

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:	Iowa Department of Human Services
Manufacturer Primary Billing Address:	Department Primary Billing Address:
Manufacturer Primary Contact Person:	Department Primary Contact Person:
Manufacturer Primary Contact Telephone:	Department Primary Contact Telephone:
Manufacturer Primary Contact e-mail:	Department Primary Contact e-mail:
Address for Notices required by Agreement (“Manufacturer Notice Address”):	Address for Notices required by Agreement (“Department Notice Address”):
Termination Date: (“Termination Date”)	Effective Date (“Effective Date”)

In consideration of the mutual covenants in this Agreement, including the General Supplemental Rebate Terms, Attachment A to this Agreement, and Attachment B 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:
Title:	Title:
Date:	Date:

General Supplemental Rebate Terms

1. PURPOSE

The Department and the Manufacturer have entered into this Agreement for the purpose of establishing a Supplemental Rebate for the Medicaid population, which will be in addition to rebates received under the CMS Rebate Agreement received pursuant to 42 U.S.C. § 1396r-8 for the Manufacturer's Covered Product(s) quarterly utilization in the Iowa Medicaid Program. The parties also intend for this Agreement to meet the requirements of federal law at 42 U.S.C. § 1396r-8.

2. DEFINITIONS

- 2.1 **AMP** shall mean the Average Manufacturer Price as set forth in 42 U.S.C. § 1396r-8; as such statute may be amended from time to time.
- 2.2 **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.
- 2.3 **Chemical Type** shall mean the number and its meaning assigned by the Food and Drug Administration (FDA), one through eight, which represents the newness of a drug formulation or a new indication for an existing drug formulation.
- 2.4 **CMS Agreement** means the Manufacturer's drug rebate contract with the Centers for Medicare and Medicaid Services (CMS) entered pursuant to 42 U.S.C. § 1396r-8.
- 2.5 **CMS Basic Rebate** means, with respect to the Covered Product(s), the quarterly payment by the Manufacturer pursuant to the Manufacturer's CMS Agreement, made in accordance with 42 U.S.C. § 1396r-8(c)(1) and 42 U.S.C. § 1396r-8(c)(3).
- 2.6 **CMS CPI Rebate** means, with respect to the Covered Product(s), the quarterly payment by the Manufacturer pursuant to the Manufacturer's CMS Agreement, made in accordance with 42 U.S.C. § 1396r-8(c)(2).

- 2.7 **Covered Product(s)** means any prescription drug product listed in Attachment A.
- 2.8 **Guaranteed Net Price** shall mean the final fixed price of the drug assured by the Manufacturer to the Department. It shall be calculated as the WAC minus the National Rebate and minus the State Supplemental Rebate necessary to equal the guaranteed net price to the Department by the Manufacturer for the Covered Product for the Quarter.
- 2.9 **Line Extension Drug** shall mean any drug meeting the definition of a Line Extension Drug as defined in any final rule published by the Centers for Medicare and Medicaid Services (CMS) clarifying Section 1927(c)(2)(C) of the Social Security Act. Line Extension Drugs must be new formulations of existing, rebatable, oral, solid dosage medications as defined by federal law. Until the final rule is published the term Line Extension Drug shall mean a drug that is designated as Chemical Type 2, 3, 4, or 6 on the Food and Drug Administration's (FDA) list of Chemical Types. *See* 77 Fed. Reg. 5339 (Feb. 2, 2012).
- 2.10 **Medicaid MCO** means a managed care organization that has contracted with the Department to provide Medicaid benefits to Medicaid members.
- 2.11 **Medicaid Population** means 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.
- 2.12 **Medicaid Utilization Information** means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Products reimbursed during a Quarter under a Medicaid State Plan. This information is based on claims paid by the Department or a Medicaid MCO for a Covered Product during a Quarter and not drugs that were dispensed during a 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. Medicaid Utilization Information 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).

- 2.13 **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.
- 2.14 **National Rebate** means the CMS Basic Rebate and the CMS CPI Rebate, collectively.
- 2.15 **Preferred Drug List (PDL)** shall mean the list developed by the Pharmaceutical and Therapeutics Committee (P & T Committee) and adopted by the Department pursuant to Iowa Code § 249A.20A.
- 2.16 **Quarter** means calendar quarter unless otherwise specified.
- 2.17 **Rebate Payment Due Date** means the date that is 30 days following Manufacturer's receipt of Medicaid Utilization Information from the Department.
- 2.18 **Recommended Drug List (RDL)** shall mean the list of drugs excluded from the Preferred Drug List pursuant to Iowa Code § 249A.20A.
- 2.19 **State Supplemental Rebate** means, with respect to the Covered Product(s), the quarterly payment by the Manufacturer pursuant to this Agreement.
- 2.20 **Step Care** shall mean a defined order of therapeutic choices within either the preferred or non-preferred drug list categories.

- 2.21 **Unit(s)** means 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).
- 2.22 **WAC** shall mean the Wholesale Acquisition Cost, which is 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 reported in MediSpan.

3. MANUFACTURER'S RESPONSIBILITIES

- 3.1 Nothing in this agreement shall be construed as relieving the Manufacturer from its obligation to provide the Department National Rebates for the Covered Product(s).
- 3.2 In addition to the National Rebates, the Manufacturer will remit to the Department a State Supplemental Rebate for Covered Product(s) included on the PDL and/or RDL. The supplemental rebate shall be paid based on utilization data for the Medicaid Population. The Manufacturer shall pay to the Department the State Supplemental Rebate amount in accordance with the formula set forth in Attachment B. This State Supplemental Rebate is in addition to the National Rebates.
- 3.3 Quarters shall be used in calculating both the National Rebates and the State Supplemental Rebate.
- 3.4 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. The Manufacturer is responsible for timely payment of the rebate by the Rebate Payment Due Date following receipt of, at a minimum, information on the number of Units paid, by NDC number.
- 3.5 The Manufacturer will pay the State Supplemental Rebate, including any applicable interest calculated in accordance with 42 U.S.C. § 1396b(d)(5).

Interest on the Rebates payable this Agreement begins accruing 38 calendar days from receipt of Iowa's Medicaid Utilization Information sent to the Manufacturer, and interest will continue to accrue until the postmark date of the Manufacturer's payment. Rebate payments mailed more than 68 days from the date of invoice shall include interest, calculated in accordance with federal guidelines.

- 3.6 Nothing in this Agreement shall be construed as prohibiting the Manufacturer from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. If the 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 Manufacturer shall make every reasonable effort to notify the Department prior to such action so that the Department can negotiate with such third party for State Supplemental Rebates on such Covered Product or remove such Covered Product from the PDL and/or RDL. Upon notification of the Manufacturer's election to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, the Covered Product shall be removed from the definition of "Covered Products."
- 3.7 Unless notified otherwise, the Manufacturer will send Rebate payments to the Department Primary Billing Address identified on the first page of this Agreement.
- 3.8 The Manufacturer must notify the Department if any Covered Product will be a Line Extension Drug. To the extent that applicable law requires redesignation of a Covered Product as a Line Extension Drug based on new indications, the Manufacturer shall notify the Department of any application to the Food and Drug Administration (FDA) for new indications for a Covered Product. This notification must occur no later than the date of the new indication application to the FDA.

4. DEPARTMENT RESPONSIBILITIES

- 4.1 Preferred Drug List: The Department shall place Covered Products in an advantaged position relative to non-preferred products regarding 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 Care.” Certain preferred drugs, including Step Care drugs, may be subject to prior authorization, i.e., preferred but with prior authorization. The Department will comply with all provisions of 42 U.S.C. § 1396r-8(d). Drugs of manufacturers who do not participate in the supplemental rebate program will be made available to Medicaid beneficiaries but may be subject to prior authorization.
- 4.2 Recommended Drug List: If the Department is prohibited by state law from placing certain pharmaceutical products on the PDL, those products may be placed on the Recommended Drug List, or RDL. Unlike the Preferred Drug List in which non-preferred drugs are subject to prior authorization, the drugs designated as non-recommended in the Recommended Drug List will not require prior authorization solely due to their status on the RDL. Otherwise, the same P&T Committee processes apply to drugs on the RDL. Some drugs may be designated as recommended due to the Manufacturer’s State Supplemental Rebate offer. The Department will publish the RDL directed at providers.
- 4.3 The established PDL and RDL shall be state run and utilized for the Medicaid Population.
- 4.4 The Department will provide State Medicaid Utilization Information for the Medicaid Population to the Manufacturer on a quarterly basis. The Department will report to the Manufacturer the Medicaid Utilization Information for claims paid during the Quarter within ninety (90) days of the last day of each Quarter. This reporting shall be done in a manner consistent with the Federal Drug Rebate program. This data will be based on paid claims data (data used to reimburse pharmacy providers) for the Iowa Medicaid Program.

- 4.5 The Department will maintain the data systems and audits as are necessary to ensure the accuracy of the data used to calculate the State Supplemental Rebate. In the event material discrepancies are discovered, the Department will make available supporting data that is then in existence concerning the claimed utilization, which may include an adjustment to the amount of the Rebates. Any such payment adjustment shall be included on the next Quarterly invoice.
- 4.6 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 Utilization Information provided by the Department. The Department and the Manufacturer will develop mutually beneficial audit procedures, should such an audit be required to resolve disputes regarding Medicaid Utilization Information.
- 4.7 Upon implementation of this Agreement, and from time to time thereafter, the Department and the 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.
- 4.8 The Department warrants that it received CMS authorization to receive State Supplemental Rebates for the Medicaid Population as provided under this Agreement and that the Manufacturer's participation in this State Supplemental Rebate program will not affect the Manufacturer's Best Price and the AMP.

5. DISPUTE RESOLUTION

- 5.1 Utilization disputes will be handled in the same manner as the National Rebates 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 the 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 the 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 441 Iowa Administrative Code Chapter 7 in writing to:

Iowa Department of 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, information disclosed by the Manufacturer in connection with this Agreement is confidential

and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of and to permit review under 42 U.S.C. § 1396r-8 by the Comptroller General. 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 shall apply to the third-party, and the Department shall have the third-party sign a written agreement ensuring the third-party will comply with all aspects of this section. In the event that the Department is required by law to disclose any provision of this Agreement or pricing information to any person other than as provided above, the Department shall provide advance written notice to the Manufacturer sufficiently in advance of the proposed disclosure to allow the Manufacturer to seek a protective order or other relief. The foregoing shall not prevent the disclosure by the Manufacturer to the Department of information regarding the National Rebates for Covered Products.

- 6.2 The parties agree that information revealing the identity of Medicaid recipients is confidential and shall not be disclosed except as necessary to carry out this Agreement or as may be required by judicial order.
- 6.3 The Manufacturer will hold the Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Medicaid Utilization Information to auditors who agree to keep such information confidential.
- 6.4 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 terminated by the Manufacturer as of the end of the calendar quarter upon ninety (90) days written notice to the Department for reasons of material breach by the Department, provided that the Department is unable to reasonably cure the breach within such ninety (90) day period.
- 7.4 This Agreement may be immediately terminated upon the occurrence of any one of the following events:
- (a) A determination by any court 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 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 determination by CMS that the State Supplemental Rebates paid or payable by the Manufacturer under this Agreement will affect or be included in Best Price or AMP calculations for determining rebates paid pursuant to 42 U.S.C. § 1396r-8.
 - (c) A determination that any Covered Product is a Line Extension Drug.

7.5 Any renewal or termination will not affect rebates due or owing on or before the effective date of termination.

8. GENERAL PROVISIONS

8.1 This Agreement will be governed and construed in accordance with 42 U.S.C. § 1396r-8, Title 42 of the Code of Federal Regulations, and all other applicable federal law and regulations.

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 The 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 the 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 The 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 the Manufacturer, the Agreement shall be automatically assigned to the new owner subject to the conditions of this Agreement.

- 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 the Manufacturer declare that this Agreement, including attachments, 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:
- Notice Provision
 - Effective Date identified on the first page of this Agreement
 - Attachment A (Covered Products)
 - Attachment B (Rebate Formula)
- 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 of the formula 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 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 Inasmuch as the State Supplemental Rebate required by this Agreement is for Iowa Medicaid Program beneficiaries, it is agreed that the State Supplemental Rebate does not establish a new Best Price or AMP for purposes of the participating Manufacturer's CMS Agreement. Performance under this Agreement shall be contingent on the non-occurrence of the event described in Section 7.3(b) of this Agreement, and on CMS's valid authorization of the Iowa Supplemental Rebate Program of which this Agreement forms a part.
- 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.

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ATTACHMENT A

Covered Products

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

Manufacturer	NDC	Product Description	Formula

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ATTACHMENT B

Rebate Formula

Manufacturer	NDC (11 digits required)	Product Description	WAC	National Rebate	Tier ¹	Formula ²	Contracted GNP	Comments

¹Tiers (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 eight 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

Levels 5-7:

This offer assumes that every drug within this range is subject to Prior Authorization (PA) and that your drug would be designated as the first, second, or third choice after a PA is received. Step care will be used to influence the prescribing choices of physicians.

Level 8:

This offer assumes that the Manufacturer's drug would be designated as one of the agents subject to Prior Authorization (PA). Step care will not be used to influence the prescribing choices of physicians, unless there are other products listed in Level 1, 2, and 3 on the Preferred Drug List (PDL). Although the prescriber must go through the PA process to determine if a medicine can be utilized, there is no interference with product selection.

²Formulas

Formula 1: Percentage of WAC. Formula for Supplemental Rebate calculation: $WAC * \% \text{ of WAC} = \text{Supplemental Rebate Amount per unit}$

Formula 2: Guaranteed Net Price. Formula for Supplemental Rebate calculation: $WAC - \text{National Rebate} - \text{Guaranteed Net Price} = \text{Supplemental Rebate Amount per Unit}$