SUPPLEMENTAL REBATE AGREEMENT

1. Parties/Period of Agreement

1.1 This Supplemental Rebate Agreement ("Agreement") is dated as of this 1st day of [MONTH YEAR] by and between the State of Maine Department of Health and Human Services (Department) and [MANUFACTURER NAME] ("Pharmaceutical Manufacturer"), for labeler codes [#####].

1.2 This Agreement is effective on [MONTH DD, YYYY] and will continue in force through [MONTH DD, YYYY].

The parties, in consideration of 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 Medicaid population, in addition to rebates received under the Medicaid Drug 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 Maine 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 **Agreement** means this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.

3.2 **Pricing definitions applicable to State Supplemental Rebate Formulas in Attachment B:**

3.2.1 **Average Manufacturer Price (AMP)** means 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.

3.2.2 **Wholesale Acquisition Cost (WAC)** means the Manufacturer's US Dollar wholesale acquisition price in effect on the last day of the 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.

3.2.3 **Guaranteed Net Price** means the final fixed price of the drug assured by the Manufacturer to the Department as the Guaranteed Net Price determines the State Supplemental Rebate for the Covered Product for the calendar quarter through the formula: WAC minus the CMS rebate minus the State Supplemental Rebate must equal Guaranteed Net Price to the State by the Pharmaceutical Manufacturer for the Covered Product for the calendar quarter.

3.3 **CMS Rebate** means, with respect to the Covered Product, the quarterly payment by the Pharmaceutical Manufacturer pursuant to Pharmaceutical Manufacturer's Medicaid Drug Rebate Agreement made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).

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 and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

3.5 **Competitive Product** means any Brand Product in the Market Basket that competes with Covered Product. The Market Basket for each drug listed on Attachment A is defined as the category the drug is placed on the Maine PDL unless otherwise defined on Attachment A.

3.6 **Covered Product** means those drugs listed on Attachment A.

3.7 **CPI Rebate** means, with respect to the Covered Product, the quarterly payment by the Pharmaceutical Manufacturer pursuant to the Pharmaceutical Manufacturer's Medicaid Drug Rebate Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).

3.8 **Maximum Allowable Cost (MAC)** shall mean the lowest reimbursement rate established by the Department for the Covered Product.

3.9 **Medicaid Drug Rebate Agreement** means the agreement in place between the Pharmaceutical Manufacturer and the U.S. Secretary of Health and Human Services, 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.

3.10 **Medicaid Member** means any person enrolled in the Department Medicaid Program and eligible to receive prescription drug benefits under a fee for service arrangement.

3.11 **Preferred Drug List (PDL)** means a document listing various pharmaceutical products covered by the Department Medicaid Program for the purpose of guiding the prescribing, dispensing and acquisition of pharmaceutical products. All drugs of manufacturers with Federal rebate agreements with CMS will remain covered, although some drugs that are Non-Preferred will require Prior Authorization consistent with Section 1927 of the Social Security Act. The DUR Committee will review drugs on a quarterly basis to make recommendations to the Department for drugs to be listed as Preferred or Non- Preferred on the PDL.

3.12 **State Medicaid Program** means 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.

3.13 **State Supplemental Rebate** means an amount paid on a calendar quarter basis by the Pharmaceutical Manufacturer to the Department for covered product utilization under the Department's fee for service Medicaid program pursuant to this Agreement. The State Supplemental Rebate is in Attachment B. For the purpose of this Agreement, the designated formula shall be listed on Attachment B.

3.14 **Step Care** means a defined order of therapeutic choices within either the preferred or non-preferred drug list categories.

3.15 **Unit** means a single capsule, tablet, milliliter or the lowest dispensable unit of a Covered Product as published in Medispan or First DataBank or another publisher of drug pricing data.

3.16 **USC** means the United States Code. All references in this agreement to USC chapters or sections will include any successor, amended, or replacement statute.

4. Department Obligations

4.1 **Preferred Drug List**: The Department will place Covered Products in an advantaged position relative to non-preferred products regarding the 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 Therapy). Certain Preferred Drugs, including Step Therapy drugs, may be subject to prior authorization. The Department will comply with all provisions of Section 1927 (d) (42 USC 1396r 8(d))

4.2 **Preferred Drug List Documentation and Publication:** The Department will communicate the inclusion of Covered Product on the Preferred Drug List to the State Medicaid Program providers through the standard notification process.

4.3 **Invoicing:** The Department will invoice the Pharmaceutical Manufacturer for State Supplemental Rebates separately from CMS Rebates using the format set forth by CMS. The Department shall submit the State Supplemental Rebate invoice to the Pharmaceutical Manufacturer within sixty (60) days after the end of each calendar quarter in which the Covered Product subject to such State Supplemental Rebate was paid for by the Department. Any amended invoice shall be submitted by the Department within fifteen (15) months after the end of the calendar quarter in which Covered Product was paid for by the Department.

4.4 **Patient Information:** The Department, its agents, employees and contractors will not provide to Pharmaceutical Manufacturer any patient identifiable information or protected health information ("PHI") or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

4.5 **Approval of Generic:** If during the duration of this Agreement a generic equivalent of any Competitive 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 Department, as defined in Attachment B, is not more than the lowest reimbursement cost for a generic equivalent.

5. Manufacturer Obligations

5.1 **State Supplemental Rebate Payment**: The Pharmaceutical Manufacturer agrees to provide a State Supplemental Rebate for each of its Covered Products that is paid by the Department and dispensed to Medicaid Members by Pharmacies for each calendar quarter that Covered Products are included in the Preferred Drug List. The Pharmaceutical Manufacturer will pay to the Department the State Supplemental Rebate amount in accordance with the formula set forth in Attachment B. Nothing in this Agreement shall be construed to relieve the Pharmaceutical Manufacturer from its obligation to pay Medicaid Drug Rebates for utilization by the Department Medicaid Members. The Department shall remit the appropriate share of the State Supplemental Rebate payments made under the Agreement to CMS as required under its approved State plan.

5.2 **Payment Timeframe:** The Pharmaceutical Manufacturer will pay to the Department the State Supplemental Rebate amount to which the Department is entitled in accordance with the formula set forth in Attachment B, within thirty-eight (38) days after receipt of the Department's invoice.

5.3 **Payment of Interest:** Payments of the State Supplemental Rebates mailed more than 38 days from the date of invoice will include the payment of interest by the Pharmaceutical Manufacturer at a rate based on the average of the bond equivalent of the weekly 90-day treasury bill auction rates during such period (as described in 42 USC § 1396b(d)(5)). Interest on the Rebates payable under this Agreement begins accruing 38 calendar days from the Manufacturer's receipt of Maine's Medicaid Utilization Information, and interest will continue to accrue until the postmark date of the Manufacturer's payment.

5.4 **Incomplete Submission:** The Pharmaceutical Manufacturer will have no obligation to pay State Supplemental Rebate amounts for claims that are not submitted as part of an invoice in accordance with Section 5.1 of this Agreement. The Pharmaceutical Manufacturer will notify State or its designee of any incomplete submission within thirty-eight (38) days of the Pharmaceutical Manufacturer's receipt of such submission pursuant to Section 6.1.

5.5 **Over/Underpayment:**The state will apply any Manufacturer overpayments against future invoice payments and any debt or underpayments owed to the Department. The state will permit credits to be shared across labelers and program types within the same Organization. In the event that a labeler has exited the Medicaid Drug Rebate Program (MDRP), no future invoices will be generated. If a refund request is received from the Manufacturer, the state will refund overpayments greater than or equal to $10,000 per labeler after accounting for any outstanding overpayments or debt owed to the Department.

5.6 **Discretion to Market**: Nothing in this Agreement shall be construed to prohibit the Pharmaceutical Manufacturer's from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that the Pharmaceutical Manufacturer is liable for the payment of State Supplemental Rebates only for Covered Products (as identified by the 11-digit NDC code) distributed (directly or through the wholesale channel) to retail Pharmacies and dispensed to Medicaid Members. If the Pharmaceutical 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 Pharmaceutical Manufacturer will make every reasonable effort to notify the Department prior to such actions.

6. Dispute Resolution

6.1 In the event a Pharmaceutical Manufacturer discovers a potential discrepancy with State Drug Utilization Data on the rebate invoice, which the Pharmaceutical Manufacturer and State in good faith are unable to resolve prior to the payment due date, the Pharmaceutical Manufacturer will submit a Reconciliation of State Invoice (ROSI) form, CMS-304, to the State. If such a discrepancy is discovered for a prior rebate period's invoice, the Manufacturer will submit a Prior Quarter Adjustment Statement (PQAS) form, CMS-304a, to the State.

6.2 If the Pharmaceutical Manufacturer disputes in good faith any part of the State Drug Utilization Data on the rebate invoice, the Pharmaceutical Manufacturer shall pay the state for the rebate units not in dispute within 38 days after receiving the State rebate invoice. Upon resolution of the dispute, the manufacturer will either pay the balance due, if any, plus interest as set forth in section 1903(d)(5) of the Act, or be issued a credit by the State by the due date of the next quarterly payment in the same 38 day time frame as the current rebate invoice.

6.3 The State and Pharmaceutical Manufacturer will use their best efforts to resolve a dispute arising

under 6.1 or 6.2 above, within 60 days of the State's receipt of the manufacturer's ROSI/PQAS

6.4 The Pharmaceutical Manufacturer will pay the amount due as a result of any ascertained underpayment, plus interest as described in section 5.3 of this Agreement, by the due date of the next quarterly payment after resolution of the dispute.

7. Term and Termination

7.1 **Effective Date:** This Agreement may be terminated prior to the effective date listed in 1.2 upon the occurrence of either of the following:

a. **Breach.** If either party commits a material breach of this Agreement, the non- breaching party shall deliver written notice mailed by certified mail, return receipt requested, of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach during the thirty (30) day period following delivery. Failure to cure will give the non-breaching party the right to cancel this Agreement after the thirty (30) day period by giving the breaching party final written notice of the cancellation of this Agreement.

b. **Without Cause.** Either party may terminate this Agreement without cause as of the end of any calendar quarter by giving the other party ninety (90) days prior written notice.

7.2 **Accrued Obligations/Remedies:** The expiration or termination of this Agreement will not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement will not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein will not be deemed an exclusive remedy unless expressly provided for as such.

7.3 **Execution, Amendment and Waiver:** Agreement will be binding only upon signature by the Department This Agreement, or any provision, may be altered, amended, or waived by written amendment executed by both parties as authorized by CMS.

7.4 **Amendments to Agreement:** 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. Section 1.2 Effective Dates
b. Section 8.4 Notices
c. Attachment A
d. Attachment B

The remainder of the Agreement will not be altered in any way except by an amendment in writing signed by both parties and authorized by CMS and the appropriate Department control agencies.

8. Miscellaneous

8.1 **Record Keeping and Audit:** During the term of this Agreement and for a period of three (3) years thereafter, both parties to the Agreement will use reasonable efforts at all times to ensure that they maintain accurate books, files and records relevant to this Agreement. At the Pharmaceutical Manufacturer's written request, the Department will make such information available for inspection

by the Pharmaceutical Manufacturer representatives or its designated auditors during regular business hours. Upon written request, each party will otherwise have the right to inspect, up to once each year, all such relevant books and records of the other party to verify compliance with the terms of this Agreement.

8.2 **Indemnification:** The Pharmaceutical Manufacturer will be responsible for and will indemnify and hold the Department harmless from all claims resulting from the acts or omissions of the Pharmaceutical Manufacturer and any of its subcontractors in its performance of this Agreement. The Department will be responsible and will indemnify and hold the Pharmaceutical Manufacturer's harmless from all claims resulting from the acts or omissions of the Department.

8.3 **Confidentiality:** Except as otherwise may be required to be disclosed by law and in accordance with the Rebate Agreement between the U.S. Secretary of Health and Human Services and the drug manufacturers, information disclosed by the Pharmaceutical Manufacturer's in connection with this Agreement will not be disclosed by the Department. Each party will maintain the confidentiality of all the terms and conditions of this Agreement throughout the term hereof and for a period of three (3) years thereafter.

8.4 **Notices:** Any notice required or permitted to be given by either party to the other will be given in person or sent by first class mail or express delivery, addressed to the other party at the address set forth below:

Company Name
Notice Contact
Address 1
Address 2
Address 3

State of Maine
Department of Health & Human Services
109 Capitol Street
11 State House Station
Augusta, ME 04333-0011

8.5 **Force Majeure:** Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, earthquake or 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.

8.6 **Assignment:** Neither party will have the right to assign this Agreement to a third party without the prior written consent of the other party, which consent will not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment will relieve any party of responsibility for the performance of any obligations that have accrued prior to such assignment.

8.7 **No Waiver of Rights:** 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 will not impair or waiver any such right or remedy in the future. Every right and remedy given by this Agreement to the parties will be exercised from time to time as often as appropriate.

8.8 **Entire Agreement**: This Agreement contains the entire agreement and understanding of the parties. This Agreement (including Attachments) may not be amended or modified except upon the written agreement of both parties.

8.9 **Governing Law:** This Agreement is governed by the laws of the State of Maine. In the event of a lawsuit involving this Agreement, venue is proper only in Kennebec County, Maine.

8.10 **Effect of Future Laws:** In the event of the enactment, promulgation, rescission, modification or judicial or CMS interpretation of any law or regulation after the date hereof which would (a) materially adversely affect the manner in which either party is obligated to perform under this Agreement, (b) adversely affect for either party the net prices or State Supplemental Rebates or other terms applicable under this Agreement, or (c) have the effect of requiring the net prices or State Supplemental Rebates or other terms applicable under this Agreement to be extended or offered to any third party, each party to this Agreement will enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of this Agreement affected by such enactment, promulgation, etc. Agreement on any such terms shall be in the sole discretion of each party. If the parties do not agree within sixty (60) days of a party's written request for negotiations, either party may terminate this Agreement with respect to the affected Covered Products upon expiration of the sixty (60) day period, with immediate effect.

8.11 **Compliance with Law:** In connection with its respective obligations under this Agreement, each party will comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements.

8.12 **Authority:** The Department and the Pharmaceutical 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 will thereby be bound.

8.13 **Best Price Contingency:** The effectiveness of this Agreement will be contingent on the Pharmaceutical Manufacturer's Best Price and AMP not being affected by State Supplemental Rebates.

8.14 **CMS Approval Contingency:** The effectiveness of this Agreement will be contingent on receipt of CMS approval by the Department, as evidenced by the CMS Exemption Letter, attached hereto as Exhibit C and incorporated by reference.

IN WITNESS WHEREOF, this Agreement has been executed by the parties set forth below:

[COMPANY NAME]	State of Maine Department of Health and Human Services
_____ Signature [SIGNATORY NAME]	_____ Signature MaineCare Pharmacy Director
_____ Date	_____ Date

State of MAINE

Attachment A
Covered Products

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

Manufacturer	NDC	Product Description	Formula

State of MAINE

Attachment B
Rebate Formula

Manufacturer	NDC	Product Description	WAC	CMS Rebate	Tier [1]	Formula [2]	Contracted Rate	Comments	Contract Effective Dates

[1] - Tiers (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
- Your drug will be one of four or more drugs in that PDL category
[2] - Formula 1: Percentage of WAC. Formula for Supplemental Rebate calculation: WAC * % of WAC = Supplemental Rebate per Unit
Formula 2: Guaranteed Net Price. Formula for Supplemental Rebate calculation: WAC- CMS Rebate - Guaranteed Net Price = Supplemental Rebate per Unit

MDDB Last Day WAC: WAC used shall be the last listed rate in the current quarter from drug information database files such as Medispan.

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE& MEDICAID SERVICES

Center for Medicaid, CHIP and Survey & Certification
Disabled and Elderly Health Programs Group

December 3, 2010

Tony Marple, Director OMS
Office ofMaineCare Services
#11 State House Station
442 Civic Center Drive
Augusta, Maine 04333

Dear Mr. Marple:

We have reviewed Maine State Plan Amendment (SPA) 10-006 received in the Boston Regional Office on May 14, 2010. Under this SPA, the State would revise the Maine multi-state supplemental rebate agreement (SRA) for "The Sovereign States Drug Consortium" (SSDC) Medicaid Multi-State Purchasing Pool previously authorized by the Centers for Medicare & Medicaid Services (CMS) under Maine SPA 06-002. The State proposes to revise several definitions. In addition, the State proposes a payment of interest provision for supplemental rebates mailed to the State more than ninety days from the invoice date and a new dispute resolution provision in the event that there is a discrepancy in the calculation of supplemental rebates. We are pleased to inform you that the attached SPA is approved, effective July 1, 2010.

We believe that the Maine multi-state SRA for the SSDC continues to be consistent with the objectives of the Medicaid program. Approval of Maine SPA 10-006 extends only to Maine's SRA with its Attachments and the SSDC Member States' Addendum to this SRA as submitted to CMS on November 22,2010. These revised SRA documents will replace the current SRA packet submitted to the CMS on July 19, 2006 and effective on January I, 2006. If changes are subsequently made to the SRA, Attachments or the Addendum submitted to CMS on November 22, 2010, any such documents should be submitted to CMS for review and authorization.

The Boston Regional Office will forward to you a copy of the CMS-179 form, as well as the pages approved for incorporation into the Maine Medicaid State Plan. If you have any questions regarding this amendment, please contact Bernadette Leeds at (410) 786-9463.

Sincerely,

Isl
Larry Reed
Director
Division of Pharmacy

cc: Brenda Harvey, Commissioner
Richard McGreal, ARA, Boston Regional Office
Chong Tieng, Boston Regional Office