Delaware State Supplemental Rebate Agreement
And
MANUFACTURER

The Delaware Department of Health and Social Services, Division of Medicaid and Medical Assistance (hereinafter "Department" or "DMMA") and MANUFACTURER (Manufacturer) have entered into this Agreement for the purpose of establishing a State Supplemental Rebate for utilization of the Manufacturer's Preferred Product(s) by Delaware Medicaid recipients, which will be in addition to rebates received under the National Drug Rebate Agreement, pursuant to Section 1927 of the Social Security Act ("the Act"), 42 U.S.C. § 1396r-8. The parties intend for this Agreement to meet the requirements of 42 U.S.C. § 1396r-8.

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein, the parties agree to enter into this Agreement in accordance with the terms and conditions as follows:

Article 1. Definitions. As used in this Agreement, the following terms have the following meanings:

1.1. **"Average Manufacturer Price"** or **"AMP"** shall have the meaning set forth in Section 1927(k)(1) of the Act as implemented by 42 C.F.R. 447.504.

1.2. **"Best Price"** shall have the meaning set forth in Section 1927(c)(1)(C) of the Act as implemented by 42 C.F.R. 447.505.

1.3. **"CMS"** shall mean the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

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

1.5. "**Covered Outpatient Drug**" will have the meaning as set forth in Sections 1927(k)(2), (k)(3) and (k)(4) of the Act as implemented by 42 C.F.R. 447.502.

1.6. **"Medicaid MCO"** means a Medicaid managed care organization that is responsible for coverage of Covered Outpatient Drugs for Medicaid Recipients who are enrolled with the managed care entity, as further described in 42 U.S.C. § 1396b(m)(1).

1.7. **"Medicaid Recipient"** shall mean any person enrolled in the Delaware Medicaid Program and eligible to receive prescription drug benefits through the Program.

1.8. "**Medicaid Utilization**" means the total number of Units of each dosage form and strength of the Manufacturer's Preferred Products reimbursed through Fee-for-Service or dispensed through Participating Medicaid MCO programs during a Quarter under the Medicaid State Plan supporting the State's invoice for State Supplemental Rebates. Fee-for-Service utilization information is based on claims paid during a Quarter. Participating Medicaid MCO utilization information is based on drugs dispensed with a date of service during a Quarter. Medicaid 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 Utilization 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).

1.9. **"National Drug Code"** or **"NDC"** shall have the meaning as set forth in 42 C.F.R. § 447.502.

1.10. **"National Drug Rebate Agreement" or "NDRA"** shall mean the rebate agreement developed and entered into by the Secretary of the United States Department of Health and Human Services or his or her designee and a manufacturer pursuant to 42 U.S.C. § 1396r-8.

1.11. **"National Unit Rebate Amount"** shall mean the computed amount to which the Medicaid Utilization data is applied by states in invoicing Manufacturer for rebates in accordance with NDRA.

1.12. **"Participating Medicaid MCO"** means a Medicaid MCO that is contracted with the DMMA to supply a prescription drug benefit to Delaware Medicaid Recipients. In order to qualify as a "Participating Medicaid MCO", the Medicaid MCO must have aligned its formulary and/or Preferred Drug List, as applicable, with the DMMA Fee-for-Service Program Preferred Drug List, assuring access to a Preferred Product is no more restrictive than the DMMA Fee-for-Service Program Preferred Drug List requirements applicable to the Preferred Product.

1.13. **"Pharmaceutical and Therapeutics Committee"** or **"P&T Committee"** shall mean the committee established for the purpose of providing Preferred Drug List recommendations to DMMA.

1.14. **"Preferred Drug List"** or **"PDL"** shall mean the list of preferred drugs adopted by the Department after consultation with the P&T Committee.

1.15. **"Quarter"** shall mean one of the four three-month periods by which the calendar year is divided.

1.16. **"State Supplemental Rebate"** shall mean the quarterly amount invoiced by the DMMA as calculated in accordance with the Contracted Products Attachment. Pursuant to 42 C.F.R. § 447.504(h), State Supplemental Rebates are excluded from AMP. Pursuant to 42 C.F.R. § 447.505(d), State Supplemental Rebates are excluded from Best Price.

1.17. **"Unit"** means drug unit in the lowest identifiable amount as specified by Manufacturer as part of the submission of data under 42 U.S.C. § 1396r-8.

1.18. **"Wholesale Acquisition Cost"** or **"WAC"** shall mean the Manufacturer's 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, if any.

Article 2. Term and Scope of Agreement.

2.1. **Term**. The term of this Agreement shall be from January 1, 2024 through December 31, 2024, unless the Agreement is otherwise terminated as set forth herein.

2.2. **Modification of Agreement**. This Agreement may be amended only by the written, mutual agreement of the parties. No amendment of this Agreement shall be binding unless it is in writing and signed by both parties.

2.3. **Entirety of Agreement**. The terms and conditions of this Agreement, which shall include any duly executed amendments thereto; any and all attached and/or expressly incorporated addenda, attachments, documents, exhibits; and any and all applicable Delaware administrative regulations along with any documents expressly incorporated therein, shall constitute the entire present agreement between the parties. Notwithstanding anything in this Agreement to the contrary, this Agreement shall have no effect whatsoever on Manufacturer's rights and obligations under its National Drug Rebate Agreement.

Article 3. Termination.

3.1. **Termination By Manufacturer**. This Agreement may not be terminated by Manufacturer, except that (i) this Agreement shall be co-terminous with Manufacturer's National Drug Rebate Agreement, in the event that such agreement is terminated for any reason, and (ii) this Agreement may be terminated by Manufacturer in its entirety as of the end of the quarter upon ninety (90) days written notice for reasons of material breach.

3.2. **Termination Without Cause By DMMA.** This Agreement may be terminated by the DMMA in its entirety or as to any Contracted Product(s) or NDC(s) as of the end of the quarter upon ninety (90) days written notice to Manufacturer.

3.3. **Termination by Either Party.** This Agreement may be immediately terminated by either party upon a modification to 42 C.F.R. § 447.504(h) removing or limiting the exclusion of the State Supplemental Rebate from AMP and/or to 42 C.F.R. § 447.505(d) removing or limiting the exclusion of the State Supplemental Rebate from Best Price.

3.4. **Non-waiver**. Failure of Manufacturer or DMMA to insist on performance of any term or condition of this Agreement or to exercise any right or privilege hereunder shall not be construed as a continuing or future waiver of such term, condition, right or privilege.

3.5. **Violation of Law**. Any party may immediately terminate this Agreement if there is a determination by any court of competent jurisdiction or any authorized governmental authority that the arrangements and transactions under this Agreement or any similar agreement constitute a violation of any law or regulation including without limitation 42 U.S.C. § 1320a-7b(b) prohibiting illegal remuneration.

3.6. **Effect on Accrued Obligations**. 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, Supplemental Rebates accrued hereunder but not yet paid and/or invoiced.

Article 4. Agreement Management and Notices.

4.1. **Notices**. All written notices, requests and communications, unless specifically required to be given by a specific method, may be: (i) delivered in person, obtaining a signature indicating successful delivery; (ii) sent by a recognized overnight delivery service, obtaining a signature indicating successful delivery; or (iii) sent by certified mail, obtaining a signature indicating successful delivery, to the address set forth below. Notice dates for web invoices, if any, shall be determined in accordance with CMS National Drug Rebate invoicing guidance (Medicaid Drug Rebate Program Release No. 80 (Jan. 5, 2010)).

To Manufacturer: **MANUFACTURER**

Address	NOTICE CONTACT ADDRESS ADDRESS CITY, STATE ZIP

To DMMA:

Address	DMMA CHIEF OF ADMINISTRATION – Alexis Bryan-Dorsey Management Services Unit 1901 N. DuPont Highway LEWIS Bldg. P.O. Box 906 New Castle, DE 19720

Article 5. Manufacturer's Rights and Responsibilities.

5.1. **State Supplemental Rebate Payment**. Manufacturer will provide the Department with the National Unit Rebate Amount for the Contracted Product(s) in accordance with Manufacturer's National Drug Rebate Agreement. Manufacturer's obligation to pay National Rebates will continue for the duration of the Manufacturer's National Drug Rebate Agreement and shall not be impacted by State Supplemental Rebates hereunder. In addition to the National Rebate, Manufacturer agrees to provide a State Supplemental Rebate to DMMA for Medicaid Utilization of Contracted Products that are designated as Preferred Products on the PDL during the Quarter. Manufacturer shall pay the State Supplemental Rebate amount in accordance with the formula set forth in the Contracted Products Attachment. For the avoidance of doubt, as is the case with National Rebates, State Supplemental Rebates applicable to Participating Medicaid MCO utilization shall be payable to the DMMA, and shall not be paid directly to the Participating Medicaid MCOs, notwithstanding the Participating Medicaid MCO utilization will be invoiced separately from Fee-For-Service Medicaid Utilization. Nothing in this Agreement shall be construed to relieve Manufacturer from its obligation to pay National Rebates under contracts, if any, with CMS for utilization by Medicaid Recipients.

A. ***Payment Timeframe.*** Manufacturer shall pay the State Supplemental Rebate amount to the Department, including any applicable interest as outlined in 5.1.C. of this Agreement, to which the Department is entitled in accordance with the formula set forth in the Contracted Products Attachment, within thirty-eight (38) days of receipt of an invoice from the Department.

B. ***Timeliness.*** Manufacturer's failure to remit the State Supplemental Rebate amount in a timely manner may result in the removal of the relevant Contracted Product from the Preferred Drug Lists, pursuant to the application of the dispute resolution process set forth in Paragraph E, below.

C. ***Interest.*** Manufacturer will pay the State Supplemental Rebates, including any applicable interest. Interest on the State Supplemental Rebates payable under Section 5.1 of this Agreement begins accruing 38 calendar days from the earlier of the postmark date of the State Supplemental Rebate invoice sent to Manufacturer or the date on which the State Supplemental Rebate invoices were made available on the Delaware Secured Server. Interest will continue to accrue until the postmark date of Manufacturer's payment. Interest on the State Supplemental Rebates is calculated in the same manner as interest on the National Rebate:

(1). Obtain yield rates of weekly auction of 13-Week Treasury bills under Investment Rate % or in the DDR.
(2). Determine the date range for which interest is owed beginning with the 38th day

from the invoice postmark date.

(3). Total the yield rates of each weekly auction for the period during which interest applies.

(4). Divide that total by the number of yield rates (i.e., the number of weeks) to determine the average interest rate. Add 10% to that number.

(5). Multiply the average interest rate by the amount of unpaid rebate to determine the amount of interest due.

(6). Divide the amount of interest by 365 days to determine the daily interest amount due.

(7). Multiply the daily interest amount by the number of days for which interest is owed. This amount represents the total interest owed.

If the date of mailing or posting of a State Supplemental Rebate payable under Section 5.1 of this Agreement is 39 days or more from the date of mailing or posting of the invoice, the interest rate will be increased by ten percentage points (10%).

D. ***Incomplete Submission***. Manufacturer shall have no obligation for claims that are not submitted as part of an invoice in accordance with Section 6.3 of this Agreement. Manufacturer shall notify DMMA of any incomplete submission within thirty-eight (38) days after Manufacturer's receipt of such submission pursuant to Section 6.3.

E. ***Over/Underpayment***. If either party discovers an error in the payment of State Supplemental Rebates by Manufacturer, it shall notify the other party 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 applicable procedures followed by the Department or CMS in disputes concerning National Rebates. In the event both parties determine that an overpayment has been made by Manufacturer, Manufacturer shall deduct such overpayment from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, the Department will refund any such overpayment to Manufacturer within thirty (30) days after its acknowledgment of the overpayment. Manufacturer will remit any underpayment, including interest accrued under Section 5.1(C) of this Agreement, to the Department within thirty (30) days after Manufacturer's acknowledgment of such underpayment. Notwithstanding anything to the contrary herein, any dispute relating to eligibility of Medicaid MCO utilization for State Supplemental Rebates hereunder shall be resolved exclusively between Manufacturer and the Department.

5.2. **Discretion to Market**. Nothing in this Agreement shall be construed to prohibit Manufacturer from discontinuing production, marketing or distribution of any Contracted Product or from transferring or licensing any Contracted Product to a third party. If Manufacturer elects to discontinue production, marketing or distribution of any Contracted Product or to transfer or license any Contracted Product to a third party, Manufacturer shall notify DMMA as soon as commercially reasonable of such action. The Department has the right to terminate this Agreement without cause upon such notification. If Manufacturer fails to notify DMMA, Manufacturer shall continue to be responsible for all State Supplemental Rebates until such notification is given.

Article 6. Medicaid Program's Rights and Responsibilities.

6.1. **Covered Benefit**. The DMMA shall provide or arrange for the provision of pharmacy services to Medicaid Recipients.

6.2. **Preferred Drug List.** As a part of its process of drug prior authorization, DMMA shall adopt and maintain a Preferred Drug List. No Contracted Product on the Preferred Drug List shall be discouraged or

disadvantaged in any way relative to any other single source brand name prescription drug in its therapeutic class unless specifically stated otherwise on the Contracted Products Attachment. Notwithstanding the forgoing, DMMA may apply prior authorization, step therapy or similar controls to all products in a particular therapeutic class, or where the Manufacturer has explicitly agreed to the terms of such controls in writing as part of its State Supplemental Rebate terms, without violation of this Section 6.2.

A. ***DMMA's Preferred Drug List Documentation and Publication.*** The DMMA shall publish its Preferred Drug List for each therapeutic class on its website within thirty (30) days after the effective date of such Preferred Drug List for that therapeutic class, and shall update such website annually or after each therapeutic class review by the P&T Committee. For the avoidance of doubt, the effective date of a drug on a PDL may pre-date by up to thirty (30) days, the publication of the applicable PDL on the applicable website.

B. ***P&T Committee***. The DMMA shall maintain a P&T Committee that shall review and recommend drug products and/or supplies for inclusion on the Preferred Drug List, at the sole discretion of DMMA.

6.3. **Invoicing**. The DMMA shall invoice State Supplemental Rebates separately from National Rebates in accordance with the formulae set forth in the Contracted Products Attachment and any applicable CMS requirements regarding invoice format. In addition, where State Supplemental Rebates are invoiced for Participating Medicaid MCO utilization, such Medicaid MCO utilization may be invoiced separately from Medicaid Fee-For-Service utilization

6.4. **CMS Authorization**. The Department respectively represents and warrants that CMS has authorized this Agreement.

Article 7. General Terms.

7.1. **Audits and Records**.

A. ***Right of Audit***. This Agreement, and all books, records, and supporting documents related thereto, shall be available for review or audit by the DMMA, the Office of Inspector General, the Medicaid Fraud Control Unit, the United States Department of Health and Human Services, the state legislative branch or state executive branch auditor or other auditor and other state and federal agencies with monitoring authority related to the subject matter of this Agreement ("**Authorized Persons**"), but subject to the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D), and Manufacturer agrees to cooperate fully with any such review or audit. Upon reasonable notice by any Authorized Person, Manufacturer shall provide, in the appropriate venue for the DMMA or at any other location designated by the Authorized Person, during normal business hours, full and complete access to the relevant portions of Manufacturer's books and billing records as they relate to payments under this Agreement. Any identified over-or under-payments shall be resolved in accordance with Section 5.1(E) of this Agreement.

B. ***Retention of Records***. Manufacturer shall maintain, during the term of this Agreement in accordance with 42 C.F.R. Part 447 and other applicable law, all business, professional and other records, written or electronic, in accordance with applicable law, the specific terms and conditions of this Agreement, and pursuant to generally accepted accounting practice. Failure to maintain books, records, and supporting documents required by this Agreement shall establish a presumption in favor of the DMMA for the recovery of any funds owed to the DMMA under the Agreement for which adequate books, records, and other documents are not available to support the purported disbursement.

7.2. **Choice of Law.** Manufacturer agrees to be bound by the laws of Delaware and agrees that this Agreement shall be construed and interpreted in accordance with Delaware law without giving effect to the conflicts of laws provision thereof. The parties agree to exclusive jurisdiction of the state and federal courts sitting in the State of Delaware for adjudication of any dispute arising out of or related to this Agreement. This provision does not supersede federal law to the extent federal law is applicable and controlling.

7.3. **Confidentiality.**

A. ***Confidential Information.*** Subject to 42 U.S.C. § 1396r-8(b)(3)(D), and subject to any other applicable state and federal law, performance of the Agreement may require Manufacturer to have access to and use of documents and data, including without limitation Medicaid Utilization data, which may be considered and/or identified as confidential and/or proprietary. Any confidential Information obtained by Manufacturer in connection with carrying out the services under this Agreement shall be kept confidential. In addition, pursuant to 42 U.S.C. § 1396r-8(b)(3)(D) and this Agreement., information pertaining to Manufacturer's National Rebate, State Supplemental Rebate, and/or the components and calculations thereof disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the DMMA or by a state contractor in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary to carry out the provisions of 42 U.S.C. § 1396r-8 , and to permit review under 42 U.S.C. § 1396r-8 by the U.S. Comptroller General. Each party shall protect the confidentiality of the other party's Confidential Information to which the receiving party obtains access by virtue of its performance under this Agreement, that either has been identified as confidential by the disclosing party or by its nature warrants confidential treatment. The receiving party shall use such Confidential Information of the other party only for the purpose of this Agreement and shall not disclose it to anyone except those of its employees, consultants, contractors, agents, and assigns who need to know the information provided that such persons and/or entities are notified of all confidentiality and non-disclosure provisions stated herein and expressly warrant and represent that they shall abide by such. These nondisclosure obligations shall not apply to Confidential Information that is or becomes public through no breach of this Agreement, which is received from a third party free to disclose it, that is independently developed by the receiving party, or that is required by law to be disclosed. In the event that either party is required by law to disclose any provision of this Agreement or any Confidential Information provided pursuant to this Agreement to any person, such party shall, to the extent permitted by applicable law, 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. This Section shall survive termination or expiration of this Agreement as to all parties.

B. ***Confidentiality of Program Recipient Identification***. Manufacturer shall ensure that all information, records, data, and data elements pertaining to applicants for and recipients of public assistance, or to providers, facilities, and associations, shall be protected from unauthorized disclosure by Manufacturer and Manufacturer's employees, by Manufacturer's corporate affiliates and their employees, and by Manufacturer's subcontractors and their employees, pursuant to 42 C.F.R. Part 431, Subpart F and any other applicable federal or state law, including the Health Insurance Portability and Accountability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH").

7.4. **Fraud & Abuse**. It is the Department's intent that the business arrangement contemplated by this Agreement is not prohibited by the provisions of 42 U.S.C. § 1320a-7b(b), prohibiting certain illegal remuneration, as such provisions may be amended from time to time. In any event, should the provisions of 42 U.S.C. § 1320a-7b(b) apply to this arrangement, it is DMMA's intent that the business arrangement contemplated by this Agreement meets the discount exception found in 42 U.S.C. § 1320a-7b(b)(3)(A), and regulatory safe harbor for discounts at 42 C.F.R. § 1001.952(h). The Department currently provides CMS full and unfettered access to all information held by DMMA regarding the implementation of health care

delivery and reimbursement policies, and shall continue to do so for the duration of State Supplemental Rebate and Preferred Drug List programs.

7.5. **Nondiscrimination.** In the performance of its obligations under this Agreement, Manufacturer shall abide by, and shall cause any Manufacturer subcontractor to abide by all applicable Federal and State laws, regulations and orders which prohibit discrimination because of race, creed, color, religion, sex, sexual orientation, national origin, ancestry, age, or physical or mental disability, including but not limited to, the Federal Civil Rights Act of 1964, the Americans with Disabilities Act of 1990 and the Federal Rehabilitation Act of 1973.

7.6. **Rules of Construction**. Unless the context otherwise requires or unless otherwise specified, the following rules of construction apply to this Agreement:

A. Provisions apply to successive events and transactions;

B. "Or" is not exclusive;

C. References to statutes and rules include subsequent amendments and successors thereto;

D. The various headings of this Agreement are provided for convenience only and shall not affect the meaning or interpretation of this Agreement or any provision hereof;

E. If any payment or delivery hereunder shall be due on any day that is not a business day, such payment or delivery shall be made on the next succeeding business day;

F. "Days" shall mean calendar days; "business day" shall mean a weekday (Monday through Friday), excepting State holidays, between the hours of 8:00 a.m. Eastern Standard Time and 5:00 p.m. Eastern Standard Time; and

G. Words in the plural which should be singular by context shall be so read, and vice versa.

7.7. **Federal Rebate Statute.** This Agreement shall be governed and construed in accordance 42. U.S.C. § 1396r-8 and all other applicable federal and state law and regulations, as may be amended from time to time.

7.8. **Severability.** In the event that any provision, term or condition of this Agreement is declared void, unenforceable, or against public policy, then said provision, term or condition shall be construed as though it did not exist and shall not affect the remaining provisions, terms, or conditions of this Agreement, and this Agreement shall be interpreted as far as possible to give effect to the parties' intent.

7.9. **Survival of Obligations**. Those obligations under this Agreement that, by their nature, are intended to continue beyond the termination or expiration of this Agreement, shall survive the termination or expiration of this Agreement.

IN WITNESS WHEREOF, DMMA has caused this Agreement to be executed on the dates shown below by representatives authorized to bind the respective parties.

MANUFACTURER	**DELAWARE DEPARTMENT OF HEALTH AND SOCIAL SERVICES**
By: _____	By: _____
Name: _____	Name: Andrew Wilson
Title: _____	Title: DMMA Director
Date: _____	Date: _____

Contracted Products Attachment

Manufacturer	NDC	Product Description	Tier	Formula	Contracted Rate	Comments

[1] Tiers

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).

[2] Formulas

- Formula 1: Percentage of WAC.
  Formula for Supplemental Rebate calculation: WAC*% of WAC=Supplemental Rebate Amount per Unit

- Formula 2: Guaranteed Net Price.
  Formula for Supplemental Rebate calculation: WAC-National Rebate-Guaranteed Net Price=Supplemental Rebate Amount per Unit