Department Log #

SUPPLEMENTAL REBATE AGREEMENT

(Manufacturer Name)

This Supplemental Rebate Agreement ("Agreement") is dated as of this ___ day of _____, ____, by and between the State of Utah Department of Health & Human Services, Division of Integrated Healthcare ("State") and _____ (Manufacturer).

RECITALS

WHEREAS, the State has the authority to enter into agreements with pharmaceutical manufacturers to collect supplemental rebates for the benefit of the State's Medicaid members providing such agreements are authorized by the Centers for Medicare & Medicaid Services (CMS); and

WHEREAS, the Pharmaceutical Manufacturer is willing to provide supplemental rebates to the State based on the actual dispensing of the Pharmaceutical Manufacturer's Covered Products under the State's Medicaid program.

NOW THEREFORE, in consideration of the foregoing and of the representations, warranties and covenants set forth below, the parties, intending to be legally bound, agree as follows:

1. **Definitions** As used herein, the following terms shall have the meanings set forth below:

1.1 **"Agreement"** means this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.

1.2 **Pricing definitions applicable to State Supplemental Rebate formulas in Attachment B:**

1.2.1 **"Average Wholesale Price" ("AWP")** shall mean the lowest published price of the Covered Product by National Drug Code ("NDC") as published by First DataBank, Medispan or Redbook on the last day of the calendar quarter that corresponds to the calendar quarter for which the State utilization data for the Covered Product is reported to the Pharmaceutical Manufacturer.

1.2.2 **"Average Manufacturer Price" ("AMP")** shall mean the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. This definition shall be consistent with the definition set forth in section 1927(k)(1) of the Social Security Act.

1.2.3 **"Wholesale Acquisition Cost" ("WAC")** shall mean the price paid by a wholesaler for drugs purchased from the wholesaler's supplier. 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, Medispan or RedBook 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.

1.2.4 **"Guaranteed Net Price"** shall mean the final fixed price of the drug assured by the Pharmaceutical Manufacturer to the State. It shall be calculated as WAC minus the CMS rebate minus the State Supplemental Rebate necessary to equal the guaranteed net price to the State by the Pharmaceutical Manufacturer for the Covered Product for the calendar quarter.

1.3 **"Basic Rebate"** shall mean, 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)(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).

1.3.1 **"Best Price"** shall mean, Best Price as set forth in 42 U.S.C. § 1396r-8; as such statute may be amended from time to time, excluding State Supplemental Rebate amounts.

1.4 **"CMS"** shall mean the Centers for Medicare & Medicaid Services (formerly known as the Health Care Financing Administration) of the U.S. Department of Health and Human Services (HHS), or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

1.5 **"Competitive Product"** shall mean 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 Utah PDL unless otherwise defined on Attachment A.

1.5.1 **"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.

1.6 **"Covered Product"** shall mean products listed on ATTACHMENT A and as a covered outpatient drug in 1927(k)(i) of the Social Security Act for which the state made payment under the state plan.

1.7 **"CPI Rebate"** means, with respect to the Covered Product(s), 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(c)(3)).

1.8 **"Maximum Allowable Cost (MAC)"** shall mean the lowest reimbursement rate established by the State for the Covered Product.

1.9 **"Medicaid Drug Rebate Agreement"** shall mean the agreement in place between the Pharmaceutical Manufacturer and the U.S. 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.

1.10 **"Medicaid Member"** shall mean any person enrolled in the State Medicaid Program and eligible to receive prescription drug benefits under a fee for service arrangement.

1.10.1 a **"Medicaid Utilization Information"** shall mean the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and where applicable, Best Price. Utilization Information excludes data from covered entities identified in Title 42 U.S.C. § 256b(a)(4) in accordance with Title 42 U.S.C. § 256b(a)(4)(A) and 1396r-8(a)(5)(C).

1.10.1 b.**"National Drug Code (NDC)"** is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code.

1.11 **"Pharmacy"** shall mean a facility licensed to dispense legend drugs, and enrolled as a State Medicaid provider.

1.12 **"Preferred Drug List"** (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 OBRA 90 rebate agreements with CMS will remain covered, although some drugs that are Non-Preferred may require Prior Authorization consistent with Section 1927 of the Social Security Act. The Pharmacy and Therapeutics Committee will review drugs on a monthly or bi-monthly basis to make recommendations to the Department for drugs to be listed as Preferred or Non-Preferred on the PDL.

1.13 **"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.

1.14 **"State Supplemental Rebate"** shall mean an amount paid on a calendar quarter basis by the Pharmaceutical Manufacturer to State for covered product utilization under State'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 as listed on Attachment B.

1.15 **"Step Care"** shall mean a potentially defined order of therapeutic choices within either the preferred on non-preferred drug list categories. (See Section 2.1c)

1.16 **"Unit"** means a 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) of Covered Product.

1.17 **"USC"** means the United States Code. All references in this Agreement to USC chapters or sections shall include any successor, amended, or replacement statute.

2. **State Obligations**

2.1 **Preferred Drug List.** To be eligible for the Supplemental Rebates specified in Attachment B:

a) State shall place and maintain Covered Product(s) on the Preferred Drug List, it being agreed that utilization shall be eligible for the State Supplemental Rebate only in quarters in which Covered Product(s) is listed on the Preferred Drug List; and

b) State shall place Covered Product(s) in an advantaged position relative to non-preferred Competitive Product(s) regarding Preferred Drug List status, and

c) Depending on the designated preferred tier, the State shall place Covered product(s) in an advantaged position relative to other preferred products (Step Care). Non-Preferred and Step Care drugs may be subject to prior authorization. Criteria for approving prior authorization will be the responsibility of the DUR Committee. These criteria will meet generally accepted clinical standards of practice for the proper use of drugs, and

d) State shall have on file the fully executed CMS Exemption Letter, attached hereto as Exhibit C and incorporated by reference.

2.2 **Preferred Drug List Documentation and Publication.** State shall communicate the inclusion of Covered Product(s) on the Preferred Drug List to State Medicaid Program providers through the standard notification process.

2.3 **Invoicing.** State shall invoice the Pharmaceutical Manufacturer for State Supplemental Rebates separately from CMS Rebates using the format set forth by CMS. State 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(s) subject to such State Supplemental Rebate was paid for by State. Any amended invoice shall be submitted by State within fifteen (15) months after the end of the calendar quarter in which covered Product was paid for by State.

2.4 **Patient Information.** State, its agents, employees and contractors shall not provide to the 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.

2.5 **Approval of Generic.** If during the duration of this Agreement a generic equivalent of any Competitive Product should become available, State will allow Covered Product(s) to remain on the Preferred Drug List so long as the net cost to the State, as defined in Attachment B, is not more than the lowest reimbursement cost for a generic equivalent.

3.0 **Pharmaceutical Manufacturers Obligations**

3.1 **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 State and dispensed to Medicaid Members by Pharmacies for each calendar quarter that Covered Product(s) are included in the Preferred Drug List. The Pharmaceutical Manufacturer shall pay to State 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 State Medicaid Members. State shall remit the appropriate share of the State Supplemental Rebate payments made under the Agreement to CMS as required under its approved state plan.

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

3.3 **Incomplete Submission**. The Pharmaceutical Manufacturer shall have no obligation to pay State Supplemental Rebate amounts for claims that are not submitted as part of an invoice in accordance with Section 2.3 of this Agreement. The Pharmaceutical Manufacturer shall 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 2.3.

3.4 **Over/Underpayment.** If either party discovers an error in the payment of State Supplemental Rebates, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally accepted applicable procedures followed by State or CMS in disputes concerning Medicaid Drug Rebates. Any overpayment shall be deducted from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, State will refund any such overpayment to the Pharmaceutical Manufacturer within thirty (30) day of the parties' acknowledgement of the overpayment. Pharmaceutical Manufacturer will remit any underpayment to State within thirty (30) days of the parties' acknowledgement of such underpayment.

3.5 **Discretion to Market**. Nothing in this Agreement shall be construed to prohibit the Pharmaceutical Manufacturer 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 shall make every reasonable effort to notify State prior to such actions.

4.0 **Term and Termination**

4.1 **Effective Date.** This Agreement shall be effective _____ (date) and shall continue in force through _____(date), unless it is terminated sooner pursuant to 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 shall give the non-breaching party the right to cancel this agreement at the end of the thirty (30) day period. The non-breaching party shall give 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.

4.2 **Accrued Obligations/Remedies**. The expiration or termination of this Agreement shall 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 shall not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein shall not be deemed an exclusive remedy unless expressly provided for as such.

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

5.0 **Miscellaneous.**

5.1 **Record Keeping and Audit.** During the term of this Agreement and for a period of three (3) years thereafter, both parties to the Agreement shall 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, State shall make such information available for inspection by the Pharmaceutical Manufacturer representatives or its designated auditors during regular business hours. Upon written request, each party shall 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.

5.2 **Indemnification.** The Pharmaceutical Manufacturer shall be responsible for and shall indemnify and hold State harmless from all claims resulting from the acts or omissions of the Pharmaceutical Manufacturer in its performance of this Agreement.

5.3 **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 in connection with this Agreement will not be disclosed by the State. Each party shall 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.

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

_____ (name)	Yoon Kim-Butterfield, MD, Medical Director
_____ (title)	Director's Office
_____(manufacturer)	Division of Integrated Healthcare
_____(address)	Utah Department of Health & Human Services
_____(address)	PO Box 143102
_____(city, state, zip)	Salt Lake City, Utah 84114-3102

5.5 **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.

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

5.7 **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 shall not impair or waiver any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate.

5.8 **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.

5.9 **Governing Law**. This Agreement shall be governed by the laws of the State of Utah. In the event of a lawsuit involving this Agreement, venue shall be proper only in Salt Lake County, Utah.

5.10 **Effect of Future Laws**. In the event of the enactment, promulgation, rescission, modification or 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 shall have the right to 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.

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

5.12 **Authority**. State 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 shall thereby be bound.

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

5.14 **CMS Approval Contingency**. The effectiveness of this Agreement shall be contingent on receipt of CMS approval.

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

(Manufacturer)	**Utah Department of Health & Human Services**
(Name)	Jennifer Strohecker
(Title)	Medicaid Director
(Manufacturer)	Utah Department of Health & Human Services
(Address)	PO Box 144002
(Address)	Salt Lake City, UT 84114-4002

_____
Signature: (Type Name)

_____
Signature: Jennifer Strohecker

_____
Date:

_____
Date:

Attachments to this Agreement include:

Attachment A and Attachment B:

Lines	Product Name
(Line number)	(Drug name)

Exhibit C: Authorization Letter from Centers for Medicare and Medicaid Services (CMS) for Utah's Supplemental Drug Rebate Agreement

ATTACHMENT A

Utah Department of Health & Human Services

Division of Integrated Healthcare

Medicaid Preferred Drug List

Covered Products

Supplemental Rebate Agreement – (Manufacturer name)

(Effective Dates)

Line #	Product ID	Drug Name	Formula
1	(NDC)	(Drug name & description)	(Formula number)
2	(NDC)	(Drug name & description)	(Formula number)
3	(NDC)	(Drug name & description)	(Formula number)
4	(NDC)	(Drug name & description)	(Formula number)
5	(NDC)	(Drug name & description)	(Formula number)

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ATTACHMENT B

Utah Department of Health & Human Services

Division of Integrated Healthcare

Medicaid Preferred Drug List

Covered Products

Supplemental Rebate Agreement – (Manufacturer name)

(Effective Dates)

Line #	Manufacturer Name	NDC	Product Description	AWP	WAC	CMS Rebate	*AT	**FN	***% of WAC	Accepted GNP	Comments
1	(Manufacturer Name)	(NDC)	(Drug & description)								(Comments)
2	(Manufacturer Name)	(NDC)	(Drug & description)								(Comments)
3	(Manufacturer Name)	(NDC)	(Drug & description)								(Comments)
4	(Manufacturer Name)	(NDC)	(Drug & description)								(Comments)
5	(Manufacturer Name)	(NDC)	(Drug & description)								(Comments)

*AT = Accepted Tier
**FN = Formula Number
***% of WAC = Accepted % of WAC (expressed as a decimal)

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

Formula 101: Percentage of WAC. Formula for Supplemental Rebate Calculation: WAC X % off WAC = Supplemental Rebate Amount per unit
Formula 102: Guaranteed Net Price. Formula for Supplemental Rebate Calculation: WAC = CMS Rebate – Guaranteed Net Price = Supplemental Rebate Amount per unit