The State has determined and defined the Product Categories in which manufacturers will bid.

3.29 “Supplemental Rebate Amount” shall mean, with respect to the Supplemental Covered Product(s), the amount(s) specified in the Attachment A or a comparative attachment that the Manufacturer has agreed to reimburse the State per unit of drug in accordance with the formula detailed in the above-referenced attachment.

3.30 “Unit” shall mean a single capsule, tablet, milliliter or other unit as published in Medispan or First DataBank, of the Covered Product.

3.31 “Unit Rebate Offset Amount or UROA” shall mean the unit amount calculated by CMS pursuant to 42 U.S.C. §1396r-8(b)(1)(C).

3.32 “U.S.C.” shall mean the United States Code. All references in this Agreement to U.S.C. chapters or sections shall include any successor, amended, or replacement statute.

3.33 “Wholesale Acquisition Cost or WAC” shall mean the Manufacturer's U.S. Dollar wholesale acquisition price in effect on the last day of a quarter on a unit basis as published by a third party source, such as Medispan or First DataBank, for each product and represents the Manufacturer's published price for a drug product to wholesalers.

MANUFACTURER'S RESPONSIBILITIES

4.1 Manufacturer will calculate and provide the State a CMS Rebate for the Covered Product(s). The CMS Rebate represents the discount obtained by multiplying the units of the Covered Product(s) reimbursed by the State in the preceding quarter by the per unit rebate amount provided to the State by CMS. CMS will calculate the CMS Rebate amount in accordance with Manufacturer's Medicaid Drug Rebate Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's Medicaid Drug Rebate Agreement.

4.2 In addition to the CMS Rebate described in Section 4.1 of this Agreement, Manufacturer will remit to the State a State Supplemental Rebate for the Supplemental Covered Product(s) that are in the State's Preferred Drug List Program. The State Supplemental Rebates will be calculated on a calendar quarter basis and the amount due provided via invoices to the invoice contact Manufacturer reports to CMS. The State Supplemental Rebates for the quarter will be determined by multiplying the number of units of the Supplemental Covered Product(s) reimbursed by the State in the preceding quarter by its Supplemental Rebate Amount. The Manufacturer's obligation for State Supplemental Rebates will continue for the duration of this Agreement. The Supplemental Rebate calculation is described in "Attachment A".

4.3 The Manufacturer's obligation for State Supplemental Rebates will begin with the Rebate Billing Period for the first calendar quarter, which begins _____ (even if this Agreement is not fully executed by such date) and will continue through the Rebate Billing Period that ends _____, subject to the Participation Commencement Date as

described in Section 3.18 *supra*. Notwithstanding the above, the State reserves the right to solicit annually more favorable State Supplemental Rebates from Manufacturer by giving written notice thereof no less than ninety (90) days prior to the yearly anniversary of the effective date of this Agreement.

4.4 The quarters to be used for calculating the 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.

4.5 Manufacturer will be required to submit the State Supplemental Rebate payment within 38 days of the Manufacturer's receipt of the State Supplemental Rebate Summary.

4.6 Manufacturer will pay the State Supplemental Rebates, including any applicable interest in accordance with Section 1903 (d)(5) of the Social Security Act (42 U.S.C. §1396b(d)(5)). 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 State's 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 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 described in Section 4.1 but will be increased by ten percentage points or the maximum allowed by State law. If the State has not received the Rebates payable under Section 4.2 of this Agreement, including interest, within 180 days of the postmark date of the State's invoice and supporting State Supplemental Rebate Summary sent to the Manufacturer, the State may deem the Manufacturer to be in default and the State may terminate its participation in this Agreement by giving the Manufacturer ninety (90) days advance written notice.

4.7 Manufacturer agrees to continue to pay State Supplemental Rebates on the Supplemental Covered Product(s) for as long as this Agreement or any of its Addenda are in force, and State Utilization Data shows that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. Manufacturer's obligation to pay State Supplemental Rebates on the Supplemental Covered Product(s) shall terminate twelve (12) months following the last expiration date of the last lot of Supplemental Covered Product sold by the Manufacturer. Notwithstanding the above, in the event Manufacturer's Supplemental Covered Product(s) is/are sold to another manufacturer, the original Manufacturer shall have no liability for rebates on utilization beyond those required by the Medicaid program. Manufacturer shall provide the State with notice of the sale of said Supplemental Covered Product(s) concurrent with Manufacturer's notice to CMS.

4.8 Unless notified otherwise, Manufacturer will send State Supplemental Rebate payments by certified mail, return receipt requested, to the address provided to Manufacturer as set forth in Section 9.2 of this Agreement.

4.9 Manufacturer must notify the State if any Covered Product will be a Line Extension Drug. To the extent that applicable law requires re-designation of a Covered Product as a Line Extension Drug based on new indications, Manufacturer shall notify the State of any application to the Food and Drug Administration (FDA) for new indications for a Covered Product. This notification must occur no later than the date of the new indication application to the FDA.

STATE'S RESPONSIBILITIES

5.1 The State will consider the Manufacturer's Supplemental Covered Product(s) for inclusion in the State's Preferred Drug List Program. The State reserves the right to select the products that will be in its Preferred Drug List Program and will only receive State

Supplemental Rebates for Manufacturer's Supplemental Covered Products that are actually included in its Preferred Drug List Program. Manufacturer shall pay State Supplemental Rebates based upon the State's utilization of Manufacturer's Supplemental Covered Product(s) that did not require prior authorization. Unless otherwise specifically agreed, the State shall not be entitled to State Supplemental Rebates for utilization of Manufacturer's Supplemental Covered Product(s) that occurred only subsequent to the obtaining of prior authorization unless the Supplemental Covered Product(s) have been assigned to a Product Category and all products in the Product Category are subject to prior authorization requirements. The State also reserves the right to determine, as a result of a Product Category review, that prior authorization is required for all preferred drugs in a Product Category. If the State determines that prior authorization is required for any Supplemental Covered Product, then the State will comply with all provisions of Section 1927(d) of the Social Security Act (42 U.S.C §1396r-8(d)) applicable to Prior Authorization programs.

5.2 The State shall notify the Manufacturer whenever one of the Manufacturer's Supplemental Covered Products is added to its Preferred Drug List (PDL) or when one of Manufacturer's Supplemental Covered Products is moved to a prior authorization status. Posting of the PDL on the State's website shall satisfy this requirement.

5.3 The State will provide aggregate State Utilization Data to the Manufacturer on a quarterly basis. This data will be based on paid claims data under the State's Medicaid Program, will be consistent with any applicable Federal or State guidelines, regulations and standards for such data, and will be the basis for the State's calculation of the State Supplemental Rebate.

5.4 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.

5.5 The State shall maintain electronic claims records for the most recent four quarters that will permit Manufacturer to verify through an audit process the Rebate Summaries provided by the State.

5.6 Upon implementation of this Agreement, and from time to time thereafter, the State and 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 State to Manufacturer are adequate for the purposes of this Agreement.

5.7 The State shall obtain CMS approval of its Medicaid plan of which this Agreement forms a part. Manufacturer shall not be obligated to remit any Supplemental Rebates that have accrued and are due under this Agreement until after the State has obtained CMS approval of its Supplemental Rebate Program of which this Agreement forms a part.

DISPUTE RESOLUTION

6.1 In the event that in any quarter a discrepancy in the State's State Utilization Data is questioned by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy to the State.

6.2 If the Manufacturer in good faith believes the State's State Utilization Data is erroneous, the Manufacturer shall pay the State that portion of the rebate claimed that is not in dispute by the required date. The balance in dispute, if any, will be paid by the Manufacturer to the State by the due date of the next quarterly payment after resolution of the dispute.

6.3 The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of written notification. Should additional information be required to resolve disputes, the State will cooperate with the Manufacturer in obtaining the additional information.

6.4 In the event that the State and the Manufacturer are not able to resolve a discrepancy regarding State Utilization Data as provided for in Sections 6.1 through 6.3, 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 6.3. 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

7.1 The parties agree that confidential information will not be released to any person or entity not a party to this contract. 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.

7.2 The Manufacturer will hold the State' State Utilization Data 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.

7.3 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 7.1 through 7.4 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.

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

NON-RENEWAL or TERMINATION

8.1 This Agreement shall be effective as of _____, and shall have the term indicated in Section 4.3, *supra*.

8.2 The State may terminate its participation in this Agreement by giving Manufacturer written notice at least sixty (60) days prior to the anniversary date of this Agreement, in which case termination shall become effective on the anniversary date of the date of execution of this Agreement. Manufacturer may terminate this Agreement and all Addenda by giving the State written notice at least sixty (60) days prior to the anniversary date of this

Agreement, in which case termination shall become effective on the anniversary date of the date of execution of this Agreement. Manufacturer's right of termination is limited to the right to terminate the entire Agreement. Manufacturer may not terminate specific Addendum/Addenda.

8.3 This agreement or a portion thereof, may be immediately terminated upon the occurrence of any of the following events:

(a) A determination that any Covered Product is a Line Extension Drug.

8.4 Notwithstanding any non-renewal or termination of this Agreement, State Supplemental Rebates will still be due and payable from the Manufacturer under Section 4.2 for any Supplemental Covered Products for which the State's obligation to reimburse arose prior to the effective date of termination of this Agreement.

8.5 On at least an annual basis or as mutually agreed upon by Manufacturer and the State, Manufacturer shall have the opportunity to decrease the Net Price of its Covered Products to increase the likelihood of product(s) utilization and/or inclusion in the State's Preferred Drug List Programs.

GENERAL PROVISIONS

9.1 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.

9.2 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 addresses set forth below.

Notice to the State shall be sent to:

State of Vermont

Department of Vermont Health Access

Name

Title

312 Hurricane Lane, Suite 201

Williston, VT 05495

Notice to Manufacturer will be sent to:

Name

Title

Manufacturer's Mailing Address

9.3 The Manufacturer agrees to be bound by the laws of the United States of America and the laws of the State of Vermont. Proper venue in any legal action shall be the venue of the State of Vermont.

9.4 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.

9.5 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.

9.6 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 9.2, *supra*.

9.7 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.

9.8 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.

9.9 This Agreement will not be altered except by an amendment in writing signed by the parties. Other than as stated herein, no individual is authorized to alter or vary the terms or make any representation or inducement relative to it, unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the State and the Manufacturer.

9.10 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.

9.11 Inasmuch as the State Supplemental Rebates required by this Agreement are for State Medicaid Program beneficiaries, it is agreed, in accordance with Medicaid Drug Rebate Program Release #102 for State Medicaid Directors and other applicable law, that the State Supplemental Rebates do not establish a new Best Price for purposes of Manufacturer's Medicaid Drug Rebate Agreement.

9.12 In the event that the State requires prior authorization of Manufacturer's Supplemental Covered Product(s) as part of a Product Category prior authorization under Section 5.1, State Supplemental Rebates shall nevertheless be payable hereunder.

9.13 If the State makes a change to a Product Category that is considered to be a material change in the structure of the supplemental rebates program, Manufacturer may be allowed to re-submit bids for the Product Category affected.

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

STATE OF VERMONT, Department OF VERMONT HEALTH ACCESS

By: _____ Date: _____

Name: _____

Title: _____

MANUFACTURER

By: _____ Date: _____

Name: _____

Title: _____

ATTACHMENT A

Covered Products & Supplemental Rebate Calculation for CCYY

NDC (11 digits required)	COVERED PRODUCT DESCRIPTION	TIER	GNUP or WAC % DISCOUNT

Additional Terms and Conditions for State Supplemental Rebates