Iowa Department of Health and Human Services

IOWA MEDICAID SUPPLEMENTAL DRUG REBATE AGREEMENT

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

Pharmaceutical Manufacturer ("Manufacturer")	**Department of the State of Iowa ("Department")**
Labeler Code(s):	**Iowa Department of Health and Human Services**
Manufacturer Primary Billing Address:	**Department Primary Billing Address:**
	Iowa Medicaid Drug Rebate PO Box 850195 Minneapolis, MN 55485-0195
Manufacturer Primary Contact Person:	**Department Primary Contact Person:**
	Shari Martin
Manufacturer Primary Contact Telephone:	**Department Primary Contact Telephone:**
	207-622-7153 EXT 71375
Manufacturer Primary Contact e-mail:	**Department Primary Contact e-mail:**
	PBA_srcontracts@changehealthcare.com
Address for Notices required by Agreement ("Manufacturer Notice Address"):	**Address for Notices required by Agreement: ("Department Notice Address"):**
	Electronic: Abby Cate, PharmD: acate@dhs.state.ia.us Physical: Iowa Department of Health and Human Services Attn: Abby Cate, PharmD, Pharmacy Consultant 1305 East Walnut Street Des Moines, IA 50319-0114
Termination Date: ("Termination Date")	**Effective Date ("Effective Date")**
12/31/2025	01/01/2025

In consideration of the mutual covenants in this Agreement, including the General Supplemental Rebate Terms, the Contracted Products Attachment to this Agreement, and for other good and valuable consideration, the receipt, adequacy and legal sufficiency of which are hereby acknowledged, the parties have entered into this Agreement and have caused their duly authorized representatives to execute this Agreement below.

Manufacturer, by:	**Department, by:**
Signature:	Signature:
Printed Name:	Printed Name: Director Kelly Garcia
Title:	Title: Director, Iowa Health and Human Services

Date:	Date:

General Supplemental Rebate Terms

1. PURPOSE

The Department and Manufacturer have entered into this Agreement for the purpose of establishing a State Supplemental Rebate for utilization of the Manufacturer's Preferred and Recommended Product(s) by the Medicaid Population, which will be in addition to rebates received under the National Medicaid Drug Rebate Agreement, pursuant to 42 U.S.C. § 1396r-8.

2. DEFINITIONS

2.1 **Average Manufacturer Price (AMP)** will have the meaning set forth in 42 U.S.C. § 1396r-8 as implemented by 42 C.F.R. § 447.504.

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

2.3 **Centers for Medicare & Medicaid Services (CMS)** will mean the division of the United States Department of Health and Human Services having the delegated authority to operate the Medicaid program.

2.4 **Contracted Product(s)** will mean any product listed on the Contracted Products Attachment of this Agreement.

2.5 **Medicaid MCO** will mean a managed care organization that has contracted with the Department to provide Medicaid benefits to Medicaid members.

2.6 **Medicaid Population** will mean all persons enrolled in a participating Medicaid program and eligible for Medicaid prescription drug benefits under the fee-for-service program or through a Medicaid MCO.

2.7 **Medicaid PDL/RDL Utilization** will mean the total number of units of the Manufacturer's Preferred Product(s) and Recommended Product(s) that are subject to the State's Preferred Drug List or Recommended Drug List and reimbursed through Medicaid Fee-for-Service or dispensed through a Medicaid MCO during a Quarter. Medicaid PDL/RDL Utilization excludes utilization 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).

2.8 **National Drug Code (NDC)** will have the meaning set forth in 42 C.F.R. § 447.502.

2.9 **National Medicaid Drug Rebate Agreement** will mean the rebate agreement entered into by CMS on behalf of 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.

2.10 **National Unit Rebate Amount (URA)** will mean the computed amount to which the Medicaid PDL/RDL Utilization is applied by the State in invoicing a Manufacturer for rebates in accordance with the National Medicaid Drug Rebate Agreement.

2.11 **Preferred Drug List (PDL)** will mean the list, inclusive of Preferred Products, developed by the Pharmaceutical and Therapeutics (P&T) Committee and adopted by the Department pursuant to Iowa Code § 249A.20A.

2.12 **Preferred Product** will mean any Contracted Product included as preferred on the PDL.

2.13 **Quarter** will mean calendar quarter unless otherwise specified**.**

2.14 **Rebate Payment Due Date** will mean the date that is 37 days following the postmark date of the State Supplemental Rebate invoice.

2.15 **Recommended Drug List (RDL)** will mean the list of Recommended Products developed by the Pharmaceutical and Therapeutics (P&T) Committee and adopted by the Department. The RDL is comprised of drugs excluded from inclusion on the PDL pursuant to Iowa Code § 249A.20A.

2.16 **Recommended Product** will mean any Contracted Product included as recommended on the RDL.

2.17 **State Supplemental Rebate** will mean the quarterly amount invoiced by the Department as calculated in accordance with the Contracted Product Attachment of this Agreement.

2.18 **Unit** will mean the drug unit in the lowest dispensable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams) and shall be the same unit as specified by the Manufacturer as part of the submission of data under 42 U.S.C. § 1396r-8.

2.19 **Wholesale Acquisition Cost (WAC)** will mean the Manufacturer's list price for the 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.

3. MANUFACTURER'S RESPONSIBILITIES

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

3.2 Manufacturer will remit to the Department a State Supplemental Rebate for Medicaid PDL/RDL Utilization of Contracted Product(s) that are designated as Preferred Products on the PDL or Recommended Products on the RDL. Manufacturer shall pay to the Department the State Supplemental Rebate amount in accordance with the formula set forth in the Contracted Products Attachment of this Agreement.

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

3.4 Interest accrues on disputed or unpaid balances after the Rebate Payment Due Date until receipt of Manufacturer's payment. Rebate payments mailed more than 68 days from the date of invoice shall include interest, calculated in the same manner as late rebate payment for the National Medicaid Drug Rebate Program.

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

3.6 Unless notified otherwise, the Manufacturer will send State Supplemental Rebate payments to the Department Primary Billing Address identified on the first page of this Agreement.

4. DEPARTMENT RESPONSIBILITIES

4.1 The Department shall publish a PDL/RDL inclusive of Preferred/Recommended Products that:

(a) Shall not be discouraged or disadvantaged in any way relative to any other drug product in its therapeutic class unless specifically stated otherwise in the Contracted Products Attachment of this Agreement.

(b) Shall not be subject to clinical edits, prior authorization, step therapy or similar utilization management controls that are more stringent than the FDA-approved product labeling unless specifically stated otherwise in the Contracted Products Attachment of this Agreement.

4.2 The established PDL and RDL shall be state run and utilized for the Medicaid Population.

4.3 The Department will provide Medicaid PDL/RDL Utilization to the Manufacturer within ninety (90) days of the last day of each Quarter. Medicaid PDL/RDL Utilization data to be supplied includes, for each NDC number: 1) Product name; 2) Number of Units; 3) Number of prescriptions; and 4) Total amount reimbursed.

4.4 In the event material discrepancies in the Medicaid PDL/RDL Utilization data are discovered by the Manufacturer, the Department will make available supporting data that is then in existence concerning the claimed utilization. If the review of all available data identifies a discrepancy that requires a reconciliation of the State Supplemental Rebate, any such reconciliation shall be made in the next quarterly invoice.

4.5 The Department shall maintain electronic claims records for the most recent four Quarters that will permit the Manufacturer to verify through an audit process the Medicaid PDL/RDL Utilization data provided by the Department. Should such an audit be required, the Department and Manufacturer will develop mutually beneficial audit procedures to resolve disputes regarding Medicaid PDL/RDL Utilization data.

4.6 Upon implementation of this Agreement, and from time to time thereafter, the Department and Manufacturer will meet to discuss any data or data system improvements that are necessary or desirable to ensure that the data and any information provided by the Department to the Manufacturer are adequate for the purposes of this Agreement.

5. DISPUTE RESOLUTION

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

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

5.3 If the Manufacturer in good faith believes the Department's calculation of the State Supplemental Rebate is erroneous, the Manufacturer shall pay the Department that portion of the State Supplemental Rebate claimed that is not disputed by the Rebate Payment Due Date. The balance in dispute, if any, plus a reasonable rate of interest as set forth in 42 U.S.C. § 1396b(d)(5), will be paid by the Manufacturer by the due date of the next quarterly payment after resolution of the dispute.

5.4 The Department and Manufacturer will use their best efforts to resolve the discrepancy within sixty (60) days of receipt of written notification. Either party may, at any time and at its own expense, hire a mutually agreed upon independent auditor to verify the accuracy of the Department's calculation of the State Supplemental Rebate or the Manufacturer's calculations and payment figures. Should an audit of pharmacy records be required to resolve disputes, the Department will cooperate with the Manufacturer and provide information by zip code of pharmacy provider upon the Manufacturer's request.

5.5 In the event that the Department and Manufacturer are not able to resolve a discrepancy within sixty (60) days, the Manufacturer may appeal in accordance with the rules for appeals to the Department outlined in Iowa Admin. Code ch. 441-7 in writing to:

Iowa Department of Health and Human Services
Administrative Appeals
Appeals Section, 5th Fl
1305 East Walnut St
Des Moines IA 50319-0114

6. CONFIDENTIALITY PROVISIONS

6.1 Pursuant to 42 U.S.C. § 1396r-8(b)(3)(D) and this Agreement, price information disclosed by the Manufacturer in connection with this Agreement is confidential and will not be disclosed by the State Medicaid Agency in a form that reveals the Manufacturer, or prices charged for drugs by the Manufacturer, except as necessary to carry out the provisions of and to permit review under 42 U.S.C. § 1396r-8 by the Secretary, the Comptroller General, the Director of the Congressional Budget Office or State Agency employees, consultants, contractors and agents, including the Iowa Medicaid Fraud Control Unit (MFCU) . To the extent that the Department utilizes the services of a third-party to develop and maintain the PDL and RDL, or to administer any part of this Agreement, all provisions of this Section 6 shall apply to the third-party, and the Department shall have the third-party sign a written agreement ensuring that the third-party will comply with all aspects of this confidentiality obligation. In the event that the Department is required by law to disclose any provision of this Agreement or rebate information to any person other than as provided above, the Department shall provide written notice to the Manufacturer sufficiently in advance of the proposed disclosure to allow the Manufacturer to seek a protective order or other relief.

6.2 Manufacturer shall ensure that all information, records and data pertaining to applicants for and recipients of public assistance shall be protected from unauthorized disclosure by the Manufacturer, its employees, consultants, contractors and agents, and corporate affiliates and their employees, pursuant to 42 C.F.R. Part 431, Subpart F and any other applicable federal or state law.

6.3 The provisions of this section and any confidentiality agreement executed pursuant to this section shall survive termination or expiration of this Agreement.

7. NONRENEWAL OR TERMINATION

7.1 This Agreement shall be effective on the Effective Date and, absent early termination pursuant to the terms of this Agreement, shall continue in force until the Termination Date.

7.2 This Agreement may be terminated by the Department, in whole or as to any Covered Product(s) or NDC(s) without cause as of the end of the calendar Quarter upon ninety (90) days written notice to the Manufacturer.

7.3 This Agreement may be immediately terminated upon the occurrence of any one of the following events:

(a) A determination by any court of competent jurisdiction or any authorized governmental authority that the arrangements and transactions under this Agreement constitute a violation of any law or regulation including without limitation 42 U.S.C. § 1320a-7b(b) prohibiting illegal remunerations. (For the purposes of this Section, "authorized governmental authority" shall mean any officer or agency of the Federal Government (e.g., Office of Inspector General, Department of Justice, Department of Health and Human Services) or the State of Iowa (e.g., Iowa Attorney General) having substantive jurisdiction over the subject matter of this Agreement; any state or federal program with which this Agreement is connected; any actions which must be taken by either party hereto in order to perform its obligations under this Agreement or any laws or regulations affecting the legality of this Agreement.); or

(b) A modification to 42 C.F.R. § 447.504(c) removing or limiting the exclusion of the State Supplemental Rebate from AMP and/or to 42 C.F.R. § 447.505(c) removing or limiting the exclusion of the State Supplemental Rebate from Best Price.

7.4 Termination of this Agreement shall have no effect upon the rights and obligations of the parties arising out of any transaction occurring prior to the

effective date of such termination including, without limitation, State Supplemental Rebates and interest accrued but not yet paid and/or invoiced.

8. GENERAL PROVISIONS

8.1 This Agreement will be governed and construed in accordance with 42 U.S.C. § 1396r-8 and all other applicable federal law and regulations as those laws and regulations may be amended from time to time.

8.2 Any notice required to be given pursuant to the terms and provisions of this Agreement will be in writing and will be sent by parcel delivery service (UPS, FedEx or DHL). Notice to the Department will be sent to the Department Notice Address identified on the first page of this Agreement. Notice to the Manufacturer will be sent to the Manufacturer Notice Address identified on the first page of this Agreement.

8.3 Manufacturer agrees to be bound by the laws of the State of Iowa and agrees that this Agreement shall be construed and interpreted in accordance with Iowa law without giving effect to the conflicts of laws provisions thereof. This provision does not supersede federal law to the extent federal law is applicable and controlling.

8.4 Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's or Manufacturer's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

8.5 Manufacturer and the agents and employees of the Manufacturer in the performance of this Agreement will act in an independent capacity and not as officers, employees or agents of the State of Iowa.

8.6 In the event of a transfer in ownership of Manufacturer, this Agreement shall be automatically assigned to the new owner subject to the conditions of this Agreement. If this Agreement is assigned by the Manufacturer, pursuant to this

section, the Manufacturer shall notify the Department of the new Manufacturer contact information and assignee shall be fully responsible for compliance with all terms and conditions of the Agreement applicable to the Manufacturer.

8.7 Nothing in this Agreement will be construed so as to require the commission of any act contrary to law. If any provision of this Agreement is found to be invalid or illegal by a court of law, or inconsistent with federal requirements, this Agreement will be construed in all respects as if any invalid, unenforceable, or inconsistent provision were eliminated, and without any effect on any other provision. The parties agree to negotiate replacement provisions, to afford the parties as much of the benefit of their original bargain as is possible.

8.8 The Department and Manufacturer declare that this Agreement, including Contracted Products Attachment, contains a total integration of all rights and obligations of both 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 both parties that any and all prior or contemporaneous agreements, promises, negotiations or representations, either oral or written, relating to the subject matter and period of time governed by this Agreement which are not expressly set forth herein are to have no force, effect, or legal consequences of any kind.

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

- Effective Date identified on the first page of this Agreement
- Contracted Products Attachment

The remainder of this Agreement will not be altered except by an amendment in writing signed by both parties and approved by CMS and the Department. Any modification to this Agreement to include non-Medicaid population groups must be authorized by CMS.

8.10 Neither party contemplates any circumstances under which indemnification of the other party would arise. Nevertheless, should such circumstances arise, the Manufacturer agrees to indemnify, defend and hold harmless the State of Iowa, 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.

8.11 Except for transfer in ownership of Manufacturer as described in Section 8.6, this Agreement is not assignable by the Manufacturer either in whole or in part without the written consent of the Department, which will not unreasonably be withheld. This Agreement is not assignable by the Department either in whole or in part without the written consent of the Manufacturer, which will not unreasonably be withheld.

8.12 Performance under this Agreement shall be contingent on the authorization of this Agreement by CMS.

8.13 It is the Department's belief that the business arrangement contemplated by this Agreement is not subject to the provisions of 42 U.S.C. § 1320a-7b(b) prohibiting illegal remuneration. Should the above provisions apply, it is the Department's belief that the business arrangement contemplated by this Agreement meets the discount exception found in 42 U.S.C. § 1320a-7b(b)(3)(A), which excludes from prohibited activities the practice of discounting or other reductions in price obtained by a provider of services or other entity under a Federal health care program, if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program. The Department currently provides CMS full and unfettered access to all information held by the Department regarding the implementation of the Iowa Medicaid Program, and shall continue to do so.

8.14 Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, terrorism, civil

commotion, destruction of production facilities and materials, fire, earthquake, 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 this Agreement.

CONTRACTED PRODUCTS ATTACHMENT

Manufacturer	NDC	Product Description	Tier[1]	Formula[2]	Contracted Rate	Comments

[1] **Tier**

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

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

[2] **Formula**

- Formula 1: Percentage of WAC.
  Supplemental Rebate Amount per Unit = WAC multiplied by Contracted Rate
- Formula 2: Guaranteed Net Price.
  Supplemental Rebate Amount per Unit = WAC minus URA minus Contracted Rate